IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN PHARMA INTERNATIONAL LIMITED,	)	
Plaintiff,	)	
v.	)	C.A. No. 06-438-GMS
ABRAXIS BIOSCIENCE, INC.	)	
Defendant.	)	

PARTIES' PROPOSED GENERAL JURY INSTRUCTIONS

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STATEMENT OF THE PARTIES' OBJECTIONS

The proposed general instructions are based on the earlier draft of instructions provided by the parties. In addition to individualized objections, the parties maintain several global objections to the instructions:

(1) Elan objects to:

(a) any reference in the jury instructions to unenforceability;

(b) the use of the word "must" to the extent that it directs the jury to a mandatory verdict or a verdict in which the jury is effectively precluded from balancing all the proofs and circumstances in its sound discretion, with the exception of references to the relationship between dependent and independent claims;

(c) any reference in the jury instructions to the reverse doctrine of equivalents;[1] and

(d) any reference in the jury instructions to the purely equitable defense of unclean hands (and to Abraxis's erroneous suggestion that a finding of unclean hands renders a patent unenforceable in toto).[2]

Further, Elan objects for purposes of reserving its rights to any instructions that are predicated on the denial to date of relief previously requested to the Court, including but not limited to Elan's request that the '025 Patent be withdrawn from the case in view of Elan's decision not to proceed with its infringement claims thereunder, and to Elan's requests in its Motions In Limine that were denied by the Court. In accordance with the Court's instructions and in the interests of expediting trial, Elan is at this time submitting

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[1] Elan objects to an instruction on the reverse doctrine of equivalents for the reasons set forth in its Motion In Limine No. 5. More specifically, the Federal Circuit has never held that the reverse doctrine of equivalents barred infringement recovery in a particular case. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.* 314 F.3d 1313, 1351 (Fed. Cir. 2004) (expressly declining to apply the reverse doctrine of equivalents); *see also Ciena Corp. v. Corvis Corp.*, 334 F. Supp. 2d 598, 604 (D. Del. 2004) (recognizing 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."). The Federal Circuit has likewise 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). Finally, Elan objects to this instruction as unsupported by anything other than attorney argument, which is insufficient to maintain this defense. *See id.*

[2] Elan objects to all references and instructions on the "unclean hands" on the grounds that the issue is a purely equitable one.

ISCO Int'l Inc. v. Conductus, Inc., 279 F. Supp.2d 489 (D. Del. 2003), does not support Abraxis's argument in favor of an unclean hands instruction. ISCO discussed inequitable conduct before the Patent Office, not "unclean hands." *Id.* at 499-500. ISCO also dealt separately with the unrelated issue of "bad faith" in the context of a Lanham Act trademark law claim unrelated to the issues in suit here. *Id.* at 504.

jury instructions that join issue even on those matters that Elan submits should not be before the jury, and notes this objection solely to preserve its rights.

(2) Abraxis objects to:

(a) any reference in the jury instructions to infringement;[3]

(b) any reference in the jury instructions to the infringement under the doctrine of equivalents;[4]

(c) any reference in the jury instruction to indirect infringement, either inducement of infringement or contributory infringement;[5]

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[3] Abraxis objects to all references and instructions on infringement as Elan already conceded it cannot prove infringement based on the Court's claim construction orders of August 17, 2007 (D.I. 271) and May 19, 2008 (D.I. 569).

[4] Abraxis objects to all references and instructions on the doctrine of equivalents as Elan's argument that the amorphous medicament in Abraxane particles is the equivalent of the claimed crystalline medicament is barred by prosecution history estoppel. *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366-67 (Fed Cir. 2003); *Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 952-53 (Fed. Cir. 1993).

During prosecution, it was contended that crystallinity was a novel and basic property that differentiated amorphous compounds from crystalline compounds. *See, e.g.*, D.I. 144, Joint Appendix at A0236, '105 App. (from which U.S. Patent No. 5,145,684 issued, which is the parent of the '363 patent) Nov. 18, 1991 Amendment at 9 ("The crystalline phase differs from non-crystalline and amorphous phases. The crystalline particles of this invention exhibit improved stability compared to particles containing a drug substance in an amorphous phase."); *id.* at A0241, Nov. 18, 1991 Amendment at 14 ("The office action indicates that Violante teaches a crystalline drug substance. However, Violante teaches a solvent precipitation technique for preparing amorphous, non-crystalline particles. In fact Violante teaches that the crystalline state is to be avoided . . . . Consequently, Violante teaches away from applicants claimed particles."); '363 Specification at 2:28-34 ("The anticancer agent is present in one or more discrete crystalline phases. The crystalline phase differs from an amorphous, i.e., non-crystalline phase which results from conventional solvent precipitation techniques for the preparation of particles in the submicron size range…").

Elan is also barred from asserting equivalence between the claimed particles containing crystalline medicament and Abraxane, which contains an amorphous medicament, by the principle of "dedication to the public." *Johnson & Johnson Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). See 5,399,363 Patent Specification 2:28-34 ("The anticancer agent is present in one or more discrete crystalline phases. The crystalline phase differs from an amorphous, i.e., non-crystalline phase which results from conventional solvent precipitation techniques for the preparation of particles in the submicron size range…").

(d) any reference in the jury instructions to willful infringement;[6]

(e) any reference in the jury instructions to a patent's presumption of validity;[7] and

(f) any reference in the jury instructions to a "clear and convincing burden" for invalidity.

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[5] Abraxis objects to all references and instructions as Elan failed to establish the requisite state of mind required for these claims. Additionally, Elan has failed to establish that Abraxane® is especially made or adapted for a use that infringes the claimed invention of the '363 patent.

[6] Abraxis objects to all references and instructions on willful infringement as Elan is barred from arguing willfulness. There is a complete absence of proof that Abraxis willfully infringed. In particular, there is no evidence that Abraxis did not possess a reasonable basis to believe that it had a substantial defense to infringement and reasonably believed that the defense would be successful if litigated, that Abraxis did not make a good faith effort to avoid infringing the patent, or that Abraxis tried to cover up any infringement or intentionally copied a product of Elan that is covered by the '363 Patent. Rather, the evidence establishes that Abraxis acted in good faith and on the reasonable belief that the amorphous and crosslinked nature of the particles in Abraxane made infringement impossible.

[7] Abraxis objects to all references and instructions on the presumption of validity as redundant and not required by Federal Circuit precedent since the presumption of validity and heightened burden of proving invalidity "are static and in reality different expressions of the same thing – a single hurdle to be cleared." *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984); *see also Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003). Moreover, the Federal Circuit has explained: "The presumption is one of law, not fact, and does not constitute 'evidence' to be weighed against the challenger's evidence." *Avia Group Int'l Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1562 (Fed. Cir. 1988). For these reasons, the Federal Circuit has recognized that a jury instruction on the presumption of validity is unnecessary. *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1258 (Fed. Cir. 2004) (affirming district court instructions that did not include presumption of validity).

Abraxis further objects to an instruction on the presumption of validity on the ground that it is a substantial question of fact in this case as to whether Elan has submitted all relevant information to the USPTO. It would be prejudicial to Abraxis to allow Elan to benefit from an additional instruction on the "presumption of validity" in light if its non-disclosure of highly material internal information. Abraxis's burden of proof may be more easily met where Abraxis produces evidence of invalidity more pertinent than that considered by the Patent and Trademark Office. *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 1423 (Fed. Cir. 1988).

2. GENERAL INSTRUCTIONS

2.1 Introduction

Members of the jury, I will now instruct you about the law that you must follow in deciding this case.

I will start by reminding you about your duties as jurors and the instructions you heard at the beginning of the case.

I will then explain the positions of the parties and the law you will apply in this case.

Last, I will explain the rules that you must follow during your deliberations in the jury room and the possible verdicts that you may return.

Please listen very carefully to everything I say.

2.2 Jurors' Duties

Remember your duties as jurors as I explained them to you at the beginning of the case. You must decide what the facts are from the evidence you saw and heard in court. Nothing I have said or will say should influence your determination of the facts in any way. Do not guess or speculate, and do not be influenced in any way by any personal feeling of sympathy for, or prejudice against, either side in this case. All parties are entitled to the same fair and impartial consideration.

You must also take the principles of law that I will now explain to you and apply them to the facts in reaching your verdict. You are bound by the oath you took to follow my instructions, even if you personally disagree with them.

All of my instructions are important, and you should consider them together as a whole. This includes the instructions that I gave you when we started and during trial. I will not repeat my earlier instructions about evidence and how to weigh and consider it. You have copies of these instructions, however, and you should refer to them as you feel necessary.

Perform these duties fairly. Do not let any bias, sympathy or prejudice that you may feel toward one side or the other influence your decision in any way.

2.3 Burdens Of Proof

This is a civil case in which the plaintiff, Elan is accusing the defendant, Abraxis of patent infringement. Elan alleges that Abraxis has infringed the asserted claims of the '363 Patent. Elan has the burden of proving its allegations of patent infringement and its alleged damages by what is called a preponderance of the evidence. That means Elan must produce evidence that, when considered in light of all of the facts, leads you to believe that what Elan claims is more likely true than not. To put it differently, if you were to put Elan's and Abraxis's evidence on the opposite sides of a scale, the evidence supporting Elan's claims would have to make the scales tip somewhat on its side.

Elan also alleges that Abraxis' alleged infringement was willful. Elan must prove its claims of willful infringement by clear and convincing evidence and not by a preponderance of the evidence, the standard that applies to Elan's other claims in this case. Clear and convincing evidence is evidence that produces an abiding conviction that the truth of a factual contention is highly probable. Proof by clear and convincing evidence is thus a higher burden than proof by a preponderance of the evidence.

In this case, Abraxis contends that Elan's patents, both the '363 Patent and the '025 Patent, are invalid and unenforceable. A patent, however, is presumed to be valid. Accordingly, Abraxis has the burden of proving that the patents are invalid and/or unenforceable by clear and convincing evidence. As I discussed earlier, clear and convincing evidence is evidence that produces an abiding conviction that the truth of a factual contention is highly probable.

Finally, keep in mind that "proof beyond a reasonable doubt" does not play any part in this case and you should, therefore, not consider it at all in your deliberations.

3. THE PARTIES AND THEIR CONTENTIONS

3.1 The Parties and Undisputed Facts [DISPUTED]

The plaintiff in this case is Elan Pharma International Limited. The defendant is Abraxis Bioscience, Inc.

[This case involves Elan's '363 Patent, which relates to certain nanoparticles of anti-cancer drugs, including a drug substance you have heard referred to a paclitaxel or taxol. In particular, the case involves infringement of the '363 Patent by Abraxis's product Abraxane(R). The case also involves certain questions regarding the validity of Elan's '363 and '025 Patents, the latter of which covers methods of administration of paclitaxel nanoparticles.][8]

[8] Abraxis objects to the bracketed language as unnecessary, argumentative, redundant, and confusing to the jury since they concern facts that are not at issue in the case.

3.2 Elan's Contentions

Elan contends that Abraxis has been and still is making, using, offering to sell, and selling in the United States Abraxane®, which Elan contends contains paclitaxel nanoparticles that infringe claims 3, 5, 10, and 11 of the '363 Patent. I may refer to these particular four claims of the '363 Patent as the "asserted patent claims" or "asserted claims." Elan also contends that Abraxis infringes the '363 Patent when it makes and supplies Abraxane® to third parties for reconstitution.

Elan asserts that these acts of infringement have been and are "willful," on Abraxis's part, as I will define for you shortly. Élan also asserts that the '363 and '025 Patents are valid and enforceable.

3.3 Abraxis's Contentions

Abraxis denies that it infringed or infringes any of claims 3, 5, 10 and 11 of the '363 Patent because Abraxane® does not satisfy every limitation of the claims. Abraxis contends that Elan has not presented evidence that either Abraxis or its customers are directly, inducing, or contributing to the infringement of any claim of the '363 Patent.

In particular, Abraxis disputes whether the particles in Abraxane consist essentially of crystalline medicament and a surface modifier that is non-crosslinked. Abraxis does not dispute that Abraxane meets the other limitations of '363 Patent claims 3, 5, 10 and 11 for purposes of determining whether there is infringement in this litigation.

Abraxis denies that it has willfully infringed any of the asserted claims of the '363 Patent and contends that Elan has not presented evidence that Abraxis willfully infringed any of the asserted claims of the '363 Patent.

Abraxis contends that claims 1, 3, 5, 10, and 11 of the '363 Patent and claims 1-3 and 13-15 of the '025 Patent are invalid for lack of enablement and failure to adequately describe the claimed invention.

Abraxis further contends that the '363 Patent is unenforceable due to inequitable conduct before the USPTO and unclean hands. Abraxis also contends that the '025 Patent is unenforceable due to inequitable conduct before the USPTO.

Finally, Abraxis contends that Elan has failed to prove its measure of damages for any alleged infringement of the '363 Patent.

3.4 Summary Of Patent Issues

In this case, you must decide several things according to the instructions that I shall give you. Specifically, they include:

3.4.1. Infringement

Has Elan proven by a preponderance of the evidence that Abraxis has been or is now infringing any of claims 3, 5, 10 and 11 of the '363 Patent by making, using, offering to sell, or selling Abraxane® in the United States?

Has Elan proven by a preponderance of the evidence that Abraxis has been or is now contributing to or actively inducing infringement of any of claims 3, 5, 10 and 11 of the '363 Patent by others, as I shall define these forms of infringement?

3.4.2 Willfulness

If you find that Abraxis's manufacture, use, sale, or offer for sale of its Abraxane® has infringed claims 3, 5, 10, 11 of '363 Patent, and/or that Abraxis has contributed to or actively induced the infringement of the claims 3, 5, 10, 11 of the '363 Patent by others, has Elan proven by clear and convincing evidence that in doing so, Abraxis acted with reckless disregard of the claims of the '363 Patent?

3.4.3 Invalidity

Has Abraxis proven by clear and convincing evidence that claims 1, 3, 5, 10 and 11 of the '363 Patent are invalid because the claims are not enabled and not properly described?

Has Abraxis proven by clear and convincing evidence that claims 1-3 and 13-15 of the '025 Patent are invalid because the claims are not properly enabled and not properly described?

3.4.4. Unenforceability

Has Abraxis proven by clear and convincing evidence that the '363 Patent is unenforceable for inequitable conduct and/or unclean hands?

Has Abraxis proven by clear and convincing evidence that the '025 Patent is unenforceable for inequitable conduct?

4. INFRINGEMENT

4.1 Claim Infringement

At the beginning of the trial I gave you some general information about patents and the patent system and a brief overview of the patent laws that relate to this case. If you would like to review my earlier instructions at any time during your deliberations, they will be available to you in the jury room.

If any person makes, uses, sells, or offers for sale something that is covered by a patent claim without the patent owner's permission, that person is said to *infringe* the patent. I will now instruct you on the specific rules you must follow in deciding whether Elan has proven that Abraxis has infringed one or more of the claims of the '363 Patent. To prove infringement of a patent, Elan must persuade you by a preponderance of the evidence that Abraxis has infringed a claim in the patent.

Remember that Elan alleges that Abraxis only infringes claims of the '363 Patent. Thus, you should not consider the '025 Patent or the '118 Patent when determining infringement. Elan has no claim for breach of the parties' 1996 confidentiality agreement.

4.2 Patent Claims

4.2.1 Patent Claims Generally

To decide whether Abraxis has infringed the '363 Patent, you will have to understand the patent "claims." The claims of a patent are the numbered sentences at the end of a patent. The patent claims at issue here are claims 1 (for validity only), 3, 5, 10, and 11 of the '363 Patent, beginning at column 14, line 6 of the patent as corrected by the attached Certificate of Correction. The claims describe the invention made by the inventor. This is what the patent owner owns and what the patent owner may prevent others from making/doing/selling. Claims may describe products, such as machines or chemicals, or they may describe methods for making or using a product.

Only the claims of the patent can be infringed. A patent may include a discussion of examples of the invention, but the examples cannot be infringed. You should not compare Abraxis's product with any specific example set out in the '363 Patent. You must only compare Abraxane® with the *claims* of the patent when making your decision regarding infringement.

Each claim of a patent represents separate patent protection given to a patent owner, and you must individually consider each of the patent claims involved in this case. The law does not require infringement of all the claims in a patent. There is infringement and entitlement to damages if a single claim of the patent has been infringed.

4.2.2 Independent And Dependent Claims

Claims are typically divided into parts called "limitations." For example, a claim that covers the invention of a table may recite the tabletop, four legs, and the glue that secures the legs to the tabletop. The tabletop, legs, and glue are each a separate limitation of the claim.

There are two types of patent claims: independent claims and dependent claims. An independent claim does not refer to any other claim of the patent. In simple terms, an independent claim stands on its own two feet. An independent claim is read alone to determine the limitations that must exist to infringe the claim. Claim 1 of the '363 Patent, for example, is an independent claim.

A dependent claim refers to at least one other claim in the patent. A dependent claim includes all of the limitations in the claims to which it refers. Therefore, to determine what a dependent claim covers, you must look at both the limitation of the dependent claim and the claim or claims to which it refers.

For example, claim 3 is a dependent claim. It refers to claim 1. For a product to infringe dependent claim 3, the product must have all the limitations of both claim 1 and claim 3. Therefore, if you find that claim 1 is not infringed, you must also find that claim 3 and all other claims depending from claim 1 are not infringed.

4.2.3 The Court Determines What Patent Claims Mean [DISPUTED]

It is the Court's duty under the law to define what the patent claims mean. I have made my determinations and I will now instruct you on the meaning of each claim. You must use the meaning that I give you for each patent claim to make your decisions if the claim is infringed or invalid. You must ignore any different definitions used by the witnesses or the attorneys.

I will discuss the limitations of each of the claims at issue for the '363 Patent and '025 Patent. I will give you a list of these claims as part of the verdict form when I conclude my instructions.

4.2.3 (a) The limitations of claim 1 of the '363 Patent are as follows:

Particles consisting essentially of:

99.9 - 10% by weight of a crystalline medicament useful in treating cancer susceptible for treatment with said medicament,

said medicament having a solubility in water of less than 10 mg/ml, and

having a non-cross-linked surface modifier adsorbed on the surface thereof in an amount of 0.1-90% by weight and sufficient to maintain an average effective particle size of less than 1000 nm,

wherein said medicament is selected from the group consisting of . alkylating agents having a bis-(2-chloroethyl)-amine group, alkylating agents having a substituted aziridine group, alkyl sulfonates, and N-alkyl-N-nitrosoureas; antimetabolites; natural products selected from the group consisting of vinca alkaloids, epipophylotoxins, adriamycine, daunomycine, doctinomycine, daunorubicin, doxorubicin, mithramycin, bleomycin, mitomycin, enzymes, biological response modifiers, camptothecin, taxol and retinoids; hormones and antagonists: radiosensitizers; platinum coordination complexes; anthracenediones; and adrenocortical suppressants.

4.2.3 (b) The limitations of claim 3 of the '363 Patent are the same as the limitations of **claim 1** except that the particles have an average effective particle size of less than 300 nm.

4.2.3 (c) The limitations of claim 5 of the '363 Patent are the same as the limitations of **claim 1** except that the anticancer agent is selected from the group consisting of piposulfan, piposulfam, camptothecin, etoposide, taxol, 1,2,4-benzotriazin-3-amine 1,4-dioxide, 1,2,4-bezotriazin-7-amine 1,4-dioxide and retinoic acid.

4.2.3 (d) The limitations of claim 10 of the '363 Patent are as follows:

In a method of treating a mammal comprising administering to the mammal an effective amount of an anticancer agent, the improvement wherein the efficacy of said anticancer agent is increased by administering said anticancer agent in the form of the particles of **claim 1**.

4.2.3 (e) The limitations of claim 11 of the '363 Patent are as follows:

In a method of treating a mammal comprising administering to the mammal an effective amount of an anticancer agent, the improvement wherein the toxicity of said anticancer agent is reduced by administering said anticancer agent in the form of the particles of **claim 1**.

4.2.3 (f) The limitations of claim 1 of the '025 Patent are as follows:

A method of administering a nanoparticulate composition to a mammal without eliciting adverse hemodynamic effects comprising

intravenously administering to said mammal an effective amount of a nanoparticulate drug composition at an infusion rate not exceeding 10 mg/min,

wherein said drug composition comprises:

(a) particles consisting essentially of from about 0.1 to about 99.9% by weight of a crystalline organic drug substance having a solubility in water of less than 10 mg/ml;

(b) a surface modifier adsorbed on the surface of the drug substance in an amount of from about 0.1 to about 99.99% by weight and sufficient to maintain an effective average particle size of from about 50 nm to about 1000 nm; and

(c) a pharmaceutically acceptable carrier therefor.

4.2.3 (g) The limitations of claim 2 of the '025 Patent are the same as the limitations of **claim 1** except that the effective average particle size is from about 50 nm to about 400 nm;

4.2.3 (h) The limitations of claim 3 of the '025 Patent are the same as the limitations of **claim 1** except that the drug is an organic therapeutic substance.

4.2.3 (i) The limitations of claim 13 of the '025 Patent are as follows:

A method of administering a nanoparticulate composition to a mammal without eliciting adverse hemodynamic effects comprising

intravenously administering to said mammal an effective amount of a nanoparticulate drug composition at an infusion rate not exceeding 10 mg/min,

wherein said drug composition comprises:

(a) particles having an effective average particle size of from about 50 to about 1000 nm and consisting essentially of

from about 0.1 to about 99.9% by weight of an organic drug substance entrapped in

from about 99.9 to about 0.1% by weight of liposome or a colloidal polymeric material; and

(b) a pharmaceutically acceptable carrier therefor.

4.2.3 (j) The limitations of claim 14 of the '025 Patent are the same as the limitations of **claim 13** except that the effective average particle size of the drug is from about 50 to about 400 nm.

4.2.3 (k) The limitations of claim 15 of the '025 Patent are the same as the limitations of **claim 13** except that the drug is an organic therapeutic substance.

4.2.3 (l) Court's Construction of the Patent Claims

The Court has defined certain claim terms in the '363 Patent and the '025 Patent as follows:

(1) "particles consisting essentially of" is construed to mean "the particles, composed of crystalline medicament and surface modifier, may also include other ingredients that do not affect their basic and novel properties, and are essentially free of solvent and other contaminants;"

[Only small amounts of such other ingredients may be included. The crystallinity of the medicament and the non-crosslinking of the surface modifier are basic and novel properties of the claimed invention.] [9]

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[9] Abraxis proposes additional sentences to the Court's Construction of "particles consisting essentially of" in order to inform the jury of the basic and novel properties of the '363 Patent, which is a question of law for the court. It is the Court's province to determine patent scope, and as a matter of law, crystallinity and non-crosslinking are basic and novel properties. *See, e.g.*, *Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984). The language of the first sentence arises from *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371, 1375 (Fed. Cir. 2002) ("consisting essentially of" allows for presence of "small amounts of components outside of the designated" substances).

The specification and file history, which make clear that a crystalline medicament and non-crosslinked surface modifier are basic and novel properties of the claim. During prosecution, it was contended that crystallinity was a novel and basic property that differentiated amorphous compounds from crystalline compounds. *See, e.g.*, JX-084 at 149 '684 file history., Nov. 18,1991 Amendment at 9 ("The crystalline phase differs from non-crystalline and amorphous phases. The crystalline particles of this invention exhibit improved stability compared to particles containing a drug substance in an amorphous phase."); *id.* at p. 154, Nov. 18, 1991 Amendment at 14 ("The office action indicates that Violante teaches a crystalline drug substance. However, Violante teaches a solvent precipitation technique for preparing amorphous, non-crystalline particles. In fact Violante teaches that the crystalline state is to be avoided . . . . Consequently, Violante teaches away from applicants claimed particles."); JX-081, '363 patent specification at 2:28-34 ("The anticancer agent is present in one or more discrete crystalline phases. The crystalline phase differs from an amorphous, i.e., non-crystalline phase which results from conventional solvent precipitation techniques for the preparation of particles in the submicron size range…").

(2) "crystalline medicament useful in treating cancer" is construed to mean "a medicament suitable for treating cancer that has a regular arrangement of atoms or molecules in a space lattice, as distinguished from amorphous;"

[The term "crystalline medicament" requires that the entire medicament, not merely a portion, be crystalline. This requirement forecloses infringement where the medicament in the formulation is "amorphous" or "largely amorphous."][10]

Similarly, it is clear that the non-crosslinked surface modifier was a basic and novel property of the claimed invention. JX-039, '363 patent file history Serial No. 07/908,125, 9/13/1993 Amendment at 6 ("Claim 1 has been amended consonant with the amendment to the claims in parent U.S. Patent No. 5,145,684 for reasons discussed fully in the parent relating to the § 112 rejection and prior art cited therein. More specifically, claim 1 has been amended to recite . . . that the surface modifier is non-crosslinked . . .") JX-084. at 155, '684 patent file history, Serial No. 07/647,105, 11/18/1991 Amendment, at 15 ("[Prior art] Motoyama is primarily directed to processes (radically different than applicants' method) which involve emulsification steps and/or heating and gelling, i.e., crosslinking, reactions.").

[10] Abraxis proposes the first additional sentence to instruction 4.2.3(l)(2) based on the Court's Claim Construction order (D.I. 217) and Order Denying Plaintiff's Motion for Reconsideration (D.I. 583).

Abraxis's proposes the second additional sentence based on the last "Whereas" clause of the Court's Claim Construction Clarification Order dated May 19, 2008, informing the jury that particles containing "largely amorphous" medicament cannot infringe the '363 patent. Elan is still pursuing a "two particles in trillions" theory of infringement. This theory was earlier supported by Dr. Munson's Second Supplemental Expert Report. Notwithstanding the Court's striking of that report, Elan continues to pursue the claim based on the testimony of Dr. Munson.

The intrinsic evidence for the '363 patent provides no support for Elan's theory that the claims reach "two particles", or even "billions of particles", in many trillions. The '363 patent describes a grinding method for creating an anti-cancer formulation composed of crystalline particles, not a method by which some small fraction of amorphous particles might migrate to the crystalline state. In distinguishing the prior art amorphous references, the applicants in no way established that every single particle in those references was amorphous. The focus throughout the specification and file history is on the gross characteristics of the formulation of particles those references described, not the characteristics of a portion of the particles. Moreover, when measuring crystallinity in the parent application, the applicants used XRPD on the population of particles (JX-082, '684 patent, at 10:66-11:2, 11:35-37.). They did not attempt to measure

(3) "non-crosslinked" is construed to mean "the individually adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages[, whether or not those crosslinkages are formed by covalent bonds];"

(4) "surface modifier" is construed to mean "a substance that modifies the surface properties of the crystalline medicament;"

(5) "adsorbed on the surface" is construed to mean "a molecule retained at the surface of the crystalline medicament that does not chemically bond with such medicament;"

(6) "in an amount of 0.1-90% by weight and sufficient to maintain an average effective particle size of less than 1000 nm" is construed to mean "an

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crystallinity on a particle by particle basis, an impossible task in a formulation with trillions of particles. There is no support for Elan's "two particle" theory anywhere in the specification or file history.

The specification and file history make clear that the crystalline medicament is present in the particles as they are obtained through the manufacturing process, and that the crystallinity of the medicament in those particles confers particular allegedly beneficial characteristics for use in treating cancer. JX-081, '363 patent at 2:28-30 ("The particles of this invention comprise an anticancer agent. The anticancer agent *is present* in one or more crystalline phases.") (emphasis added), Abstract ("Dispersible particles consisting essentially of a crystalline [medicament] …."); 7:5-8 ("A simple screening process has been developed whereby compatible surface modifiers and anticancer agents can be selected which provide stable dispersions of the desired particles"); 7:46-48 ("The resulting dispersion is stable and consists of the dispersion medium and the above-described particles."); 5:22-26 ("The particles of this invention can be prepared by a method comprising the steps of dispersing an anticancer agent in a liquid dispersion medium and applying mechanical means in the presence of grinding media to reduce the particle size of the anticancer agent …."); JX-084 at 149 '684 file history., Nov. 18,1991 Amendment at 9 ("The crystalline particles of this invention exhibit improved stability compared to particles containing a drug substance in an amorphous phase."); JX-039 at 0042, Oct. 29, 1992 IDS at 3 ("amorphous materials and formulations tend to exhibit unacceptably poor stability and/or short shelf lives."). Elan's "two particles in trillions" theory is inconsistent with the specification and file history of the patent. The Court's order that a largely amorphous product cannot meet the claim limitations is correct, and the jury must be instructed accordingly.

amount of surface modifier that maintains the size of the particles such that at least 90% of the particles have a number average particle size of less than about 1000 nanometers;"

This construction also applies to claims 1, 2, 3 of the '025 Patent for the term "sufficient to maintain an effective average particle size."

(7) "surfactant" is construed to mean "a stabilizing agent that reduces interfacial tension between oil and water."

(8) "without eliciting adverse hemodynamic effects" is construed to mean "the claimed method of intravenous administration does not elicit undesired effects on the physical aspects of blood circulation (such as reduction in arterial blood pressure and cardiac function) associated with administration of nanoparticles in the mammals to whom the nanoparticles are administered."

(9) "at an infusion rate not exceeding 10 mg/min" is construed to mean "intravenously administering the composition at a rate not exceeding 10 milligrams per minute."

(10) "organic drug substance" is construed to mean "a crystalline carbon-based therapeutic or diagnostic agent suitable for administration to a mammal."

(11) "colloidal polymeric material" is construed to mean "a polymer capable of forming a suspension of the organic drug substances."

For any of the terms of the patent claims not specifically defined above, you are to give such words their plain and ordinary meaning in applying the claim(s).

Elan's Objections

Elan objects to Abraxis's proposed constructions in (1), (2), and (3) because (as Abraxis admits) Abraxis has included "proposed additions" not included in the governing Claim Construction Order of August, 2007. Elan also objects to the last two sentences of (2), which import the term "entire," which the Court has made clear it did not intend to impose as an additional claim limitation. Elan further objects to Abraxis's reliance on *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371, 1375 (Fed. Cir. 2002) for the proposition that '"consisting essentially of" allows for presence of 'small amounts of components outside of the designated" substances'" because judgment in that case has been vacated. *See Talbert Fuel Systems Patents Co. v. Unocal Corp.*, 537 U.S. 802 (2002) (vacating and remanding case).; Accordingly, *Talbert Fuel Sys.* has absolutely no precedential value.

Elan further objects to proposed constructions (1) and (2) as seeking to determine or require a finding of non-infringement based on Abraxis's unsubstantiated and argumentative positions as to what the "basic and novel" properties of the claimed invention are. There is substantial evidence of record that the possible admixture of amorphous or partially amorphous particles, or of crosslinked surface modifiers, alongside crystalline, non-crosslinked-albumin modified, particles would have no effect on the basic and novel properties of the '363 Patent's claimed invention, which include the stabilization for delivery to a tumor of nanoparticles of paclitaxel.

Elan further objects to Abraxis's proposed constructions as they invite an erroneous jury finding that Abraxis may "avoid infringement merely by adding elements [even when] each element recited in the claims is found in the accused [product]." *Suntiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1336 (Fed. Cir. 1999) (citing *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700. 703 (Fed. Cir. 1983)). If all the elements of a claimed invention are found in an accused product, infringement is present no matter what other elements the infringer has also added. "Any other reasoning would allow an infringer to avoid infringement merely by adding additional elements to an infringing device." *Id.* The claimed invention of the '363 Patent is surface-modified crystalline nanoparticles -- it is not a "product." If, as the evidence suggests, many such particles exist in the product Abraxane, the simultaneous presence of other particles in that product, which do not change the basic and novel properties of the claimed particles, does not affect the infringement analysis, and this should be made clear to the jury.

Finally, Elan tenders a formal objection to the extent that any of the Court's constructions from its August, 2007 claim construction order, or its constructions as applied in light of the May 19, 2008 claim construction order, are inconsistent with the claim construction submissions proffered by Elan during briefing.

4.2.4 Infringement – Basic and Novel Properties [DISPUTED]

With respect to claims 3, 5, 10 and 11 of the '363 Patent, there can be no infringement where the accused product contains additional, unclaimed ingredients that materially affect the basic and novel properties of the invention. To determine the basic and novel properties of the claimed invention, you should consider the language of the patent specification and prosecution history, including any distinctions made by the applicant between the claimed invention and the prior art.

[Elan bears the burden of proving by a preponderance of the evidence that these additional, unclaimed ingredients do not have such a material effect.]

4.3 Failure to Produce Evidence – Adverse Inference

Dr. Harry Brittain was retained as an expert by Elan in this case. Dr. Brittain performed tests on Abraxane® for Elan. Prior to this trial, Abraxis requested that Elan provide it with documents related to this testing. Elan failed to produce these documents. I have been asked to decide whether this action by Elan was proper. I have determined that under the Federal Rules of Civil Procedure it was not. As a result, I instruct you that you may infer that the contents of these documents would have been unfavorable to Elan's case on infringement.

4.4 Patent Infringement (Direct)

A patent owner may enforce his right to stop others from making, using, selling, or offering for sale the patented invention by filing a lawsuit for patent infringement. Here, Elan has sued Abraxis and has alleged that Abraxis's product directly infringes at least one claim of the '363 Patent. I will refer to Abraxis's product, Abraxane®, as the accused product.

Deciding whether a claim has been directly infringed is a two-step process. First, the meaning of the patent claim is determined as a matter of law. That job is for the Court, and I have instructed you as to what the key terms of the asserted claims mean as a matter of law. In the second step, you must compare each claim as I have interpreted it to the accused product to determine whether every element of the claim can be found in the accused product. This element-by-element comparison is your responsibility as the jury for this case.

There are two ways in which a patent claim may be directly infringed. First, a claim may be literally infringed. Second, a claim may be infringed under what is called the "doctrine of equivalents." I will explain literal and doctrine of equivalents infringement shortly.

Keep in mind that intent to infringe, actual knowledge of a patent, or knowledge that one is infringing a patent, are not part of a claim of patent infringement. In short, direct infringement can be established even if Abraxis had a good faith belief that its actions were not infringing the '363 Patent and even if Abraxis did not know of the patent.

4.4.1 Literal Infringement

For Abraxis's product, Abraxane®, or for a method involving Abraxane to literally infringe any one of the claims of the '363 Patent, Abraxane or the method involving Abraxane must include each and every limitation in the claims, exactly as written. That is why it is called *literal* infringement. If Abraxane or the method involving Abraxane omits any limitation recited in a patent claim, it does not literally infringe that claim.

4.4.2 Infringement Under the Doctrine Of Equivalents [DISPUTED]

If you do not find literal infringement by Abraxis as to a particular claim of the '363 Patent, you must decide whether infringement has been proven under the "doctrine of equivalents." I have referred to the "doctrine of equivalents" before. Now it is time to explain this term.

For there to be infringement under the doctrine of equivalents, every claim element must be present in the accused product. A claim element may be present in an accused product in one of two ways, either literally or under the doctrine of equivalents. A claim element is literally present if it exists in the accused product just as it is described in the claim, either as I have explained that language to you or, if I did not explain it, as you understand it from the evidence presented during trial.

A claim element is present in an accused product under the doctrine of equivalents if the differences between the claim element and a corresponding aspect of the accused product are insubstantial. One way to determine this is to look at whether or not the accused structure performs substantially the same function, in substantially the same way, to achieve substantially the same result as the element in the claimed invention. Another way is to consider whether or not people of ordinary skill in the art believe that the structure of the accused product and the element recited in the patent claim are interchangeable.

Another test may be used to determine equivalence under the doctrine of equivalents, especially when, as here, the patent claims define a product, such as a chemical compound or a chemical composition, that includes a mixture or combination of chemical compounds. When defendant's product changes one or more ingredients of a claimed compound or composition so that there is no literal infringement, it is appropriate for you to consider whether the changed ingredient has substantially the same purpose, quality and function as the claimed ingredient. In

other words, consideration must be given to the purpose for which an ingredient is used in Plaintiff's patented combination and in defendant's product, the qualities the ingredient has when combined with the other ingredients, and the function it is intended to perform.

It is not a requirement under doctrine of equivalents infringement that those of ordinary skill in the art knew of the equivalent when the patent application was filed or when the patent issued. The question of whether Abraxis's product and its limitations are equivalent to those defined in Elan's claims is to be determined as of the time of the alleged infringement.

Also, slight changes in technique or improvements made possible by technology developed after the patent application is filed may still be equivalent for doctrine of equivalents purposes. [You should take into account, however, that it is more difficult to establish equivalency to a claim element where the accused infringer was awarded a separate patent covering the accused product.][11]

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[11] Abraxis proposes the additional sentence based on *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*.

"We have not directly decided whether a device -- novel and separately patentable because of the incorporation of an equivalent feature -- may be captured by the doctrine of equivalents, although we have held that when a device that incorporates the purported equivalent is in fact the subject of a separate patent, a finding of equivalency, while perhaps not necessarily legally foreclosed, is at least considerably more difficult to make out." 493 F.3d 1368, 1380 (Fed. Cir. 2007). *See also Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1569 (Fed. Cir. 1996).

Elan objects to Abraxis's proposed instruction as an incorrect representation of the law and an improper instruction and adverse inference. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 493 F.3d 1368, 1380 (Fed. Cir. 2007).

4.4.3 Infringement Despite Defendant's Improvements or Patents on Improvements [DISPUTED]

The fact that a product may constitute an improvement on the claimed invention does not mean that it cannot infringe the patent. The tests for infringement remain as I have instructed you – if you find Abraxane includes all of the elements of at least one of claims of the '363 patent, either literally or under the doctrine of equivalents, then the '363 patent claims are infringed by Abraxane, despite Abraxis's improvements [or patents.][12]

[12] Abraxis objects to the bracketed language as an incorrect statement of the law. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1380 (Fed. Cir. 2007) ("We have not directly decided whether a device -- novel and separately patentable because of the incorporation of an equivalent feature -- may be captured by the doctrine of equivalents, although we have held that when a device that incorporates the purported equivalent is in fact the subject of a separate patent, a finding of equivalency, while perhaps not necessarily legally foreclosed, is at least considerably more difficult to make out."). *See also Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1569 (Fed. Cir. 1996).

4.4.4 Reverse Doctrine of Equivalents

In some cases, even though an allegedly infringing product includes all of the limitations of at least one of the patent claims, there still may be no infringement. This will be the case where Abraxis's product is so far changed in principle that although it performs the same or similar function to produce substantially the same result as that defined by a patent claim, it does so in a substantially different way.

4.5 Indirect Infringement

In addition to stopping infringement by those who are directly infringing, a patent owner also has the right to stop those who are known as "indirect infringers." Without liability for indirect infringement, a company could cause or help others to infringe without fear of being sued by the patent holder.

There are two types of indirect infringers. First, there are those who encourage or induce others to infringe a patent; this is known as "inducing infringement." Second, there are those who contribute to infringement by, for example, supplying them with components used in the patented invention. I will explain to you in a moment the precise requirements for finding someone has induced or contributed to infringement by another person.

In this case, Elan accuses Abraxis of inducing and contributing to the infringement of claims 3, 5, 10 and 11 of the '363 Patent. It is your job to determine whether Elan has proven inducement of or contributory infringement by a preponderance of the evidence. Keep in mind that there can be no indirect infringement unless someone is directly infringing the patent. Thus, to prove that Abraxis is inducing another person to infringe or contributing to the infringement of another, Elan must prove by a preponderance of the evidence that Abraxis or another person is directly infringing a claim of the patent. Such proof may be based on circumstantial evidence you have heard in this case, rather than direct evidence of infringement.

4.5.1 Inducing Patent Infringement

Inducement to infringe requires someone purposefully urging or encouraging another to infringe a patent – inducement to infringe cannot occur unintentionally. This is different from direct infringement, which, as I have told you, can occur without any intent to infringe. To be liable for inducement to infringe, the accused inducer must have known of the patent and actively encouraged or instructed another person how to use a product in a manner that you find infringes the asserted patent claims. For example, an accused inducer may be liable for inducing infringement if it provided instructions or directions to perform the infringing act through labels, advertising or other materials with the specific intent to cause an end user to infringe. You may find that Abraxis induced infringement even if there is an express warning against infringement, if the material containing the warning nonetheless encourages the infringing activities under the circumstances.

Thus, to prove that Abraxis induced infringement of the '363 Patent, Elan must prove by a preponderance of the evidence the following things:

(1) Abraxis actively encouraged or instructed another person how to use a product in a way you, the jury, finds directly infringes the '363 Patent claims;

(2) Abraxis knew of the '363 Patent; and

(3) Abraxis knew and intended that its actions would cause direct infringement by another.

All three of these things must be proven by either direct or circumstantial evidence before you may find that Abraxis induced patent infringement.

4.5.2 Contributory Infringement

A second form of indirect infringement is contributory infringement. Contributory infringement can occur when someone supplies a component that is used to infringe one of the patent claims. The necessary proof to show contributory infringement is focused on the intent of the person supplying the component and the nature of that component. Specifically, to prove contributory infringement by Abraxis of the '363 Patent, Elan must prove by a preponderance of the evidence the following three things:

(1) Abraxane® is not a common component used for significant non-infringing uses, but rather, is especially made or adapted for a use that infringes the '363 Patent;

(2) Abraxis knew of the '363 Patent and sold Abraxane® knowing that Abraxane was especially made for a use that infringes the '363 Patent.

(3) Someone then bought Abraxane® and actually used it in a way that infringes each limitation of an asserted claim of the '363 Patent.

All three of these things must be proven by direct or circumstantial evidence before you may find that Abraxis contributed to the patent infringement.

4.6 Determination Of Infringement

Taking each asserted claim of the '363 Patent separately, if you find that Elan has proven by a preponderance of the evidence that each element of the claim is present, either literally or under the doctrine of equivalents, in Abraxis's accused product, Abraxane®, then you must find that Abraxis's accused product infringes that claim. You must analyze Abraxis's accused product separately under each asserted claim.

4.7 Willful Infringement [DISPUTED]

In this case, Elan argues that Abraxis infringed and, further, that Abraxis infringed willfully. Even if you have decided that Elan has infringed, you must address the additional issue of whether or not this infringement was willful. Willfulness requires you to determine two things: first, whether Abraxis acted despite an objectively high likelihood that its actions infringed a valid patent; and second, that this objectively high risk was either known or so obvious that it should have been known to Abraxis. To prove willful infringement, Elan must establish that Abraxis willfully infringed by clear and convincing evidence. That is Elan must prove willfulness in such a way that you have been left with an abiding conviction that willful infringement was highly probable.

In deciding whether or not Abraxis committed willful infringement, you must consider all of the facts, which include but are not limited to:

(1) Whether or not Abraxis intentionally copied a product of Elan that is covered by the '363 Patent,

(2) Whether or not Abraxis possessed a reasonable basis to believe that it had a substantial defense to infringement and reasonably believed that the defense would be successful if litigated.

(3) Whether or not Abraxis made a good faith effort to avoid infringing the patent, for example, Abraxis took remedial action upon learning of the patent by ceasing infringing activity or attempting to design around the patent;

(4) Whether or not Abraxis tried to cover up its infringement; [and

(5) You may consider whether a fair and reasonable competitor would have secured legal advice or a professional legal opinion that would clear it of the alleged infringement. However, the absence of an opinion of counsel does not require you to find willfulness.][13]

[13] Abraxis objects to the inclusion of the last factor for willful infringement. The Federal Circuit has stated that "invoking the attorney-client privilege or work product protection does not give rise to an adverse inference." *In re Seagate Tech., LLC*, 497 F.3d 1360, 1370 (Fed. Cir. 2007) (citing *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp*., 383 F.3d 1337, 1344-45 (Fed. Cir. 2004). Similarly, the Federal Circuit has made clear that an adverse inference is not appropriate when the party has not obtained an opinion of counsel:

> When the defendant had not obtained legal advice, is it appropriate to draw an adverse inference with respect to willful infringement? The answer, again, is "no." *Knorr-Bremse*, 383 F.3d at 1345.

Elan contends that omission of an instruction on competent legal advice is legal error. *In re Seagate Tech., LLC*, 497 F.3d 1360, 1369 (Fed. Cir. 2007) ("Although an infringer's reliance on favorable advice of counsel, *or conversely his failure to proffer any favorable advice*, is not dispositive of the willfulness inquiry, it is crucial to the analysis.") (emphasis supplied). *See also* Final Jury Instructions for District of Delaware in *Energy Transportation Group, Inc. v. Sonic Innovations, Inc. et al*, C.A. No. 05-422 -GMS (D. Del. Jan. 4, 2008). *See also* AIPLA Model Patent Jury Instruction 13 (2008) ("[A]lso In making the determination as to willfulness, you must consider the totality of the circumstances. The totality of the circumstances comprises a number of factors, which include, but are not limited to whether [the Defendant] intentionally copied the claimed invention or a product covered by [the Plaintiff]'s patent, *[whether [the Defendant] relied on competent legal advice,*] and whether [the Defendant] presented a substantial defense to infringement, including the defense that the patent is invalid [or unenforceable]." (emphasis supplied) (citing *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (*en banc*)).

5. VALIDITY

Abraxis contends that certain claims of the '363 Patent and the '025 Patent are invalid for failure to satisfy the legal requirements of patentability. In particular, Abraxis contends that claims 1, 3, 5, 10, and 11 of the '363 Patent and claims 1-3 and 13-15 of the '025 Patent are invalid for lack of enablement and failure to meet the written description requirement. I will now instruct you on each of these defenses.

5.1 Presumption Of Validity

The granting of a patent by the Patent Office carries with it the presumption that the patent's subject matter is new, useful and constitutes an advance that was not, at the time the invention was made, obvious to one of ordinary skill in the art. The law presumes, in the absence of clear and convincing evidence to the contrary, that the Patent Office acted correctly in issuing the patent. Nevertheless, once the validity of a patent has been put at issue, it is the responsibility of the jury to review what the Patent Office has done consistent with these instructions on the law.

Abraxis has the burden of proving invalidity of each patent claim by clear and convincing evidence.

5.2 Enablement [DISPUTED]

Abraxis contends that the asserted claims of the '363 and/or '025 Patent are invalid because the patent specification lacked an enabling disclosure.

Patent law requires that the disclosure or written description portion of a patent be sufficiently detailed to enable those skilled in the art to make and use the full scope of the claimed invention. The purpose of this requirement is to ensure that the public, in exchange for the patent rights given to the inventor, obtains from the inventor a full disclosure of how to carry out the claimed invention.

To meet this requirement, the patent disclosure must allow a person of ordinary skill in the art to practice the invention without undue experimentation. Because descriptions in patents are addressed to those skilled in the art to which the invention pertains, an applicant for a patent need not expressly include information that is commonly understood by persons skilled in the art. Moreover, the fact that some experimentation may be required for a skilled person to practice the claimed invention does not mean that the specification is not enabling. A specification is enabling so long as undue experimentation is not needed.

Factors to consider in determining whether a disclosure would require undue experimentation include testimony (including but not limited to expert opinion) and other evidence indicating

(1) the time and cost of any necessary experimentation;

(2) how routine any necessary experimentation would be to those of ordinary skill in the art;

(3) whether the '363 Patent and/or '025 Patent discloses specific working examples of the claimed invention;

(4) [whether the inventor attempted but failed to enable his invention in a commercial product embodying the claimed invention;][14]

(5) the amount of guidance presented in the '363 Patent and/or '025 Patent;

(6) the nature and predictability of the technical field of the invention;

(7) the level of ordinary skill in the field; and

(8) the scope of the claimed invention.

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[14] Abraxis proposes this factor to inform the jury that the failure to produce a commercial product is strong evidence of non-enablement. *Ormco Corp. v. Align Technology, Inc.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007).

Elan objects to this factor for the reasons set forth in its Motion in Limine No. 1. Commercial development of an invention is in most cases not a consideration for enablement. Abraxis' citation of *Ormco Corp. v. Align Technology, Inc.*, 498 F.3d 1307, 1318-19 (Fed. Cir. 2007) is not persuasive. In that case, inventors testified at deposition that commercial software incorporated their invention. This implied that the commercial products represented attempts to follow the patent specification. However, deposition testimony also showed that the commercial products could not successfully use the invention. Thus, the inventor attempted but failed to enable the invention in a commercial product. The Federal Circuit held that "[i]f an inventor attempts but fails to enable his invention in a commercial product that purports to be an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement."

In this case, there is no evidence that Elan makes a commercial product, much less that Elan attempted but failed to use the claimed invention in a commercial product. (The evidence does show that Elan's customers successfully use the claimed invention or the closely related invention of the '684 patent in products.)

Elan's business model is to assist its customers in developing commercial drug formulations. It does not make or sell any drug formulations of its own. Its situation is distinct from that in Ormco, where the patentees' commercial product failed to enable the invention. Inclusion of this instruction is prejudicial to Elan by making its business model possible evidence of non-enablement.

5.3 The Written Description Requirement

Abraxis contends that claims 1, 3, 5, 10, and 11 of the '363 Patent and claims 1-3 and 13-15 of the '025 Patent are invalid because they lack an adequate written description.

The patent law requires that a patent application contain an adequate written description of the invention to ensure that the inventor was in possession of the full scope of the invention at the time the patent application was filed.

The specification and claims as originally filed must convey to persons of ordinary skill in the art that the inventor had invented the full scope of the subject matter that is spelled out in the claims that ultimately issued as a patent. The description must be sufficiently clear that persons of ordinary skill in the art will recognize that the applicant made the invention having each of the limitations described in the claims.

That is, to prove a claim invalid for lack of an adequate written description, Abraxis must prove by clear and convincing evidence that the applications for the '363 Patent and the '025 Patent do not reasonably convey to a person of ordinary skill in the art that the inventors had possession of the invention at the time of the application as that invention was finally claimed in the issued patent. While no particular form of written description is required, the application must describe the claimed subject matter in terms that establish that Elan was in possession of the full scope of the claimed inventions, including all of the limitations.

5.4 Level of Ordinary Skill in the Art

In this case, a person of ordinary skill in the art would have a Ph.D. or the equivalent in pharmaceutical sciences, chemistry, chemical engineering, or biological sciences, and at least two years of practical experience in formulating drug compositions at the time the application for the '363 patent was filed.

Alternatively, a person of ordinary skill in the art could be someone with a Master's degree in pharmaceutical sciences, or the equivalent, with two or more years of practical experience, specifically in the development of nanoparticulate pharmaceutical compositions.

6. ENFORCEABILITY

In addition to claims of invalidity, Abraxis asserts that Elan may not enforce either the '363 Patent or the '025 Patent against Abraxis, because Abraxis alleges that the applicants for the patent acted inequitably when prosecuting their respective patent applications. Remember that a finding of unenforceability with respect to *any claim* in a patent renders the *entire patent* unenforceable.

For reasons that I will explain, Abraxis also asserts that Elan may not enforce the '363 Patent against Abraxis because Elan has unclean hands.

6.1 Inequitable Conduct

Abraxis contends that Elan may not enforce the '363 Patent or the '025 Patent against Abraxis because Elan engaged in inequitable conduct before the Patent and Trademark Office during prosecution of the '363 and '025 Patents. Elan denies this allegation.

Applicants for a patent have a duty to prosecute patent applications in the Patent and Trademark Office with candor, good faith, and honesty. This duty of candor and good faith extends to all inventors named on a patent application, all patent attorneys and patent agents involved in preparing and prosecuting the application, and every other person involved in a substantial way with the prosecution of the patent application and continues for the entire time the application is before the Patent Office. An intentional failure to meet this duty of candor and good faith is referred to as "inequitable conduct."

Abraxis must prove inequitable conduct by clear and convincing evidence. To determine whether the '363 Patent or the '025 Patent was obtained through inequitable conduct, you must determine whether a person having this duty of candor and good faith withheld or misrepresented information, or submitted false information, that was material to the examination of the patent application, and that this individual or individuals acted with an intent to deceive or mislead the PTO.

6.1.1 Materiality [DISPUTED]

Information or statements are material if they establish, either alone or in combination with other information or statements, that the invention sought to be patented more likely than not failed to satisfy one or more of the requirements for a patent. Examples of such requirements would include that the invention be new, useful, enabled and non-obvious, among others. Information or statements also are material if they refute or are inconsistent with a position that the applicant for a patent took when opposing an argument made by the examiner that the invention was not patentable or when making an argument to the examiner that the invention was patentable. [Adverse testing data that is directly related to an important issue of patentability, along with the applicant's interpretation of that data, is material information.][15]

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[15] Abraxis proposes the last sentence of the first paragraph based on *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1365-66 (Fed. Cir. 2007) (test data refuting applicant's position on patentability found to be material).

Elan objects to Abraxis's proposed inclusion of language purporting to define "adverse testing data" as material. The patentee's obligation under 35 U.S.C. Section 112 is to teach the public how to use his invention without undue experimentation, and to show that he was in possession of a way to make the invention work at the time he filed his application for patent. There is no obligation to teach the public how not to make the claimed invention. Abraxis's citation of *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1366 (Fed. Cir. 2007) is inapposite. In that case, inequitable conduct was found when, in the face of five rejections of the claims, applicant continued to withhold from the Examiner the fact that a claimed oil was not appreciably superior to the frying oil of the prior art, when such superiority was highly relevant to the claimed point of novelty. *Id*. at 1366. In this case, applicants never submitted that every listed surface modifier would be compatible with every listed drug, but to the contrary, described a "simple screening process" Col. 7, lns. 5-8.

It is inherent in the process of "screening" that some candidate surface modifiers will be "screened out." It could hardly have come as a surprise to the PTO or those of ordinary skill in the art that a screening process could involve some number of unsuccessful combinations, and it would be a misnomer to refer to the rejected modifiers as "failed experiments." Rather, the experiment as a whole (the screening process, not the particular match of a given surface modifier) is successful when some modifiers do not qualify, but some do, as suitable stabilizers.

Elan further objects to this instruction as improperly suggesting that any and all alleged screening "failures" must be reported to the PTO in order to meet the enablement requirement and comply with the duty of disclosure. The Federal Circuit has rejected just such a contention in *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

Information that is cumulative of, or in other words, adds little to or has no more bearing on the examination of an application than information the examiner already had, is not material.

You must next consider whether or not there was an intent to mislead or deceive the Patent Office.

> 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).

This proposed language is also improper with respect to the alleged "contamination problem." Abraxis cites *Cargill*, but this case is distinguishable. There is no evidence that "contamination" was an issue during examination, so Elan's allegedly adverse testing data is not material. *Cargill* 476 F.3d at 1365.

6.1.2 Intent

If you determine that material information was withheld from the Patent and Trademark Office, you must next determine whether this was done with an intent to deceive or mislead the Patent and Trademark Office. Intent to deceive the Patent and Trademark Office may be found from direct evidence. Such direct evidence is rare, however, and as a result, the law allows deceptive intent to be inferred from the facts and surrounding circumstances.

When a patentee has knowingly misrepresented a material fact or submitted false material information, and when the natural consequence of those intentional acts would be that to deceive the Patent and Trademark Office, an inference that the patentee intended to deceive may be appropriate. Simple negligence is insufficient for a holding of inequitable conduct.

In determining whether or not there was intent to deceive or mislead the Patent and Trademark Office, you should consider the totality of the circumstances, including the nature of the conduct and evidence of the absence or presence of good faith.

6.1.3 Balancing of Materiality and Intent

If Abraxis has proven by clear and convincing evidence that information was withheld by a person with the duty of good faith and candor, you must then balance the degree of materiality and the degree of intent to deceive or mislead the Patent and Trademark Office to determine whether or not the evidence is sufficient to establish clearly and convincingly that there was inequitable conduct committed in the prosecution of the '363 or '025 Patents. Where the materiality of the withheld information is high, the showing of intent needed to establish inequitable conduct is proportionally less. Likewise, when the showing of intent is high, the showing of materiality may be proportionally less.

6.2 Unclean Hands

The owner of a patent may be barred from enforcing the patent against an infringer where the owner of the patent acts or acted inequitably, unfairly, or deceitfully towards the infringer or the Court in a way that has immediate and necessary relation to the relief that the patent holder seeks in a lawsuit. This is referred to as "unclean hands," and it is a defense that Abraxis contends precludes any recovery by Elan in this lawsuit.

To decide the issue of unclean hands, you must consider and weigh all the facts and circumstances in view of the principles noted above to determine whether you believe that, on balance, Elan acted in such an unconscionable way towards Abraxis or the Court in the matters relating to the controversy between Elan and Abraxis that, in fairness, Elan should be denied the relief it seeks in this lawsuit.

Although the question of whether Elan's claims are barred by unclean hands is one that I will decide, I will ask for your findings so that I can consider them in making that decision. You should make determinations on this issue as you would for any other issue in this case because I will consider them seriously in making my determination.

7. DAMAGES

7.1 Generally

If, after considering all of the evidence and the law as I have stated it, you have determined either that: (i) no asserted '363 Patent claim is infringed by Abraxis, or (ii) the infringed claims are invalid, then your verdict should be for Abraxis and you need go no further in your deliberations. If at least one asserted claim is infringed and is not invalid, you must then turn to the issue of damages.

7.2 Compensatory Damages In General

In the context of this dispute, patent law provides that in the case of infringement of a valid patent claim, the owner of the patent shall be awarded a reasonable royalty for the use made of the invention by the infringer.

It is not relevant to the question of damages whether Abraxis benefited from, realized profits from or even lost money as a result of the acts of infringement. It is also not relevant if Abraxis did not foresee that it would cause Elan damage at the time that it infringed the asserted claims. The only issue is the amount of the reasonable royalty which Elan should receive to compensate it for Abraxis's infringement.

7.3 Burden Of Proof

Elan has the burden of proving damages by a preponderance of the evidence and is entitled to all damages that can be proven with reasonable certainty. On the one hand, reasonable certainty does not require proof of damages with mathematical precision. Mere difficulty in ascertaining damages is not fatal to Elan's right to recover. On the other hand, Elan is not entitled to speculative damages; that is, you should not award any amount of loss that, although possible, is wholly remote or the result of mere conjecture. You may base your evaluation of reasonable certainty on opinion evidence. Any doubts regarding the computation of the amount of damages should be resolved against Abraxis and in favor of Elan.

7.4 Date Damages May Begin

In this case, you should begin calculating damages as of January 7, 2005.

7.5 Reasonable Royalty As A Measure Of Damages

In this case, Elan seeks damages in the amount of a reasonable royalty for Abraxane®. A royalty is an amount of money that someone pays a patent owner to be able to use the patented invention. A reasonable royalty is the amount of money that would be agreed to in a hypothetical arm's-length negotiation between Elan and Abraxis, with both operating under the assumption that the negotiated patent is valid and would be infringed by Abraxane.

The reasonable royalty must be calculated as of the point in time just prior to when infringement would begin, which in this case would be the January 7, 2005 time period.

In the hypothetical arm's-length negotiation, you must assume that both parties are willing participants. You must assume that the person negotiating on behalf of Abraxis was willing to take a license and would have known that the asserted claims were valid, enforceable and infringed by Abraxis. You must also assume that Elan would have been willing to grant a license. Finally, you must assume that both Elan and Abraxis knew all pertinent information at the time of the hypothetical negotiations.

Having that in mind, you may consider any relevant fact in determining the reasonable royalty for Abraxis's use of the patented invention, including the opinion testimony of experts.

7.6 Factors For Determining Reasonable Royalty

In determining the amount of a reasonable royalty, you may consider evidence on any of the following factors:

(1) The royalties received by Elan for the licensing of others under the '363 Patent;

(2) The rates paid by a licensee of Elan, Abraxis, or others for the use of other patents comparable to the '363 Patent;

(3) The nature and scope of the license, as exclusive or nonexclusive, or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold;

(4) The absence of any policy by Elan to maintain its patent exclusivity by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that exclusivity;

(5) The commercial relationship between Elan and Abraxis, such as whether they are competitors in the same territory in the same line of business, or whether they are inventors or promoters;

(6) The duration of the '363 Patent and the length of the licenses;

(7) The established profitability of Abraxane® as made under the patent, its commercial success and its current popularity;

(8) The utility and advantages of Elan's patented inventions over the old modes or devices, if any, that had been used for working out similar results;

(9) The nature of the patented invention, the character of the commercial embodiment, and the benefits to those who have used the invention;

(10) The extent to which Abraxis has made use of the invention, and any evidence that shows the value of that use;

(11) The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or comparable inventions;

(12) The portion of the realizable profit that should be credited to the invention as distinguished from non-patented limitations, the manufacturing process, business risks, or significant features or improvements added by Abraxis;

(13) The opinion testimony of qualified experts; and

(14) Any other economic factor that a normally prudent business person would, under similar circumstances, take into consideration in negotiating the hypothetical license.

7.7 Interest

None of the parties' calculations include interest. Therefore, in arriving at your damages calculation, you should not consider interest in any way because it is the function of the Court to award interest.

7.8 Closing Statement – Damages [DISPUTED]

The fact that I have instructed you regarding damages should not be construed as suggesting which party is to prevail in this case. Instructions regarding damages are given for your guidance in the event that the evidence leads you to find in favor of Elan. Finally, if you find Elan is entitled to damages, you may not include or add to the award any sum for purposes of punishing Abraxis or to set an example. Nor should you award Elan any amount for any lost profits.

If you find that Elan is entitled to damages for past infringement by Abraxis, you should determine the monetary value of these past damages by applying a reasonable royalty to Abraxis's revenue from infringing sales and/or other infringing activities during the infringement period and entering the resultant dollar value in the applicable space on the Verdict Form.

[To compensate Elan for any future infringing use of the '363 Patent claims by Abraxis, you should enter in the applicable space on the verdict form the percentage rate that you determine is the reasonable royalty rate.][16]

[16] Abraxis objects to the paragraph in brackets as the issue of future damages is not a matter for the jury to decide. *See Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1316 (Fed. Cir. 2007) (no right to a jury trial on the amount of ongoing royalty); *Amado v. Microsoft Corp.*, 517 F.3d 1353, 1362 n.2 (Fed. Cir. 2008) ("[T]he proper amount of the eventual award. . . . of course, is a matter committed to the sound discretion of the district court."); *z4 Techs., Inc. v. Microsoft Corp.*, 434 F. Supp. 2d 437, 444-45 (E.D. Tex. 2006) (severing claims for damages for post-verdict infringement).

8. DELIBERATIONS AND VERDICT

8.1 Introduction

My instructions on the law are now finished. I will end by explaining how you will conduct your deliberation in the jury room and about your possible verdicts.

When you start deliberating, do not talk to the court officer, to me, or to anyone but each other about the case. If you have any questions or messages, you must write them on a piece of paper, sign them and give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take some time to get back to you. Any questions or messages normally should be sent through your foreperson, who by custom of this Court is juror No. 1.

One more thing about messages. Never write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that your vote is split, or whatever your vote happens to be. Your votes should stay secret until you are finished.

8.2 Unanimous Verdict

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, each juror must agree to the verdict. Your verdict must be unanimous.

Each of you must decide the case for yourself, but you should do so only after an impartial consideration of the evidence with your fellow jurors. Talk with each other, listen carefully and respectfully to everyone's views, and keep an open mind as you listen to what your fellow jurors have to say. Try your best to work out your differences. Do not hesitate to change your mind if you are convinced that other jurors are right and that your original position was wrong. But do not surrender your honest convictions as to the weight or effect of evidence solely because of the opinion of your fellow jurors or for the purpose of returning a verdict. Remember at all times that you are not partisans. You are judges – judges of the facts, and, in the end, your vote must be exactly that – your own vote. Your sole interest is to seek the truth from the evidence in the case.

A verdict form has been prepared for you. You will take this form to the jury room and when you have reached unanimous agreement as to your verdict, you will have your foreperson fill in, date, and sign the form. You will then return to the courtroom and your foreperson will give your verdict.

8.3 Duty To Deliberate

You are now free to talk about the case in the jury room. In fact, it is your duty to consult with each other, to talk with each other about the evidence, and to make every reasonable effort you can to reach unanimous agreement, if you can do so without violence to your individual judgment. No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. You should feel free to speak your minds.

Listen carefully to what the other jurors have to say, and then decide for yourself. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience.

8.4 Court Has No Opinion

Let me finish by repeating something that I said to you earlier. Nothing that I have said or done during this trial, nothing about my instructions, and nothing about the form of the verdict was meant to convey what I think your verdict should be or to influence your decision in any way. You must decide the case yourselves based solely on the evidence presented.