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.	)	

EXHIBIT 12: PARTIES' PROPOSED JURY INSTRUCTIONS

TABLE OF CONTENTS

Page

EXHIBIT 22: PRELIMINARY JURY INSTRUCTIONS AND 1
PARTIES' PROPOSED JURY INSTRUCTIONS 1
1. PRELIMINARY INSTRUCTIONS 1
1.1 Introduction 1
1.2 The Parties And Their Contentions 2
1.3 Duties Of The Jury 6
1.4 Evidence 7
1.5 Credibility Of Evidence – Weighing Conflicting Testimony 9
1.6 Burdens Of Proof 10
1.7 General Guidance Regarding Patents 14
1.8 Conduct Of The Jury 21
1.9 Course Of The Trial 23
1.10 Trial Schedule 24
1.11 Glossary Of Patent Terms 25
2. GENERAL INSTRUCTIONS 27
2.1 Introduction 27
2.2 Jurors' Duties 28
2.3 Burdens Of Proof 29
3. THE PARTIES AND THEIR CONTENTIONS 33
3.1 The Parties and Undisputed Facts 33
3.2 Elan's Contentions 34
3.3 Abraxis's Contentions 35
3.4 Summary Of Patent Issues 38
3.4.1 Infringement 38, 35
3.4.2 Willfulness 38, 35
3.4.3 Invalidity 34, 35
3.4.4. Unenforceability 41
4. INFRINGEMENT 42
4.1 Claim Infringement 42
4.2 Patent Claims 44

4.2.1 Patent Claims Generally 44
4.2.2 Independent And Dependent Claims 48
4.2.3 The Court Determines What Patent Claims Mean 51
4.3 Failure To Produce Evidence – Adverse Inference in Infringement 67
4.4 Patent Infringement (Direct) 71
4.4.1 Literal Infringement 73
4.4.2 Infringement Under the Doctrine Of Equivalents 75
4.4.3 Infringement Despite Defendant's Improvements or Patents on Improvements 81
4.4.4 Reverse Doctrine of Equivalents 83
4.5 Indirect Infringement 84
4.5.1 Inducing Patent Infringement 85
4.5.2 Contributory Infringement 89
4.6 Determination Of Infringement 91
4.7 Willful Infringement 93
5. Validity 98
5.1 Presumption Of Validity 100
5.2 Enablement 103
5.3 The Written Description Requirement 107
5.4 Obviousness 111
5.4.1 Scope and Content of the Prior Art 115
5.4.2 Differences Over the Prior Art 118
5.4.3 Level of Ordinary Skill 121
5.4.4 Secondary Considerations 124
5.5 Definiteness Under 35 U.S.C. § 112 128
5.6 Obviousness-Type Double Patenting 132
6. Enforceability 133
6.1 Inequitable Conduct 134
6.1.1 Materiality 136
6.1.2 Intent 138
6.1.3 Balancing of Materiality and Intent 139
6.2 Unclean Hands 140

7. DAMAGES 141
7.1 Generally 141
7.2 Compensatory Damages In General 142
7.3 Burden Of Proof 144
7.4 Date Damages May Begin 145
7.5 Reasonable Royalty As A Measure Of Damages 147
7.6 Factors For Determining Reasonable Royalty 148
7.7 Interest 150
7.8 Closing Statement – Damages 151
8. DELIBERATIONS AND VERDICT 152
8.1 Introduction 152
8.2 Unanimous Verdict 153
8.3 Duty To Deliberate 154
8.4 Court Has No Opinion 155

1. PRELIMINARY INSTRUCTIONS[1, 2, 3]

1.1 Introduction [AGREED]

Members of the jury: now that you have been sworn, I am going to give you some preliminary instructions to guide you in your participation in the trial.

These instructions will give you some general rules and guidance that might apply to any civil case. However, because this is a patent trial which will deal with subject matter that is not within the every day experience of most of you, I will also give you some preliminary instructions regarding patents to assist you in discharging your duties as jurors.

---

[1] These Preliminary Instructions are modeled after the Preliminary Jury Instructions - Patent (GMS) (Rev. 1/18/06) ("GMS Instructions").

[2] The parties have met and conferred to find common ground on jury instructions when possible. In cases for which these efforts have succeeded, a single joint jury instruction is provided and marked as AGREED.

(1) Both parties have drawn many of their instructions from particular sets of "model" or "form" instructions that have been promulgated by various courts and bar groups. In some instances, Elan and Abraxis have chosen instructions on a particular topic from different sets of model instructions, and cannot agree on which is better adapted to this case;

(2) The parties differ as to which language best expresses governing case law.

(3) The parties differ as to which form of jury instruction(s) will, on the facts of this case, most clearly and fairly frame the issues for the jury.

(4) The parties have met and conferred concerning their respective proposed jury instructions, however had not had a full opportunity to lodge objections. Accordingly, the parties reserve the right to supplement their objections and to continue to negotiate the differences between their respective positions.

(5) Elan has informed Abraxis that it intends to serve objections, but as of 11:00 p.m. EDT on April 7, 2008 it had not served them on Abraxis. As Elan has deprived Abraxis of the opportunity to respond to its objections, Abraxis reserves the right to supplement its objections if necessary.

[3] To the extent that the parties are permitted to present or argue claims, defenses, or theories not otherwise currently disclosed, both parties reserve the right to update and supplement their proposed instructions to take into account such theories. The parties also submit these proposed jury instructions prior to adjudication of the pending motions *in limin*e. Insofar as the Court's rulings on those motions alter the scope of the issues in this case, both parties reserve the right to revise their proposed instructions accordingly. Furthermore, the inclusion of any proposed instruction does not constitute consent by either party to include that instruction in the final set of jury instructions.

1.2 The Parties And Their Contentions [DISPUTED]

Elan's Proposed Instruction

Before I begin with those instructions, however, allow me to give you an overview of who the parties are and what each contends. You may recall that during the process that led to your selection as jurors, I advised you that this is a civil action for patent infringement arising under the patent laws of the United States.

The parties in this case are the plaintiff, Elan Pharma International Limited, and the defendant, Abraxis Bioscience, Inc. The dispute between the parties relates to very small particles of paclitaxel, an anti-cancer drug, that is marketed by Abraxis using the name Abraxane®. During the trial, the parties will offer testimony to familiarize you with this technology. Elan owns U.S. Patent No. 5,399,363, which it alleges Abraxis infringes.[4] Because the numbers are so long, patents are usually referred to by their last three digits. For example, Patent No. 5,399,363 is called simply "the '363 Patent." Elan contends that Abraxis makes, uses, sells, and offers for sale its Abraxane® product, which infringes this patent and that such infringement is willful. I, and the attorneys and witnesses, may refer to Abraxane® as the "accused product." An "accused product" simply refers to a product that Elan asserts infringes its patent. Elan seeks damages for Abraxis's alleged infringement. Elan does not contend that all of the claims of the '363 Patent are infringed by Abraxis. Instead, Elan asserts that only certain claims are infringed. They may be called the "asserted claims." You will determine whether or not the accused product infringes any of the asserted claims of Elan's patent.

[4] Elan contends that the only live issues in this case relate to the '363 Patent. Elan has elected not to prosecute its claims as to its U.S. Patent No. 5,834,025 ("the '025 Patent") pending a Patent and Trademark Office decision on Elan's application for reissue of the '025 patent or appeal of the Court's construction of that Patent. Accordingly, Elan has limited its proposed instructions herein to the '363 Patent. These proposed jury instructions are submitted subject to the parties' respective positions on the mootness of Abraxis's '025 Patent invalidity and unenforceability defenses and counterclaims. Elan maintains a standing objection to any instruction on "invalidity or unenforceability of the '025 Patent.

Persons or companies sued for allegedly infringing a patent can deny infringement. They can also defend a charge of infringement by proving the patent is invalid. In this case, Abraxis denies that it infringes Elan's patent and asserts what are called affirmative defenses and counterclaims to the charges of infringement. I will tell you more about infringement in a few minutes. I will instruct you as to defenses to a charge of infringement and possible damages resulting from a finding of infringement in my instructions to you at the close of the evidence.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as Abraxis's counterclaims for invalidity and unenforceability of the '025 patent remain live issues in this case. Abraxis also objects that Elan's proposed instruction does not refer to Abraxis's contentions regarding the unenforceability of the '363 Patent.

Abraxis's Proposed Instruction

Before I begin with those instructions, however, allow me to give you an overview of who the parties are and what each contends. You may recall that during the process that led to your selection as jurors, I advised you that this is a civil action for patent infringement arising under the patent laws of the United States.

The parties in this case are the plaintiff, Elan Pharma International Limited, and the defendant, Abraxis BioScience, Inc. The dispute between the parties relates to an anti-cancer drug that is marketed by Abraxis using the name Abraxane®. During the trial, the parties will offer testimony to familiarize you with this technology.

This case involves two different patents owned by Elan.[5] The first is U.S. Patent No. 5,399,363, which Elan alleges Abraxis infringes. Because the numbers are so long, patents are usually referred to by their last three digits. For example, Patent No. 5,399,363 is called simply "the '363 Patent." Elan contends that Abraxis makes, uses, sells, and offers for sale its Abraxane® product, which infringes this patent [and that such infringement is willful.][6] I, and the attorneys and witnesses, may refer to Abraxane® as the "accused product." An "accused product" simply refers to a product that Elan asserts infringes its patent. Elan seeks damages for Abraxis's alleged infringement. Elan does not contend that all of the claims of the '363 Patent are infringed by Abraxis. Instead, Elan asserts that only certain claims are infringed. These may be called the "asserted claims." You will determine whether or not the accused product infringes any of the asserted claims of the '363 Patent.

---

[5] Abraxis contends that the jury should be instructed on its counterclaims for invalidity and unenforceability of the '025 Patent.

[6] Abraxis objects to all references and instructions on willful infringement. If the Court requires an instruction on willful infringement, Abraxis consents to the language in brackets.

Persons or companies sued for allegedly infringing a patent can deny infringement. They can also defend a charge of infringement by proving the patent is invalid or unenforceable. In this case, Abraxis denies that it infringes the '363 Patent and asserts what are called affirmative defenses and counterclaims to the charges of infringement.

The second patent in this case, U.S. Patent No. 5,834,025, which I will refer to as the '025 Patent, is also owned by Elan. Earlier in this lawsuit, Elan alleged that Abraxis also infringed the '025 Patent. Abraxis counterclaimed with charges of invalidity and unenforceability. While Elan has withdrawn its claims of infringement of the '025 Patent, Abraxis's contentions remain live issues. Therefore, you will determine whether or not the '025 Patent is invalid and unenforceable.

I will tell you more about infringement in a few minutes. I will instruct you as to defenses to a charge of infringement and possible damages resulting from a finding of infringement in my instructions to you at the close of the evidence.

Elan's Objections

Elan objects to Abraxis's proposed instructions on the '025 Patent for the reasons set out in n.4 on p. 2.

1.3 Duties Of The Jury [AGREED]

So, let me begin with those general rules that will govern the discharge of your duties as jurors in this case. It will be your duty to find from the evidence what the facts are. You and you alone will be the judges of the facts. You will then have to apply to those facts to the law as I will give it to you both during these preliminary instructions and at the close of the evidence. You must follow that law whether you agree with it or not. In addition to instructing you about the law, at the close of the evidence, I will provide you with instructions as to what the claims of the patents mean. Again, of course, you are bound by your oath as jurors to follow these and all the instructions that I give you, even if you personally disagree with them. All the instructions are important, and you should consider them together as a whole.

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. Also, do not let anything that I may say or do during the course of the trial influence you. Nothing that I may say or do is intended to indicate, or should be taken by you as indicating, what your verdict should be.

1.4 Evidence [AGREED]

The evidence from which you will find the facts will consist of the testimony of witnesses; (the testimony of witnesses consists of the answers of the witnesses to questions posed by the attorneys or the court – you may not ask questions). Evidence will also consist of documents and other things received into the record as exhibits, and any facts that the lawyers agree to or stipulate to or that I may instruct you to find. Certain things are not evidence and must not be considered by you. I will list them for you now:

(1) Statements, arguments, and questions by lawyers are not evidence.

(2) Objections to questions are not evidence. Lawyers have an obligation to their clients to make objections when they believe evidence being offered is improper under the rules of evidence. You should not be influenced by the objection or by the Court's ruling on it. If the objection is sustained, ignore the question. If it is overruled, treat the answer like any other. If you are instructed that some item of evidence is received for a limited purpose only, you must follow that instruction.

(3) Testimony that the Court has excluded or told you to disregard is not evidence and must not be considered.

(4) Anything you may have seen or heard outside the courtroom is not evidence and must be disregarded. You are to decide the case solely on the evidence presented here in the courtroom.

There are two kinds of evidence: direct and circumstantial. Direct evidence is direct proof of a fact, such as testimony of an eyewitness. Circumstantial evidence is proof of facts from which you may infer or conclude that other facts exist. As a general rule, the law makes no

distinction between these two types of evidence, but simply requires that you find facts from all the evidence in the case, whether direct or circumstantial or a combination of the two.

1.5 Credibility Of Evidence – Weighing Conflicting Testimony [AGREED]

You are the sole judges of each witness's credibility. You should consider each witness's means of knowledge; strength of memory; opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; whether it has been contradicted; the witness's biases, prejudices, or interests; the witness's manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.

If you find the testimony to be contradictory, you must try to reconcile it, if reasonably possible, so as to make one harmonious story of it all. But if you can't do this, then it is your duty and privilege to believe the testimony that, in your judgment, is most believable and disregard any testimony that, in your judgment, is not believable. This instruction applies to the testimony of all witnesses, including expert witnesses.

1.6 Burdens Of Proof [DISPUTED]

Elan's Proposed Instruction

As I have already told you, in this case, Elan is the owner of the '363 Patent which it contends Abraxis infringes. Elan, therefore, has the burden of proving infringement by what is called a preponderance of the evidence. That means Elan has to produce evidence which, considered in the light of all the facts, leads you to believe that what the patent owner alleges is more likely true than not. To put it differently, if you were to put Elan's and Abraxis's evidence on opposite sides of a scale, the evidence supporting Elan's allegations would have to make the scale tip somewhat on its side. If Elan fails to meet this burden, the verdict should be for Abraxis. Elan must also prove its damages by a preponderance of the evidence.

In this case, Abraxis asserts that Elan's '363 patent is invalid. A patent, however, is presumed to be valid. Accordingly, the party challenging the patent has the burden of proving by clear and convincing evidence that the patent is invalid. 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.

Elan also contends that Abraxis willfully infringed the patent in suit. Elan must prove willful infringement by clear and convincing evidence. Those of you who have sat on criminal cases will have heard of proof beyond a reasonable doubt. That requirement does not apply to a civil case; therefore, you should put it out of your mind.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as Abraxis's counterclaims for invalidity and unenforceability of the '025 patent remain live issues in this case. Abraxis also objects that

Elan's proposed instruction does not refer to Abraxis's contentions regarding the unenforceability of the '363 Patent.

Abraxis objects to Elan's substitution of "should" for "must" in the fifth sentence of the first paragraph from the GMS Instructions, 5-6. If Elan fails to meet its burden of proof, the jury should not be instructed that it may nonetheless find for Elan, as Elan's instruction would permit. Elan's instruction is also unbalanced, as its proposed instruction 4.6 provides that the jury "must" find for Elan if it determines that Elan meets its burden of proof.

Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, or failure to meet the written description requirement. In this case, the prior art and the information establishing lack of enablement and lack of written description were not available to the USPTO, so the clear and convincing standard and the presumption of validity should not apply. *See KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1745, 167 L. Ed. 2d 705 (2007) (noting that rationale underlying presumption of validity "diminished" where art is not disclosed to the PTO).

In the event that the Court finds Abraxis bears a "clear and convincing" evidentiary burden, Abraxis objects to the sentence, "A patent, however, is presumed to be valid" as unnecessary and unfairly prejudicial, in view of the instructions that the jury will receive on the burden of proof for invalidity. *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1259 (Fed Cir. 2004) (refusing to find error in district court's decision not to include instruction regarding the presumption of validity). Abraxis's objections to all references about a patent's presumption of validity are further explained in Abraxis's objection to Elan's Proposed Instruction 5.1.

Elan's proposed instruction also confuses the jury for two reasons. First, Elan's proposed instruction does not clarify that the standard for the burdens of proof for invalidity, unenforceability and willful infringement are the same. In contrast, Abraxis's proposed instruction uses the same language to describe the burden of proof for each claim, emphasizing that each claim requires the identical burden of proof.

Second, Elan's proposed instruction may confuse the jury since the issues are presented out of order. In contrast, Abraxis's proposed instruction presents the claim of willful infringement before the claims of invalidity and unenforceability, the order in which the case will be presented to the jury.

Abraxis's Proposed Instruction

As I have already told you, in this case, Elan is the owner of the '363 Patent which it contends Abraxis infringes. Elan, therefore, has the burden of proving its allegations of infringement and its alleged damages by what is called a preponderance of the evidence. That means Elan has to produce evidence which, considered in the light of all the facts, leads you to believe that what the patent owner alleges is more likely true than not. To put it differently, if you were to put Elan's and Abraxis's evidence on opposite sides of a scale, the evidence supporting Elan's allegations would have to make the scale tip somewhat on its side. If Elan fails to meet this burden, the verdict must be for Abraxis. Elan must also prove its damages by a preponderance of the evidence.

[Elan also contends that Abraxis willfully infringed the patent in suit. Elan must prove willful infringement by clear and convincing evidence. 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.][7]

In this case, Abraxis asserts that Elan's patents, both the '363 Patent and the '025 Patent, are invalid and unenforceable. The party challenging the patent has the burden of proving [by clear and convincing evidence][8] that the patent is invalid and/or unenforceable. [As I mentioned

[7] Abraxis objects to the inclusion of all references and instructions on willful infringement. If the Court requires an instruction on willfulness, Abraxis proposes the language in brackets.

[8] Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement. If the Court requires an instruction on clear and convincing evidence of invalidity, Abraxis proposes the language in brackets.

earlier, clear and convincing evidence is evidence that produces an abiding conviction that the truth of a factual contention is highly probable.] [9]

Those of you who have sat on criminal cases will have heard of proof beyond a reasonable doubt. That requirement does not apply to a civil case; therefore, you should put it out of your mind.

Elan's Objections:

Elan objects to Abraxis's instructions on the '025 Patent for the reason set forth in n.4 on p. 2.

Elan objects to Abraxis's omitting a statutory instruction on the presumption of validity, 35 U.S.C. 282, and the burden of proof for invalidity.

[9] Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement. If the Court requires an instruction on clear and convincing evidence of invalidity, Abraxis proposes the language in brackets.

1.7 General Guidance Regarding Patents [DISPUTED]

Undisputed Section of the Instruction

I will now give you a general overview of what a patent is and how one is obtained.

Constitutional Basis For Patent Grant

The United States Constitution, Article I, Section 8, grants the Congress of the United States the power to enact laws "to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

Exclusionary Right And Term Of A Patent

The United States Patent and Trademark Office is responsible for reviewing patent applications and granting patents. Once the "Patent Office" or "PTO" has issued a patent, the patent owner has the right to exclude others from making, using, selling, or offering for sale the invention throughout the United States for the length of the patent term. A person who, without the patent owner's authority, makes, uses, sells, or offers to sell, within the United States, a product that is covered by one or more claims of a valid patent infringes the patent. A person can also induce others to infringe a patent or contribute to the infringement of others. These are types of indirect infringement.

The Parts Of A Patent

I will next briefly describe the parts of a patent and some of the procedures followed by those attempting to obtain patents. Many of the terms used by me in this description are contained in a "Glossary of Patent Terms," which I will give to you along with a copy of these preliminary instructions. Feel free to refer to the Glossary throughout the trial.

For an invention to be patentable, it must be new, useful, and, at the time the invention was made, must not have been obvious to a person having ordinary skill in the art to which the subject matter pertains. Under the patent laws, the United States Patent and Trademark Office examines patent applications and issues patents. A person applying for a patent must include a number of items in his or her application, including: (1) a detailed description of the invention in terms sufficiently full, clear, concise and exact to enable any person skilled in the art to which the invention pertains to be able to make and use the invention; (2) a disclosure of the best mode of carrying out the invention known to the inventor at the time of filing; and (3) one or more claims.

The application includes a written description of the invention called a "specification" and may include drawings that illustrate the invention. The specification concludes with one or more claims that particularly and distinctly define the subject matter that the inventor regards as his invention. When a patent application is received at the Patent and Trademark Office, it is assigned to an examiner, who examines the application, including the claims, to determine whether the application complies with the requirements of the U.S. patent laws. The examiner reviews the prior work of others in the form of voluminous files of patents and publications. This type of material is called "prior art." Prior art is generally technical information and knowledge that was known to the public either before the invention by the applicant or more than one year before the filing date of the application. Documents found in the search of prior art are sometimes called "references." In conducting the search of prior art, the examiner notes in writing on the file the classes or subclasses of art searched. The compilation of the papers concerning the proceedings before the Patent Office is called the "prosecution history," "file wrapper," or "file history." The PTO does not have its own laboratories or testing facilities.

The examiner may "reject" the application claims if he believes that they are applications for inventions that are not patentable in light of the prior art, or because the patent specification does not adequately describe the claimed inventions. The applicant may then amend the claims to respond to the examiner's rejections. If, after reviewing the prior art maintained at the PTO, the examiner concludes that the claims presented by the applicant define the applicant's claimed invention over the most relevant known prior art in a manner that is patentable and that the patent meets the other requirements for patentability, the application is granted as a U.S. patent.

Elan's Proposal for the Disputed Section

Summary Of The Patent Issues

In this case, you must decide several things according to the instructions that I will give you at the end of the trial. Those instructions will repeat this summary and will provide more detail. One thing you will *not* need to decide is the meaning of the patent claims. That is one of my jobs – to explain to you what the patent claims mean. The word "claims" is a term of art and I will instruct you on its meaning at trial's end. Meanwhile, you will find a definition in the glossary attached to these preliminary instructions. In essence, you must decide:

(1) Whether Elan has proven by a preponderance of the evidence that Abraxis's accused product infringes one or more of the asserted claims of the '363 Patent;

(2) If you find that one or more of Elan's asserted claims are infringed whether, by clear and convincing evidence, that infringement was willful;

(3) Whether those asserted claims of Elan's that have been infringed have been proven by Abraxis by clear and convincing evidence to be invalid; and

(4) For those patents that are valid and infringed, whether Elan has proven its alleged measure of damages for the infringement by a preponderance of the evidence.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as Abraxis's counterclaims for invalidity and unenforceability of the '025 patent remain live issues in this case. Abraxis also objects that Elan's proposed instruction does not refer to Abraxis's contentions regarding the unenforceability of the '363 Patent.

Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement. Abraxis also objects to all references and instructions on willful infringement.

Abraxis's Proposal for the Disputed Section

Summary Of The Patent Issues

In this case, you must decide several things according to the instructions that I will give you at the end of the trial. Those instructions will repeat this summary and will provide more detail. One thing you will *not* need to decide is the meaning of the patent claims. That is one of my jobs – to explain to you what the patent claims mean. The word "claims" is a term of art and I will instruct you on its meaning at trial's end. Meanwhile, you will find a definition in the glossary attached to these preliminary instructions. With respect to the '363 Patent, you must decide:

(1) Whether Elan has proven by a preponderance of the evidence that Abraxane infringes one or more of the asserted claims of the '363 Patent;

(2) [If you find that one or more of Elan's asserted claims are infringed whether Elan has proven by clear and convincing evidence that infringement was willful;][10]

(3) Whether certain claims of the '363 Patent have been proven by Abraxis [by clear and convincing evidence][11] to be invalid;

(4) Whether Abraxis has proven by clear and convincing evidence that the '363 Patent is unenforceable for inequitable conduct or unclean hands; and

[10] Abraxis objects to all references and instructions on willful infringement. If the Court requires an instruction on willful infringement, Abraxis consents to the language in brackets.

[11] Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement. If the Court requires an instruction on clear and convincing evidence of invalidity, Abraxis proposes the language in brackets.

(5) If you find that the claims of the '363 Patent are valid, enforceable, and infringed, whether Elan has proven its alleged measure of damages for the infringement by a preponderance of the evidence.

With respect to the '025 Patent, you must decide:

(a) Whether Abraxis has proven [by clear and convincing evidence][12] that certain claims of the '025 Patent are invalid; and

(b) Whether Abraxis has proven by clear and convincing evidence that the '025 Patent is unenforceable for inequitable conduct.

Elan's Objections:

Elan objects to Abraxis's instructions on the '025 Patent for the reason set forth in n.4 on p. 2.

Elan objects to Abraxis's omitting a statutory instruction on the presumption of validity, 35 U.S.C. 282, and the burden of proof for invalidity.

[12] Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement. If the Court requires an instruction on clear and convincing evidence of invalidity, Abraxis proposes the language in brackets.

1.8 Conduct Of The Jury [AGREED]

Now, a few words about your conduct as jurors. First, I instruct you that during the trial you are not to discuss the case with anyone or permit anyone to discuss it with you. Until you retire to the jury room at the end of the case to deliberate on your verdict, you simply are not to talk about this case. If any lawyer, party, or witness does not speak to you when you pass in the hall, ride the elevator, or the like, remember it is because they are not supposed to talk with you nor you with them. In this way, any unwarranted and unnecessary suspicion about your fairness can be avoided. If anyone should try to talk to you about the case, bring it to the court's attention promptly.

Second, do not read or listen to anything touching on this case in any way. Third, do not try to do any research or make any investigation about the case on your own. Finally, do not form any opinion until all the evidence is in. Keep an open mind until you start your deliberations at the end of the case.

During the trial, I will permit you to take notes. A word of caution is in order. There is always a tendency to attach undue importance to matters which one has written down. Some testimony that is considered unimportant at the time presented, and thus not written down, takes on greater importance later in the trial in light of all the evidence presented. Therefore, you are instructed that your notes are only a tool to aid your own individual memory and you should not compare your notes with other jurors in determining the content of any testimony or in evaluating the importance of any evidence. Your notes are not evidence, and are by no means a complete outline of the proceedings or a list of the highlights of the trial. Above all, your memory should be your greatest asset when it comes time to deliberate and render a decision in this case. So, if you do take notes, leave them in your seat at the end of the day, and my Deputy

will collect them and return them to your seat the next day. And, remember that they are for your own personal use.

I will give you detailed instructions on the law at the end of the case, and those instructions will control your deliberations and decision.

1.9 Course Of The Trial [AGREED]

This trial, like most jury trials, comes in seven stages or phases. We have already been through the first phase, which was to select you as jurors. The remaining stages are:

(2) These preliminary instructions to you;

(3) Opening statements, which are intended to explain to you what each side intends to prove and are offered to help you follow the evidence. The lawyers are not required to make opening statements at this time, or they may defer this opening until it is their turn to present evidence;

(4) The presentation of the evidence, which will include live witnesses and may also include previously recorded testimony, as well as documents and things;

(5) My final instructions on the law to you;

(6) The closing arguments of the lawyers, which will be offered to help you make your determination; and, finally, and

(7) Your deliberations, during which you will evaluate and discuss the evidence among yourselves and determine the outcome of the case. Please keep in mind that evidence is often introduced somewhat piecemeal. So, as the evidence comes in, you as jurors need to keep an open mind. We will begin shortly, but first I want to outline the anticipated schedule of the trial.

1.10 Trial Schedule [AGREED]

Though you have heard me say this during the *voir dire*, I want to again outline the schedule I expect to maintain during the course of this trial. This case is expected to take ten (10) court days to try. We will normally begin the day at 9:00 a.m. promptly. We will go until 1:00 p.m. and, after a one hour break for lunch, proceed from 2:00 p.m. to 4:30 p.m. There will be a fifteen minute break at 11:00 A.M. and another fifteen minute break at 3:15. The only significant exception to this schedule may occur when the case is submitted to you for your deliberations. On that day the proceedings might last beyond 5:00 p.m. We will post a copy of the schedule for your convenience in the jury deliberation room.

1.11 Glossary Of Patent Terms [AGREED]

Applicants – The named inventors who are applying for the patent.

Assignment – Transfer of ownership rights in a patent or patent application from one person or company to another.

Claims – The part of a patent that defines the invention. These are found at the end of the patent specification in the form of numbered paragraphs.

Dependent Claims - A claim that refers to at least one other claim in the patent. A dependent claim includes all of the elements and limitations of the claims to which it refers.

Disclosure Of Invention – The part of the patent specification that explains how the invention works and usually includes a drawing.

File Wrapper, File History Or Prosecution History – The written record of proceedings in the United States Patent and Trademark Office ("Patent Office" or "PTO"), including the original patent application and later rejections, responses to the rejections and other communications between the Patent Office and the applicant.

Independent Claims - A claim that may be read alone to determine the elements and limitations that must exist to infringe the claim.

Patent Application – The initial papers filed in the Patent Office by an applicant. These typically include a specification, drawings, claims and the oath (Declaration) of the applicant.

Patent Examiners – Personnel employed by the Patent Office having expertise in various technical areas who review (examine) patent applications to determine whether the claims of a patent application are patentable and whether the disclosure adequately describes the invention.

Prior art – Any information that is used to describe public, technical knowledge prior to the invention by the applicant or more than a year prior to the filing of his/her application.

Prior Art References – Any item of prior art (publication, patent or product) used to determine patentability.

Specification – The part of the patent application or patent that describes the invention, and may include drawings. The specification does not define the invention, only the claims do.

2. GENERAL INSTRUCTIONS[13]

2.1 Introduction [AGREED]

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.

[13] Unless otherwise noted, these instructions are modeled upon and substantially incorporate the text of the Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004) ("2004 Delaware Instructions"). The parties note that these instructions have not been formally adopted by the Judges of this District, and further are mindful of the drafters' admonition in the Preface to those Draft Uniform Instructions that litigants ought "to independently ensure that the case law reflected by the instructions is accurate given the facts and circumstances of each case." The parties have in appropriate instances provided customized, updated, and/or supplemental language for certain respective proposed instructions, in each case providing accompanying authority therefor.

2.2 Jurors' Duties [AGREED]

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 [DISPUTED]

Elan's Proposed Instruction

This is a civil case in which the plaintiff, Elan is charging the defendant, Abraxis with patent infringement. Elan alleges that Abraxis has infringed the asserted claims of the '363 Patent. Elan has the burden of proving patent infringement by what is called a preponderance of the evidence. That means Elan has to 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.

In this case, Abraxis is urging that Elan's patent is invalid or unenforceable. A patent, however, is presumed to be valid. Accordingly, Abraxis has the burden of proving that the patent is invalid or unenforceable by clear and convincing evidence. 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 addition, 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.

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.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as Abraxis's counterclaims for invalidity and unenforceability of the '025 patent remain live issues in this case. Abraxis also objects that

Elan's proposed instruction does not refer to Abraxis's contentions regarding the unenforceability of the '363 Patent.

Elan's proposed instruction also confuses the jury for two reasons. First, Elan's proposed instruction does not clarify that the standard for the burdens of proof for invalidity, unenforceability and willful infringement are the same. In contrast, Abraxis's proposed instruction uses the same language to describe the burden of proof for each claim, emphasizing that each claim requires the identical burden of proof.

Second, Elan's proposed instruction confuses the jury since the issues are presented out of order. In contrast, Abraxis's proposed instruction presents the claim of willful infringement before the claims of invalidity and unenforceability, the order in which the case will be presented to the jury.

Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement. *See* Abraxis's Objections to Elan's Proposed Instruction 1.6.

Abraxis's Proposed Instruction

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.][14]

In this case, Abraxis contends that Elan's patents, both the '363 Patent and the '025 Patent, are invalid and unenforceable. 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.] [15]

[14] Abraxis objects to all references and instructions on willful infringement. If the Court requires an instruction on willful infringement, Abraxis proposes the language in brackets.

[15] Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement. If the Court requires an instruction on clear and convincing evidence of invalidity, Abraxis proposes the language in brackets.

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.

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004).

Elan's Objections:

Elan objects to Abraxis's instructions on the '025 Patent for the reason set forth in n.4 on p. 2.

Elan objects to Abraxis's omitting a statutory instruction on the presumption of validity, 35 U.S.C. 282, and the burden of proof for invalidity.

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 will hear referred to a paclitaxel or taxol.

As further background to the technical matters that are at issue in this case, the dispute between the parties relates to an anti-cancer drug made and marketed by Abraxis under the trade name Abraxane®. Abraxane® contains particles. The particles contain an anti-cancer drug, paclitaxel (also sometimes referred to as taxol) and a surface modifier, human albumin adsorbed (which means retained) to the surface of the anticancer drug. The particles in Abraxane® have an average effective particle size of less than 300 nanometers. That is, at least ninety percent of the particles in Abraxane® are less than 300 nanometers. Paclitaxel is a medicament (or drug) useful for treating cancer. Paclitaxel particles in Abraxane® have been treated or "surface modified" in such a way as to make them better suited for successful administration in human cancer patients. A nanometer is a unit of measure, just like inches, feet, and miles. By definition, a nanometer is a billionth of a meter, so small that it can only be observed by specialized instruments. During the trial, the parties offered testimony to further familiarize you with nanotechnology.

Abraxis's Objections

Abraxis objects to the inclusion of undisputed facts in the jury instructions as unnecessary, confusing to the jury and redundant since they concern facts that are not at issue in the case. *See* Abraxis's Proposed Instructions 3.3 and 4.6.

3.2 Elan's Contentions [DISPUTED]

Elan contends that Abraxis has been and still is making, using, offering to sell, and selling in the United States a nanoparticle form of paclitaxel, marketed as Abraxane®, that infringes 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 also asserts that these acts of infringement have been and are "willful," on Abraxis's part, as I will define for you shortly.]

Abraxis's Objections

Abraxis objects to the inclusion of all references and instructions on willful infringement. If the Court requires an instruction on willful infringement, Abraxis consents to the language in brackets.

3.3 Abraxis's Contentions [DISPUTED]

Elan's Proposed Instruction

Abraxis denies that it infringed or infringes any of the asserted patent claims.

Abraxis denies that it has willfully infringed any of the asserted patent claims.

Abraxis further contends that the asserted patent claims of the '363 Patents are invalid for various reasons that will be discussed later.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as Abraxis's counterclaims for invalidity and unenforceability of the '025 Patent remain live issues in this case. Abraxis also objects that Elan's proposed instruction does not refer to Abraxis's contentions regarding the unenforceability of the '363 Patent. Abraxis also objects to all references and instructions on willful infringement. Abraxis also objects that Elan's proposed instruction fails to focus the jury's attention on crystallinity and cross-linking, the central infringement issues in this case.

Abraxis's Proposed Instruction

Abraxis denies that it infringed or infringes any of claims 1, 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 99.9-10% by weight of a *crystalline* medicament and 0.1-90% by weight of a surface modifier that is essentially free of intermolecular crosslinkages. Abraxis does not dispute that Abraxane meets the other limitations of '363 Patent claims 1, 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.][16]

Abraxis contends that claims 1, 3, 5, 10, and 11 of the '363 Patent are invalid for several reasons: the specification failed to enable those in the field to make and use the claimed invention; the specification failed to adequately describe the claimed invention; the claimed invention was obvious in light of the prior art; and the claims are indefinite.

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

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

[16] Abraxis objects to all references and instructions on willful infringement. If the Court requires an instruction on willful infringement, Abraxis proposes the language in brackets.

Abraxis also contends that claims 1-3 and 13-15 of the '025 Patent are invalid for several reasons: the specification failed to enable those in the field to make and use the claimed invention; the specification failed to adequately describe the claimed invention; and the claims are indefinite.

Abraxis further contends that the '025 Patent is unenforceable due to inequitable conduct before the USPTO.

Elan's Objections:

Elan objects to Abraxis's instructions on the '025 Patent for the reason set forth in n.4 on p. 2.

Elan objects to Abraxis's omitting a statutory instruction on the presumption of validity, 35 U.S.C. 282, and the burden of proof for invalidity.

3.4 Summary Of Patent Issues [DISPUTED]

Elan's Proposed Instruction

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 one of the asserted claims of the '363 Patent by making, using, offering to sell, or selling in the United States a nanoparticle form of paclitaxel, marketed as Abraxane®?

Has Elan proven by a preponderance of the evidence that Abraxis has been or is now contributing to or actively inducing infringement of any one of the asserted claims 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 the '363 Patent, and/or that Abraxis has contributed to or actively induced the infringement of the '363 Patent by others, has Elan persuaded you that it is highly probable 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 the claims of the '363 Patent are invalid because the claims are obvious, indefinite, not enabled, or not properly described in the '363 Patent?

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as Abraxis's counterclaims for invalidity and unenforceability of the '025 patent remain live issues in this case. Abraxis objects that

Elan's proposed instruction does not refer to Abraxis's contentions regarding unenforceability of the '363 Patent.

Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement. Abraxis also objects to all references and instructions on willful infringement.

Abraxis's Proposed Instruction

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 1, 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 1, 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 1, 3, 5, 10, 11 of '363 Patent, and/or that Abraxis has contributed to or actively induced the infringement of the claims 1, 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?][17]

3.4.3 Invalidity

Has Abraxis proven [by clear and convincing evidence][18] that claims 1, 3, 5, 10 and 11 of the '363 Patent are invalid because the claims are not enabled, not properly described, obvious, and/or indefinite?

[17] Abraxis objects to all references and instructions on willful infringement. If the Court requires an instruction on willful infringement, Abraxis proposes the language in brackets.

[18] Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement. If the Court requires an instruction on clear and convincing evidence of invalidity, Abraxis proposes the language in brackets.

Has Abraxis proven [by clear and convincing evidence][19] that claims 1-3 and 13-15 of the '025 Patent are invalid because the claims are not properly enabled, not properly described, and/or indefinite?

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?

Elan's Objections:

Elan objects to Abraxis's instructions on the '025 Patent for the reason set forth in n.4 on p. 2.

Elan objects to Abraxis's omitting a statutory instruction on the presumption of validity, 35 U.S.C. 282, and the burden of proof for invalidity.

Elan also objects to Abraxis's instructions on infringement of claim 1 of '363 patent. Elan has determined to assert claims 3, 5, 10 and 11 of the '363 patent.

[19] Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement. If the Court requires an instruction on clear and convincing evidence of invalidity, Abraxis proposes the language in brackets.

4. INFRINGEMENT

4.1 Claim Infringement [DISPUTED]

Elan's Proposed Instruction

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.

As I stated before, Elan alleges that Abraxis infringes certain claims of the '363 Patent. If any person makes, uses, sells, or offers for sale that which 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 patent here. To prove infringement of a patent, Plaintiff must persuade you by a preponderance of the evidence that Defendant has infringed a claim in the patent.

Abraxis's Comments

Abraxis objects to the first sentence of the second paragraph of Elan's proposed instruction as unnecessary and redundant. Abraxis also objects that Elan's proposed instruction fails to clarify that the '025 Patent is not relevant to Elan's claims for infringement.

Abraxis's Proposed Instruction

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 when determining infringement.

Source: Adapted from the Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004).

Elan's Objections:

Elan objects to Abraxis's final paragraph as unnecessary and confusing.

4.2 Patent Claims

4.2.1 Patent Claims Generally [DISPUTED]

Elan's Proposed Instruction

To decide whether Abraxis has infringed Elan's 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 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 also includes 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.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as claim 1 of the '363 patent is still at issue. Abraxis objects that Elan's proposed instruction fails to clarify that disclosed but unclaimed information is "dedicated to the public" and cannot be infringed. *See Johnson & Johnson Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). Clarification is necessary as Elan's pretrial submissions suggest that it intends to introduce evidence that

Abraxis used information disclosed but unclaimed in the '363 patent as evidence of infringement and willfulness.

Abraxis's Proposed Instruction

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, 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. All information which is disclosed but not claimed cannot be infringed and is available for the public's use. 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.

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004); *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002).

Elan's Objections:

Elan objects in discussion of claim 1 as Elan is not asserting infringement of this claim. Section 4.2.2 of the Jury Instructions, and Elan's proposed Section 4.2.3 address this issue.

4.2.2 Independent And Dependent Claims [DISPUTED]

Elan's Proposed Instruction

Claims are typically divided into parts called "elements." 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 element 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 elements 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 elements in the claims to which it refers. Therefore, to determine what a dependent claim covers, you must look at both the elements 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 elements of both claim 1 and claim 3.

Abraxis's Objections

Abraxis objects that Elan's proposed instruction fails to clarify that a dependent claim cannot be infringed if the underlying independent claim is not infringed. *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359 (Fed. Cir. 2007). Clarification is necessary as Elan alleges infringement based on claims that depend on independent claim 1, whose elements and limitations are the central issues of contention.

Abraxis's Proposed Instruction

Claims are typically divided into parts called "elements" or "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 element or 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 elements or 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 elements or limitations in the claims to which it refers. Therefore, to determine what a dependent claim covers, you must look at both the elements of the dependent claim and the claim or claims to which it refers. If you find that an independent claim is not infringed, you must also find that all claims depending from that independent claim are not infringed.

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 elements or 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.

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004); *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359 (Fed. Cir. 2007).

Elan's Objections:

Elan objects to Abraxis's final paragraph as confusing and redundant.

4.2.3 The Court Determines What Patent Claims Mean [DISPUTED]

Elan's Proposed Instructions

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 asserted claims at issue. I will give you a list of the asserted claims of the '363 Patent as part of the verdict form when I conclude my instructions.

4.2.3 (a) The limitations of claim 3 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 300 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 5 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 anticancer agent is selected from the group consisting piposulfan, piposulfam, camptothecin, etoposide, taxol, 1,2,4-benzotriazin-3-amine 1,4-dioxide, 1,2,4-benzotriazin-7-amine 1,4-dioxide and retinoic acid.

4.2.3 (c) 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,

the **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 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 (d) 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 particles,

the **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 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.

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

(a) "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;"

(b) "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;"

(c) "non-crosslinked" is construed to mean "the individually adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages;"

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

(e) "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;"

(f) "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 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;"

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

For any of the terms of the asserted '363 Patent claims not specifically defined above, you are to give such words their plain and ordinary meaning in applying the claim(s).

Abraxis's Objections

Abraxis objects to Elan's proposed instruction for several reasons. First, Elan mischaracterizes claims 3, 5, 10, and 11 of the '363 patent as independent claims. Elan's characterization improperly directs the jury's focus from independent claim 1, the claim from which claims 3, 5, 10, and 11 depend. Consequently, Elan's exclusion of claim 1 is also improper. In addition, repeating the lengthy claim language from independent claim 1 is unnecessary and can only serve to confuse the jury.

Second, Elan's exclusion of the claims of the '025 patent are improper as Abraxis's counterclaims for invalidity and unenforceability of the '025 patent remain live issues in this case. Abraxis also objects that Elan's proposed instruction does not refer to Abraxis's contentions regarding unenforceability of the '363 Patent.

Abraxis also objects to the exclusion of claims 1-3, 13-15 of the '025 patent as Abraxis's counterclaims for invalidity and unenforceability remain live issues in dispute. Abraxis also objects to the exclusion of the phrases "without eliciting adverse hemodynamic effects," "at an infusion rate not exceeding 10 mg/min," organic drug substance," "colloidal polymerical material," and the footnote to the phrase "in an amount of 0.1-90% by weight and sufficient to maintain an average effective particle size of less than 1000 nm" as they are relevant to the claims of the '025 patent.

Abraxis proposes the following instruction to clarify the relationship between the independent and dependent claims at issue, and more succinctly summarize the claims at issue.

Abraxis also 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-cross-linking 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 language of the second sentence derives from the claim, 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.*, 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."); *id*. at A0002, '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…").

Similarly, it was made clear that a non-crosslinked surface modifier was a basic and novel property of the claimed invention. D.I. 144, Joint Appendix at A0069, '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 . . .") *id.* at A0052, '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.").

Abraxis's Proposed Instruction

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.

First, I will discuss the limitations of the claims of the '363 Patent at issue. I will give you a list of the relevant claims of the '363 Patent as part of the verdict form when I conclude my instructions.

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004).

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**.

Next, I will discuss the limitations of the claims at issue of the '025 Patent. I will give you a list of the claims at issue of the '025 Patent as part of the verdict form when I conclude my instructions.

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.

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

(a) "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.[20, 21] The crystallinity of the medicament and the non-crosslinking of the surface modifier are basic and novel properties of the claimed invention.

(b) "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;"

(c) "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;"

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

[20] Abraxis proposes these two sentences as a proposed addition to the Court's Claim Construction Order, dated August 17, 2007. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 984 (Fed Cir. 2007) ("construing and determining the scope of the claims in a patent, is strictly a legal question for the court").

[21] *See 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).

(e) "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;"

(f) "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 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;"[22]

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

(h) "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."

(i) "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."

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

[22] Under the Court's Claim Construction Order dated August 17, 2007, this construction also applies to claims 1, 2, 3 of the '025 Patent for the term "sufficient to maintain an effective average particle size."

(k) "colloidal polymerical 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 instructions on the '025 Patent for the reason set forth in n.4 on p. 2.

4.2.4 **Infringement – Basic and Novel Properties**

Elan Proposes:

The beginning of claims 3 and 5 use the phrase particles "consisting essentially of." Patent claims including the language "consisting essentially of" will be infringed only if you find that any elements added by Defendant beyond those in the claims do not materially affect the novel and basic features of the claimed invention.

§ 3.3.4 2004 Delaware Instructions.

Abraxis Proposes:

With respect to claims 1, 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.

An ingredient has a material effect on the basic and novel properties of the invention if the effect is of importance or of consequence to those of ordinary skill in the art. In this litigation, you will have to determine whether the amorphous medicament and any crosslinked surface modifier found in Abraxane have a material effect on the basic and novel properties of the claimed invention. Elan bears the burden of proving by a preponderance of the evidence that these additional, unclaimed ingredients do not have such a material effect.

Source: *Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1319-1320 (Fed. Cir. 2006); *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354-57 (Fed. Cir. 1998); *Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1574-75 (Fed. Cir. 1984).

Abraxis's Comments

Abraxis contends that determination of the basic and novel properties of the claimed invention is an issue of law for the Court. *See, e.g., Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984). Abraxis proposes this instruction in the event the Court determines the basic and novel properties of the claimed invention of the '363 Patent are an issue for the jury to decide.

4.3 Failure To Produce Evidence – Adverse Inference [DISPUTED]

Elan's Proposed Instruction

You have heard that Abraxis did not provide any response to Elan's request for Abraxis to identify the existence of any opinions of counsel as to infringement or validity of the '363 patent. Under the totality of circumstances analysis for the objective recklessness standard of willfulness, it is appropriate for a jury to consider whether a defendant obtained advice of counsel as part of the totality of the circumstances in determining willfulness. You should thus infer from Abraxis's failure to respond to Elan that Abraxis failed to obtain an opinion of counsel on infringement or validity of the '363 patent.

Elan's Comments

Elan proposes this instruction based on *Energy Transportation Group Inc. v. William Demant Holding A/S*, C.A. No. 05-422-GMS (D. Del. Jan. 4, 2008) (Sleet, J.) in light of Abraxis's failure to respond to discovery requests. Fed.R.C.P. 26, 33.

Abraxis's Objections

Abraxis objects to Elan's instruction as an improper addition to its proposed set of jury instructions for three reasons. First, contrary to the parties' agreement that Elan would provide its proposed instructions on March 7, 2008, Elan first provided this proposed instruction to Abraxis at 6:47 pm EDT on April 7, 2008, the day they were scheduled to be filed.

Second, Elan's instruction is legally erroneous. 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). The Federal Circuit has made clear that an adverse inference is not appropriate either when a party invokes the attorney-client privilege, or when the party has not obtained an opinion of counsel:

> "When the attorney-client privilege and/or work-product privilege is invoked by a defendant in an infringement suit, is it appropriate for the trier of fact to draw an adverse inference with respect to willful infringement? The answer is "no." Knorr-Bremse, 383 F.3d at 1344.

> 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.

Third, in light of the facts that the requested instruction is contrary to controlling case law and made at the 11th hour, more than one month after Elan's proposed instructions were due, Abraxis also objects to this instruction as being made in bad faith, and as an attempt to distract from Abraxis's own proposed instruction for an adverse inference, which is warranted by the evidence as a result of Elan's failure to produce critical evidence in the case.

Since Elan served this instruction nearly one month late, after 5:00 p.m. EDT on the day the instructions were due, Abraxis reserves the right to supplement this objection.

Abraxis's Proposed Instruction

You have heard that Elan, including Elan's retained expert witnesses and persons they relied on, withheld and destroyed evidence regarding its testing of the crystallinity of the paclitaxel in Abraxane®. You should infer from Elan's failure to produce this evidence that such evidence would have been unfavorable to Elan's position on infringement, particularly on crystallinity.

Abraxis's Comments

Abraxis proposes this instruction as Elan refused to produce and destroyed results from certain tests conducted by its experts Drs. Brittain, Munson, Winkler and Barich, as detailed in Abraxis's motion in limine nos. 1 and 2 and supporting declarations and exhibits. This Court has recognized an instruction directing an adverse inference to be an appropriate sanction for the non-production of evidence in a patent case. *Liafil, Inc. v. Learning 2000, Inc.*, 2002 U.S. Dist. LEXIS 24803, *9 (D. Del. Dec. 23, 2002) (Sleet, J.).

4.4 Patent Infringement (Direct) [DISPUTED]

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 will tell you shortly 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.]

Parties' Objections

Abraxis objects to the inclusion of the language in brackets. Abraxis objects to the third paragraph of Elan's proposed instruction as it references the doctrine of equivalents. *See* Abraxis's Objection to Instruction 4.4.2. If the Court requires an instruction on the doctrine of equivalents, Abraxis consents to the inclusion of the third paragraph.

Abraxis objects to the fourth paragraph of Elan's proposed instruction as any reference to intent or mental culpability is unnecessary, redundant, and confusing to the jury.

4.4.1 Literal Infringement [DISPUTED]

Elan's Proposed Instruction

Elan's patent claim(s) are literally infringed if Abraxis's product includes every element in at least one of Elan's asserted claims. If Abraxis's product omits any element recited in one of Elan's asserted claims, Abraxis does not literally infringe that claim.

Abraxis's Objections

Abraxis objects to Elan's addition to the 2004 Delaware Instructions, § 3.3.1. Elan's insertion of the language of "at least one" and "one of" is unnecessary, redundant, and confusing in light of Instruction 4.2.1.

Abraxis's Proposed Instruction

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. Each claim limitation must be literally found in Abraxane® exactly as written in the claim.

If Abraxane® or the method involving Abraxane® omits any single limitation recited in a patent claim, it does not literally infringe that claim. You must determine literal infringement with respect to each patent claim individually.

Source: Adapted from Jury Instructions in Becton, Dickinson and Company v. Tyco Healthcare Group, LP, No. 02-1694 (GMS).

Elan's Objection:

Elan objects to the phrase "exactly as written in the claim" in the last sentence of the first paragraph as unnecessary, redundant, and confusing.

4.4.2 Infringement Under the Doctrine Of Equivalents [DISPUTED]

Elan's Proposed Instruction

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 elements are equivalent to those defined in Elan's claims is to be determined as of the time of the alleged infringement.

Equivalence is determined at the time of the activities accused of infringement and is not limited by what was known at the time the patent application was filed or when the patent issued. Thus, the inventor need not have foreseen, and the patent need not describe, all potential equivalents to the invention covered by the claims. 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.

Abraxis's Objections

Abraxis objects to the inclusion of an instruction on the doctrine of equivalents for several reasons. First, 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…").

Second, Elan is 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…").

In the event the Court requires an instruction on doctrine of equivalents, Abraxis objects to Elan's proposed instruction for several reasons:

First, Abraxis objects that Elan's proposed instruction fails to emphasize that infringement under the doctrine of equivalence requires the infringing element perform the same function, in substantially the same way, to achieve substantially the same result. *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1569 (Fed. Cir. 1996) (infringement not found where element did not operate in substantially the same way).

Second, Abraxis objects that Elan's proposed instruction fails to emphasize that infringement under the doctrine of equivalents is considerably more difficult to establish where the accused infringer was awarded a separate patent covering the accused product. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1380 (Fed. Cir. 2007).

Third, Abraxis objects that Elan's proposed instruction fails to clarify that Elan is barred from contending that amorphous is the equivalent of crystalline and that crosslinked is the equivalent of non-cross-linked.

Abraxis's Proposed Instruction

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.

However, simply because the substituent performs the same general function to achieve the same result as the required element also does not necessarily establish equivalency. The result also must be achieved in substantially the same way.

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 elements 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 considerably more difficult to establish equivalency to a claim element where the accused infringer was awarded a separate patent covering the accused product.

In the context of this case, you are not to consider "amorphous" to be the equivalent of "crystalline," nor are you to consider "crosslinked" to be the equivalent of "non-crosslinked."

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004); *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1569 (Fed. Cir. 1996); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1380 (Fed. Cir. 2007).

Elan's Objection:

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

Elan objects to the final paragraph as an improper instruction and adverse inference.

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

Elan's Proposed Instructions

Abraxis may have presented evidence or argument to the effect that certain characteristics of the accused product Abraxane® represents an improvement over the invention defined in Elan's '363 Patent claims. Relatedly, you may have seen and heard evidence that Abraxis obtained its own patents on aspects, characteristics, formulations, or uses for Abraxane®, or that Abraxane has been praised in the medical community for its efficacy. All of these contentions may or may not be true, but none of them means that Abraxane® cannot infringe Elan's patent claims. As long as you have found that Abraxane® includes all of the claim elements of at least one of Elan's '363 Patent claims, or if you find that Abraxane is equivalent to such claim(s) under the doctrine of equivalents, then Elan's patent claims are infringed by Abraxis without regard to any improvements made or patents obtained by Abraxis in connection with Abraxane®.

Abraxis's Objections

Abraxis objects to all references and instructions on the doctrine of equivalents. *See* Abraxis's Objection to Instruction 4.4.2. If the Court decides that such an instruction is required, Abraxis proposes the following instruction.

Abraxis objects to the first two sentences as contrary to law, In particular, Elan's proposed instruction erroneously states that patents on Abraxane are irrelevant to infringement, including under the doctrine of equivalents, which is not the law. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 493 F.3d 1368, 1379-80 (Fed. Cir. 2007) ("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.") (citations omitted). In addition, Abraxis objects to Elan's changes to the 2004 Delaware Instructions as unnecessary, redundant, and confusing to the jury.

Abraxis's Proposed Instruction

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

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004).

4.4.4 Reverse Doctrine of Equivalents [DISPUTED]

In some cases, even though an allegedly infringing product includes all of the elements 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. If Abraxis comes forward with evidence that the reverse doctrine of equivalents applies, to prove infringement Elan, which retains the burden of proof, must rebut that evidence by a preponderance of the evidence.

Abraxis's Comment

Abraxis proposes this instruction based on the Uniform Jury Instructions for the United States District Court for the District of Delaware (1993); *Graver Tank & Mfg. Co., Inc. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950); *SRI Int'l v. Matshshita Elec. Corp.*, 775 F.2d 1107, 1123-24 (Fed. Cir. 1985).

Elan's Objection:

Elan objects to an instruction in the reverse doctrine of equivalents for the reasons set forth in its Motion In Limine No. 5.

4.5 Indirect Infringement [AGREED]

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 1, 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 [DISPUTED]

Elan's Proposed Instructions

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. 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 or should have known 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.

Abraxis's Objections

Abraxis objects to the last two sentences of the first paragraph of Elan's proposed jury instructions as unnecessary, redundant and confusing to the jury.

Abraxis also objects that Elan's proposed instruction does not properly instruct the jury that specific intent to infringe is required to prove inducement. *DSU Medical Corp. v. JMS Co. Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006).

Abraxis's Proposed Instruction

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.

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 acted with the specific intent of encouraging infringement. It is not enough that Abraxis intended to cause the acts alleged to constitute infringement; Abraxis must have intended those acts actually to constitute infringement; and

(3) Abraxis knew or should have known 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.

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004); *DSU Medical Corp. v. JMS Co. Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006).

Elan's Objection:

Elan objects to the subpart (2) of Abraxis's jury instruction after the phrase "Abraxis knew of the '363 Patent" as redundant with subparts (1) and (3) and thus confusing and unfairly prejudicial.

4.5.2 Contributory Infringement [DISPUTED]

Elan's Proposed Instruction

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) The Abraxane® lyophilized powder supplied by Abraxis is not a common component used for significant non-infringing uses, but rather, the component is especially made or adapted for a use that infringes the claimed invention;

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

(3) Someone then bought the Abraxane® powder and actually reconstituted it with saline 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.

Abraxis's Objections

Abraxis objects to Elan's proposed amendments to the 2004 Delaware Instructions, § 3.9 as unnecessary and argumentative. Abraxis proposes simpler substitutions setting forth the test for contributory infringement.

Abraxis's Proposed Instruction

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.

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004).

4.6 Determination Of Infringement [DISPUTED]

Elan's Proposed Instruction

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 at least one asserted 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.

Abraxis's Objections

Abraxis objects to Elan's insertion of "at least one" into the 2004 Delaware Instructions, § 3.12 as unnecessary and confusing to the jury in light of Abraxis's Proposed Instruction 4.2.1. Abraxis also objects that Elan's proposed instruction fails to focus the jury's attention on crystallinity and cross-linking, the infringement issues in contention in the case.

Abraxis's Proposed Instruction

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 or limitation of the asserted claim is literally present in Abraxane®, then you must find that Abraxis infringes that claim. You must analyze Abraxane separately under each asserted claim.

Remember that in this litigation, Abraxis disputes whether the particles in Abraxane® consist essentially of 99.9-10% by weight of a *crystalline* medicament and 0.1-90% by weight of a surface modifier that is essentially free of intermolecular crosslinkages. Abraxis does not dispute that Abraxane meets the other limitations of '363 Patent claims 1, 3, 5, 10 and 11 for purposes of determining whether there is infringement in this litigation.

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004).

Elan's Objection:

Elan objects to Abraxis's second paragraph as argumentative and confusing.

4.7 Willful Infringement [DISPUTED]

Elan's Proposed Instruction[23]

In this case, Elan argues that Abraxis willfully infringed Elan's patent.

To prove willful infringement, Elan must first persuade you that Abraxis infringed a valid and enforceable claim of the '363 Patent. The requirements for proving such infringement were discussed in my prior instructions.

In addition, to prove willful infringement, Elan must persuade you that it is highly probable that Abraxis acted with reckless disregard of the claims of the '363 Patent.

To demonstrate such "reckless disregard," Elan must satisfy a two-part test. The first part of the test is objective. Elan must persuade you that Abraxis acted despite an objectively high likelihood that its actions constituted infringement of a valid and enforceable patent. The state of mind of Abraxis is not relevant to this inquiry. You should focus on whether a reasonable person in the position of Abraxis, after learning of the patent, could have reasonably believed that it did not infringe or reasonably believed the patent was invalid or unenforceable. If a reasonable person in the position of Abraxis could not have held such belief, then you need to consider the second part of the test.

The second part of the test does depend on the state of mind of Abraxis. Elan must persuade you that Abraxis actually knew, or it was so obvious that Abraxis should have known, that its actions constituted infringement of a valid and enforceable patent.

[23] This instruction is modeled after the Model Patent Jury Instructions for the Northern District of California (Rev. 11/29/07) in view of the recent change to the willful infringement standard enunciated in *In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (*en banc*); 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) (noting that obtaining competent legal advice is proper factor in considering totality of circumstances.).

In deciding whether Abraxis acted with reckless disregard of Elan's patent, you should consider all of the totality of the circumstances surrounding the alleged infringement including, but not limited to, the following:

(1) Whether Abraxis acted in a manner consistent with the standards of commerce for its industry, *e.g.*, the time at which Abraxis became aware of the invention of Elan's '363 Patent, and whether from that time Abraxis behaved as a fair and reasonable competitor would have. 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;

(2) Whether the evidence tends to show that Abraxis intentionally copied Elan's patented invention;

(3) The strength of any defenses Abraxis raised at trial;

(4) Whether Abraxis tried to cover up its infringement; and

(5) Whether Abraxis obtained competent legal advice.

Abraxis's Objections

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.

Abraxis objects that Elan's proposed instruction misstates the standard established by *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007). Among other inaccuracies, Elan omits the "clear and convincing evidence" standard which it carries for the entire inquiry. *Id.* Further, *In re Seagate* expressly rejects a "due care" or "reasonableness" standard, which Elan includes in its proposal. *Id.* Abraxis also objects that *In re Seagate* establishes a "threshold inquiry" for the "objective recklessness" determination, which Elan miscites as a "two-part test." *Id*. Abraxis objects that Elan's proposed instruction includes an incomplete listing of factors in determining willfulness, and does not reflect the current state of the law.

Abraxis further objects that Elan's proposed instruction improperly references Abraxis's decision not to secure legal advice on its alleged infringement. *Id* ("we also reemphasize that there is no affirmative obligation to obtain opinion of counsel"); *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1341 (Fed. Cir. 2004) ("no adverse inference that an opinion of counsel was or would have been unfavorable flows from an alleged infringer's failure to obtain or produce an exculpatory opinion of counsel"); *see also* 2008 Federal Circuit Bar Association Model Patent Jury Instructions, § 3.8 ("2008 Federal Circuit Instructions") (noting that an instruction on opinion of counsel is given only if the alleged infringer relies upon an opinion of counsel).

Finally, Abraxis objects that Elan's proposed instruction is confusing to the jury. For all these reasons, Abraxis proposes the instruction from the 2008 Federal Circuit Instructions as it is shorter and easier to understand.

Abraxis's Proposed Instruction

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 three things: first, that Abraxis was aware of the '363 Patent; second whether Abraxis acted despite an objectively high likelihood that its actions infringed a valid patent; and third, 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.

Source: Federal Circuit Bar Association Model Patent Jury Instructions (2008);

Elan's Objection:

Elan objects to Abraxis's proposed instruction as not in compliance with controlling case law. See n.23 on p. 88.

Elan also objects to omission of an instruction on competent legal advice for the reasons set out in Section 4.3. 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).

5. VALIDITY

[DISPUTED]

Elan's Proposed Instruction

Abraxis contends that several claims of the '363 Patent are invalid for failure to satisfy the legal requirements of patentability. In particular, Abraxis contends that the asserted claims are invalid for obviousness, lack of written description, lack of enablement and indefiniteness. I will now instruct you on each of these defenses.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as Abraxis's counterclaims for invalidity of the '025 patent remain live issues in this case.

Abraxis's Proposed Instruction

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 claims are invalid for lack of enablement, failure to meet the written description requirement, obviousness, and indefiniteness and that claims 1-3 and 13-15 of the '025 Patent are invalid for lack of enablement, failure to meet the written description requirement, and indefiniteness. I will now instruct you on each of these defenses.

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004).

Elan's Objection:

Elan objects to Abraxis's instructions on the '025 Patent for the reason set forth in n.4 on p. 2.

5.1 Presumption Of Validity [DISPUTED]

Elan's Proposed Instruction

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. As a result, Elan does not have to prove that the claims of the '363 Patent are valid as a condition of asserting it. You are to start with the presumption, without having to hear any evidence on the matter, that the patent is valid. You may later reject this presumption, but only if you are presented by Abraxis with clear and convincing evidence that the presumption is incorrect in this case. Each of the asserted claims of the '363 Patent is presumed valid independently of the validity of each other claim.

Abraxis as the defendant has the burden of proving invalidity by clear and convincing evidence the invalidity of each claim that it may attempt to invalidate.

Abraxis's Objections

Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement.

Abraxis objects to all references and instructions on the presumption of validity as not required by Federal Circuit precedent and redundant in light of Abraxis's Proposed Instructions 1.6, 1.7, 2.3, and 3.4. It is well established that:

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 12557, 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 art and 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 art and 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).

Abraxis further objects to this instruction to the extent that the Court allows Abraxis's claims of inequitable conduct and unclean hands to be decided by the jury, on the ground that this instruction does not apply to those defenses and creates the risk that the jury will apply a presumption where it does not belong.

Abraxis further objects that this instruction fails to give the jury appropriate instruction as to what is needed to rebut the presumption. Specifically, Elan's instruction fails to state that "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." *See* 2004 Delaware Instructions, § 4.1.

If the Court requires the instruction, Abraxis proposes the following instruction based on the 2004 Delaware Instructions, § 4.1.

Abraxis's Proposed Instruction

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. Consequently, Abraxis has the burden of proving by clear and convincing evidence the invalidity of each claim that it may attempt to invalidate.

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. Furthermore, the 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.

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004); *see Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 1423 (Fed. Cir. 1988).

Elan's Objection:

Elan objects to Abraxis's proposed instruction as incomplete.

5.2 Enablement [DISPUTED]

Elan's Proposed Instructions

Abraxis contends that the asserted claims of the '363 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 practice the 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 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[24] 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;

[24] *See Johns Hopkins Univ. v. CellPro*, 894 F. Supp. 819, 836 (D. Del. 1995) (listing factors to be considered by the jury in determining whether undue experimentation is required).

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

(4) the amount of guidance presented in the '363 Patent;

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

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

(7) the scope of the claimed invention.

Abraxis's Objections

Abraxis objects to Elan's proposed enablement instruction for several reasons. First, Abraxis objects to Elan's proposed instruction to the extent it seeks a final determination on enablement, which is an issue of law for the Court.

Second, Abraxis objects to Elan's proposed instruction as Abraxis's counterclaims for invalidity of the '025 patent remain live issues in this case.

Third, Abraxis objects that the list of factors in Elan's proposed instruction excludes some of the factors from *Johns Hopkins v. CellPro*, 894 F. Supp. 819, 836 (D. Del. 1995), and is incomplete. Abraxis proposes the use of the more complete and up-to-date list of enablement factors from the 2008 Federal Circuit Instructions instead.

Fourth, Abraxis objects that Elan's proposed instruction does not inform the jury that the specification must enable the "full scope" of the invention. The Federal Circuit has recently emphasized that a patentee must enable the "full scope" of the invention to satisfy the enablement requirement. *See Sitrick v. Dreamworks LLC*, 2008 U.S. App. LEXIS 2251 *12 (Fed. Cir. Feb. 1, 2008); *Automotive Techs Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004); *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

Fifth, Abraxis objects that Elan's proposed instruction does not 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).

Sixth, Abraxis objects that Elan's proposed instruction does not inform the jury that the enablement requirement includes the requirement that the invention be useful for its intended purpose. *See Impax Labs., Inc. v. Aventis Pharms.*, Inc., 468 F.3d 1366, 1381 (Fed. Cir. 2006); *In re Fisher*, 421 F.3d 1365, 1378 (Fed. Cir. 2005); *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999).

Abraxis's Proposed Instructions

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 the specification lacked a sufficiently full and clear description of the claimed invention.

To be sufficiently full and clear, the specification must contain enough information to have allowed persons of ordinary skill in the field of technology of the patent to make and use the full scope of the claimed invention at the time the patent application was filed. The specification must contain sufficient information such that persons of ordinary skill in the art could make and use the claimed invention in a manner that is useful for its intended purpose. This is known as the "enablement" requirement. If a patent claim is not enabled, it is invalid.

In order to be enabling, the patent must permit persons of ordinary skill in the field of technology of the patent to make and use the full scope of the invention without having to conduct undue experimentation. However, some amount of experimentation to make and use the invention is allowable. In deciding whether a person of ordinary skill in the field of technology relevant to this case would have to experiment unduly in order to make and use the invention, you may consider several factors:

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

(2) How routine any necessary experimentation is in the field of the patent;

(3) Whether the 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;

(5) The amount of guidance presented in the patent;

(6) The nature and predictability of the field;

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

(8) The scope of the claimed invention – A patentee who chooses broad claim language must make sure the broad claims are fully enabled.

Source: Federal Circuit Bar Association Model Patent Jury Instructions (2008); *Automotive Techs Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004); *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003); *Impax Labs., Inc. v. Aventis Pharms.*, Inc., 468 F.3d 1366, 1381 (Fed. Cir. 2006); *In re Fisher*, 421 F.3d 1365, 1378 (Fed. Cir. 2005); *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999); *Ormco Corp. v. Align Technology, Inc.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007); *Sitrick v. Dreamworks LLC*, 2008 U.S. App. LEXIS 2251 *12 (Fed. Cir. Feb. 1, 2008).

Elan's Objection:

Elan objects to Abraxis's instructions on the '025 Patent for the reason set forth in n.4 on p. 2.

In addition, Elan objects because "time and cost of experimentation" (subsection (1)) is not a legally cognizable basis for finding lack of enablement. *See Enzo Biochem v. Calzene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999); *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). Elan generally objects to Abraxis's misstatement of the law of enablement.

5.3 The Written Description Requirement [DISPUTED]

Elan's Proposed Instruction

Abraxis contends that several claims of the '363 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 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 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 elements 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 patent application does 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. No particular form of written description is required.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as Abraxis's counterclaims for invalidity of the '025 patent remain live issues in this case.

Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement.

Abraxis objects that the proposed instruction does not require a description of the "full scope" of the claimed invention. The Federal Circuit has held that a patentee must have possession of the "full scope" of the invention to satisfy the written description requirement. *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1259 (Fed. Cir. 2004).

Abraxis proposes the addition of "and limitations" to clarify that the terms "elements" and "limitations" are interchangeable in the context of patent claims.

Abraxis's Proposed Instruction

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 elements and 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][25] 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 elements and limitations.

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1259 (Fed. Cir. 2004).

[25] Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement. If the Court requires an instruction on clear and convincing evidence of invalidity, Abraxis proposes the language in brackets.

Elan's Objection:

Elan objects to Abraxis's instructions on the '025 Patent for the reason set forth in n.4 on p. 2.

5.4 Obviousness [DISPUTED]

Elan's Proposed Instruction[26]

In order to be patentable, an invention must not have been obvious to a person of ordinary skill in the art at the time the invention was made[[,]]. The issue is not whether the claimed invention would be obvious today to you, as a layperson, to me as a judge, or to a person unusually expert in the art, nor whether it would be obvious in hindsight based upon the advanced state of the art in 2008, but whether it would have been obvious to one of ordinary skill in the art at the time it was made.

In determining obviousness or non-obviousness of the subject matter of each of the asserted claims of the '363 Patent, you should take the following steps:

1. Determine the scope and content of the prior art relied upon by Abraxis;
2. Identify the differences, if any, between each asserted claim of the '363 Patent and the prior art;
3. Determine the level of ordinary skill in the pertinent art at the time the invention of the '363 Patent was made; and
4. Consider any secondary or objective factors of non obviousness.

In addition, you may consider whether there was an apparent reason to combine or modify the prior art references in the fashion claimed by the '363 Patent, but in doing so, you must guard against slipping into the use of hindsight.

[26] This instruction is based on § 4.8 of the Draft Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004) as supplemented by the Model Patent Jury Instructions for the Northern District of California (Rev. 11/29/07), in view of the recent clarification to the law on obviousness. *See generally KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 167 L. Ed. 2d 705 (2007).

Against this background, you will then decide whether the Abraxis has provided clear and convincing evidence that the subject matter of each asserted claim of the '363 Patent would have been obvious to a person of ordinary skill in the pertinent art at the time of the invention of the '363 Patent.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction to the extent that it seeks a final determination from the jury on obviousness, which is an issue of law. *See Hewlett-Packard Co. v. Mustek Sys.*, 340 F.3d 1314, 1325 (Fed. Cir. 2003). Abraxis objects to all references and instructions that Abraxis bears a "clear and convincing" burden of proof for its invalidity defenses based on theories of obviousness, lack of enablement, and failure to meet the written description requirement.

Abraxis also objects to Elan's proposed instruction as it is prejudicial and argumentative. Abraxis instead proposes the Court adopt the instruction from 2008 Federal Circuit Instructions, § 4.3b which incorporates the most recent clarifications to the law on obviousness.

Abraxis's Proposed Instructions

Even though an invention may not have been identically disclosed or described before it was made by an inventor, in order to be patentable the invention must also not have been obvious to a person of ordinary skill in the field of technology of the patent at the time the invention was made.

Abraxis may establish that a patent claim is invalid by showing, by clear and convincing evidence, that the claimed invention would have been obvious to persons of ordinary skill in the art at the time the invention was made. For the claim to be invalid because it would have been obvious you must first evaluate the following factors:

(1) What is the scope and content of the prior art;

(2) What are the differences, if any, between the invention and the prior art;

(3) What was the level of ordinary skill in the art at the time the invention was made; and

(4) What evidence is there, if any, of certain additional considerations relating to the obviousness or non-obviousness of the invention?

You must decide, in view of the evidence presented to you on these factors, whether or not the claimed invention, considered as a whole, would have been obvious to one having ordinary skill in the art at the time the invention was made. You must make this determination separately for each of the inventions described in claims 1, 3, 5, 10, and 11 of the '363 Patent.

Before doing so, however, you must keep in mind that it is not permissible to use hindsight in assessing whether the invention is invalid for obviousness. You cannot look at the invention knowing what persons of ordinary skill in the art know today. Rather, you must place

yourself in the shoes of a person having ordinary skill in the field of technology of the patent at the time the invention was made.

Abraxis contends that the inventions are obvious in view of a combination of more than one "prior art" reference. In placing yourself in the shoes of a person having ordinary skill in the field of technology relevant to this case at the time the invention was made, you may also consider whether such a person would have been motivated to combine these prior art references in order to arrive at the claimed invention.

I will now provide you more detailed instructions on each of these factors.

Source: Federal Circuit Bar Association Model Patent Jury Instructions (2008).

Elan's Objection:

Elan objects to Abraxis's instructions on the '025 Patent for the reason set forth in n.4 on p. 2.

Elan further objects that Abraxis's proposed instruction is inferior to Draft Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004).

5.4.1 Scope and Content of the Prior Art [DISPUTED]

Elan's Proposed Instruction[27]

As I just instructed you, in arriving at your decision on the issue of whether or not the claimed invention is obvious to one of ordinary skill in the art, you must first determine the scope and content of the prior art. This means that you must determine what prior art is reasonably pertinent to the particular problem with which the inventor was faced. Prior art is reasonably pertinent if, although in a field not exactly the same as that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have presented itself as worthy of an inventor's attention in considering his problem. Scope and content of the prior art includes references from those areas a person with ordinary skill in the art would look at in solving a particular problem. Prior Art includes any of the following:

1. Patents that issued before July 1, 1991;
2. Patents having a publication date before July 1, 1991;
3. United States Patents that have a filing date prior to December 12, 1990.

You must consider all of the factors I listed in the previous paragraph, and those I will list in the following instructions, to consider what specifically each of these multiple prior art references relied upon by Abraxis would teach one of ordinary skill in the art. You will be provided with a jury verdict form on which you will be required to list which specific combinations of single prior art references, if any, you conclude by clear and convincing

[27] This instruction is based on § 4.8 of the Draft Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004) as supplemented by the Model Patent Jury Instructions for the Northern District of California (Rev. 11/29/07), in view of the recent clarification to the law on obviousness. *See generally KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 167 L. Ed. 2d 705 (2007).

evidence would have taught or reasonably suggested all the elements of particular Elan '363 Patent claims.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction for several reasons. First, contrary to the parties' agreement that Elan would provide its proposed instructions on March 7, 2008, Elan amended its proposed instruction after March 7 and only informed Abraxis of its amendments at 6:47 pm EDT on April 7, 2008, the day they were scheduled to be filed.

Second, Elan's proposed language "Prior Art includes any of the following…" is irrelevant since the Elan has already admitted that Abraxis's prior art references constitute prior art for purposes of the '363 Patent.

Third, the dates of July 1, 1991 and December 12, 1990 in the instruction improperly seek to claim benefit of the filing date of the '684 Patent and establish a date of invention not supported by the evidence. For purposes of determining the validity of the '363 Patent, Elan is not entitled to claim benefit of the filing date for the '684 Patent since the '363 Patent introduces new matter. For example, the '684 Patent provides no support for the average effective particle size limitation in the claims of the '363 Patent. Nor is there evidence that Elan had conceived of the claimed inventions of the '363 patent by December 12, 1990.

Finally, Abraxis objects to Elan's proposed instruction as prejudicial and unbalanced. Elan's proposed instruction is allegedly based on the 2004 Delaware Instructions and the Model Patent Jury Instructions for the Northern District of California (Rev. 11/29/07) ("2007 N.D. Cal. Instructions"). Elan's instruction, however, deviates significantly from the model instructions. Consequently, Abraxis proposes the Court adopt the language from the instruction from the 2008 Federal Circuit Instructions, § 4.3bi.

Since Elan served this instruction nearly one month late, after 5:00 p.m. EDT on the day the instructions were due, Abraxis reserves the right to supplement this objection.

Abraxis's Proposed Instructions

"Prior art" includes previous products, articles and methods that were offered for sale, printed publications or patents that disclose the invention or elements of the invention. Once you decide whether or not specific references are prior art, you must also decide what those references would have disclosed or taught to one having ordinary skill in the field of technology of the patent at the time the invention was made.

In order for a reference to be relevant for you to consider in deciding whether or not the claimed invention would have been obvious, the reference must be within the field of the inventor's endeavor, or if it is from another field of endeavor, the reference must be reasonably related to the particular problem or issue the inventor faced or addressed when making the invention described in the '363 Patent. A reference from a field of endeavor other than the inventor's is reasonably related to the problem or issue the inventor faced if the reference is one which, because of the matter with which the reference deals, logically would have commended itself to the attention of the inventor when considering the problem or issue he faced in this case. It is for you to decide what the problem or issue was that the inventor faced at the time the invention in claims 1, 3, 5, 10, and 11 of the '363 Patent was made.

Source: Federal Circuit Bar Association Model Patent Jury Instructions (2008).

Elan's Objection:

Elan objects to Abraxis's proposed instruction as insufficiently detailed to assist the jury.

5.4.2 Differences Over the Prior Art [DISPUTED]

Elan's Proposed Instruction[28]

Your analysis must determine the impact, if any, of such differences on the obviousness or nonobviousness of the invention as a whole, and not merely some portion of it.

In analyzing the relevance of the differences between the claimed invention and the prior art, you do not need to look for precise teaching in the prior art directed to the subject matter of the claimed invention. You may take into account the inferences and creative steps that a person of ordinary skill in the art would have employed in reviewing the prior art at the time of the invention. For example, if the claimed invention combined elements known in the prior art and the combination yielded results that were predictable to a person of ordinary skill in the art at the time of the invention, then this evidence would make it more likely that the claim was obvious. On the other hand, if the combination of known elements yielded unexpected or unpredictable results, or if the prior art teaches away from combining the known elements, then this evidence would make it more likely that the claim that successfully combined those elements was not obvious.

Importantly, a claim is not proved obvious merely by demonstrating that each of the elements was independently known in the prior art. Most, if not all, inventions rely on building blocks long since uncovered, and claimed discoveries almost of necessity will likely be combinations of what is already known. Therefore, you should consider whether a reason existed at the time of the invention that would have prompted a person of ordinary skill in the art in the relevant field to combine the known elements in the way the claimed invention does. The

[28] This instruction is based on §7.2 AIPLA's Model Patent Jury Instructions,(2008); citing KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1742-43 (2007); Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966); Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1536-37 (Fed. Cir. 1983); Medtronic, Inc., v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1567-68 (Fed. Cir. 1983).

reason could come from the prior art, the background knowledge of one of ordinary skill in the art, the nature of the problem to be solved, market demand, or common sense.

If you find that a reason existed at the time of the invention to combine the elements of the prior art to arrive at the claimed invention, this evidence would make it more likely that the claimed invention was obvious.

Again, you must undertake this analysis separately for each claim that [the Defendant] contends is obvious.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as Elan amended its proposed instruction after March 7 and only informed Abraxis of its amendments at 6:47 pm EDT on April 7, 2008, the day they were scheduled to be filed. Since Elan served this instruction nearly one month late, after 5:00 p.m. EDT on the day the instructions were due, Abraxis reserves the right to supplement this objection.

Abraxis's Proposed Instruction

The second question you must answer in determining whether or not the claimed invention was obvious at the time it was made is what differences there are, if any, between the prior art and the patented invention. In analyzing this issue, do not focus solely on the differences between the prior art and the claimed invention because the test is not whether there are differences. Rather, the test is whether or not the claimed invention, as a whole, would have been obvious to one having ordinary skill in view of all the prior art at the time the claimed invention was made.

Source: Federal Circuit Bar Association Model Patent Jury Instructions (2008).

Elan's Objection:

Elan objects to Abraxis's proposed instruction as incomplete and insufficiently detailed to assist the jury.

5.4.3 Level of Ordinary Skill [DISPUTED]

Elan's Proposed Instruction[29]

You should put yourself in the position of a person of ordinary skill in the field at the time the claimed invention was made and you should not consider what is known today or what is learned from the teaching of the patent. Factors to be considered in determining the level of ordinary skill in the pertinent art include the educational level of the inventor, the types of problems encountered in the art, the prior art patents and publications, the activities of others and prior art solutions to the problems encountered by the inventor, the sophistication of the technology, and the education of others working in the field.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as prejudicial and unbalanced. While Elan's proposed instruction appears to be based on the 2004 Delaware Instructions, § 4.8.3, Abraxis objects to the first sentence of Elan's instruction as unnecessary, redundant, and confusing to the jury. Consequently, Abraxis proposes the instruction from the 2008 Federal Circuit Instructions, § 4.3biii.

[29] This instruction is based on § 4.8 of the Draft Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004) as supplemented by the Model Patent Jury Instructions for the Northern District of California (Rev. 11/29/07), in view of the recent clarification to the law on obviousness. *See generally KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 167 L. Ed. 2d 705 (2007).

Abraxis's Proposed Instruction

The third question you must answer in determining whether the claimed invention was obvious at the time it was made is the level of ordinary skill in the field at the time. It is for you to decide what the level of ordinary skill was at the time the invention was made based on the evidence presented to you in this ease. In doing so, you may consider any evidence relating to this issue that is introduced at trial, including in particular any evidence introduced of:

(1) The educational level and experience of the inventor at the time the invention was made;

(2) The education level and experience of other persons working in the field of the invention at the time the invention was made;

(3) The types of problems encountered in the field at the time the invention was made;

(4) The sophistication of the technology in the field at the time the invention was made;

(5) The teachings and disclosures of prior art references such as patents and publications; and

(6) The teachings and disclosures of any references that, while not prior art to the invention, nonetheless contain teachings or disclosures of what the level of ordinary skill in the field may have been at the time the invention was made.

Source: Federal Circuit Bar Association Model Patent Jury Instructions (2008).

Elan's Objection:

Elan objects to Abraxis's proposed instruction as unduly confusing and prejudicial.

5.4.4 Secondary Considerations [DISPUTED]

Elan's Proposed Instruction[30]

In concluding whether a claim is obvious you should consider any of the following factors that you find have been shown by the evidence:

(1) commercial success of a product due to the merits of the claimed invention. Evidence concerning commercial success may take the form of sales figures coupled with market share data, or sales figures alone. The commercial success may be shown through the sales of anyone practicing the claimed inventions, including Abraxis. In determining whether Elan's '363 Patented invention was commercially successful or useful, Elan need not show that Elan itself commercialized a product based upon the '363 Patent;

(2) a long felt need for the solution provided by the claimed invention;

(3) unsuccessful attempts by others to find the solution provided by the claimed invention;

(4) copying of the claimed invention by others;

(5) unexpected and superior results from the claimed invention;

(6) acceptance by others of the claimed invention as shown by praise from others in the field or from the licensing of the claimed invention; and

(7) the voluntary taking of licenses and paying royalties under the '363 Patent by others.

[30] This instruction is based on § 4.8 of the Draft Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004) as supplemented by the Model Patent Jury Instructions for the Northern District of California (Rev. 11/29/07), in view of the recent clarification to the law on obviousness. *See generally KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 167 L. Ed. 2d 705 (2007).

The presence of any of the listed factors may be considered by you as an indication that the claimed invention would or would not have been obvious at the time the claimed invention was made. Although you should consider any evidence of these factors, the relevance and importance of any of them to your decision on whether the claimed invention would have been obvious is up to you.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as prejudicial and unbalanced. While Elan's proposed instruction appears to be based on the 2007 N.D. Cal. Instructions, § 4.3b Obviousness – (Alternative 2) and the 2004 Delaware Instructions, § 4.8.6, Elan's proposed instruction includes several unfairly argumentative amendments. Consequently, Abraxis proposes the instruction from the 2008 Federal Circuit Instructions, § 4.3biv.

Abraxis's Proposed Instruction

The fourth question you must answer in determining whether or not the invention was obvious at the time it was made is what evidence there is, if any, of additional considerations relating to the obviousness or non obviousness of the invention. You may consider in your analysis any evidence that was presented to you in this ease regarding the presence or absence of the following factors in deciding whether or not the invention would have been obvious at the time it was made:

(1) Whether or not the claimed invention proceeded in a direction contrary to accepted wisdom in the field;

(2) Whether or not there was long felt but unresolved need in the art that was satisfied by the claimed invention;

(3) Whether or not others had tried but failed to make the claimed invention;

(4) Whether or not others copied the claimed invention;

(5) Whether or not the claimed invention achieved any unexpected results;

(6) Whether or not the claimed invention was praised by others;

(7) Whether or not others have taken licenses to use the claimed invention;

(8) Whether or not experts or those skilled in the art at the making of the claimed invention expressed surprise or disbelief regarding the claimed invention;

(9) Whether or not products incorporating the claimed invention have achieved commercial success; and

(10) Whether or not others having ordinary skill in the field of the invention independently made the claimed invention at about the same time the inventor made the claimed invention.

Source: Federal Circuit Bar Association Model Patent Jury Instructions (2008).

Elan's Objection:

Elan objects to Abraxis's proposed instruction as incorrect in view of controlling case law.

5.5 Definiteness Under 35 U.S.C. § 112 [DISPUTED]

Elan's Proposed Instruction[31]

The Patent Laws require the claims of a patent to be sufficiently definite that one skilled in the art can determine the limits of the claimed invention. Abraxis alleges that certain of Elan's '363 Patent claims do not meet this requirement and thus should be considered invalid. You must initially presume that the claims of Elan's '363 Patent meet this "definiteness" requirement. Then you must decide whether Abraxis has proven by clear and convincing evidence that any of these claims is invalid for failure to meet this definiteness requirement.

The amount of detail required to be included in claims depends on the particular invention and the prior art, and is not to be evaluated in the abstract but in conjunction with the patent specification, prosecution history, and drawings as a whole. If the claims, read in light of the patent's specification, drawings, and prosecution history, reasonably apprise those skilled in the art of the proper scope of the invention, and if the language is as precise as the subject matter permits, then the claims are not indefinite. If Abraxis has shown by clear and convincing evidence that the claims do not provide such reasonable definiteness, then you may so find.

Simply because some claim language may not be precise does not automatically render a claim invalid. You must determine whether one of ordinary skill in the art would understand what is covered when the claim is read in light of the specification, drawings, and prosecution history. Even if that person of ordinary skill would need to make certain scientific experimentation in order to determine the limits of the claims of the patent, that would not necessarily be a basis for holding the claims invalid, unless you found that the amount of

[31] This instruction is adapted from the Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (March 1993). No instruction on definiteness was included in the 2004 draft for the uniform instructions.

experimentation required would be excessive.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction for several reasons. First, Abraxis objects to the jury deciding indefiniteness, other than in the form of an advisory verdict, as indefiniteness is a question of law for the judge. *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1380 (Fed. Cir. 2005) ("indefiniteness is a question of law.").

Second, Abraxis objects as Elan's instruction improperly references the presumption of validity.

Third, Abraxis objects to Elan's proposed additions to the Model Instruction on the burden of proof as unnecessary and redundant in light of instructions 1.6, 1.7, 2.3, and 3.4.

Fourth, Abraxis objects to Elan's proposed instruction as a whole because, while Elan's proposed instruction is allegedly based on the 1993 Delaware Instructions, Elan's prejudicial and argumentative amendments constitute a substantial part of its proposed instruction.

Consequently, Abraxis proposes the instruction adapted from the American Bar Association Model Jury Instructions for Patent Litigation (2005) for use in obtaining an advisory verdict.

Abraxis's Proposed Instruction

The patent laws have requirements for the way in which patent claims are written. Patent claims must be sufficiently clear that a person of ordinary skill in the field of the invention reading them is able to determine what the claims cover and what they do not cover. A person of ordinary skill is a person of average education and training in the field. If a patent claim does not meet this requirement, then the claim is said to be indefinite, and the claim is invalid.

The amount of detail required for a claim to be definite depends on the particular invention, the prior art and the description of the invention contained in the patent. A patent claim, when read along with the rest of the patent, must reasonably inform those skilled in the field of the invention what the patent claims cover. Simply because claim language may not be precise does not automatically mean that the claim is indefinite. The claim language need only be as precise as the subject matter permits.

Abraxis contends that claims 1, 3, 5, 10, and 11 of the '363 Patent are indefinite because the terms "average effective particle size" and "sufficient to maintain" in independent claim 1 are indefinite and not adequately defined in the specification.

Abraxis contends that claims 1-3 and 13-15 of the '025 Patent are indefinite because the term "effective average particle size" in independent claims 1 and 13 is indefinite. Abraxis also contends that claims 1-3 of the '025 Patent are indefinite because the claim term "sufficient to maintain" in independent claim 1 is indefinite and not adequately defined in the specification.

You are to apply the standards discussed above to Abraxis's contentions. If you find that Abraxis has proved that it is highly probable that claims 1, 3, 5, 10, and 11 of the '363 Patent or claims 1-3 and 13-15 of the '025 Patent are indefinite because a person of ordinary skill in the art

would not understand what is, and what is not, covered by the claims, you must then find that those claims are invalid.

Source: Adapted from American Bar Association Model Jury Instructions for Patent Litigation (2005).

Elan's Objection:

Elan objects to Abraxis's instructions on the '025 Patent for the reason set forth in n.4 on p. 2.

Elan objects to Abraxis's third, fourth, and fifth paragraphs as argumentative.

5.6 Obviousness-Type Double Patenting [DISPUTED]

Patent laws preclude Elan from obtaining more than one patent for an obvious modification of the same invention. This prevents Elan from obtaining a second patent claiming the same subject matter. It does not preclude a second patent on subject matter that was disclosed but not claimed in the first patent. The primary purpose of the double patenting doctrine is to prevent the extension of the statutory period of monopoly that would occur if successive patents were allowed on the same basic concept.

Elan is the owner of both the '363 Patent and the earlier-granted U.S. Patent No. 5,145,684. Abraxis contends that the claims of the '363 Patent are invalid for double patenting in light of Elan's claims in the '684 patent. To resolve this contention, you should evaluate the *claims* of the '363 Patent for obviousness in light of the *claims* of the '684 Patent.

If you find that claims 1, 3, 5, 10, or 11 of the '363 Patent are invalid for double patenting in light of the claims of the '684 Patent, but otherwise valid, enforceable and infringed, you must calculate damages as of October 26, 2007. I will remind you of this point later when I talk about the date damages begin.

Source: Donald S. Chisum, Chisum on Patents, vol. 3A § 9.01 (Matthew Bender & Company 2005); *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993); *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 2008 U.S. App. LEXIS 4969, *24 (Fed. Cir. Mar. 7, 2008).

Parties' Objections

Abraxis proposes this instruction as an advisory opinion in the event the Court's rejects Abraxis's proposed date damages begin in Section 7.4. Elan objects to the inclusion of this instruction since the issue is moot in view of the terminal disclaimer filed in the '363 patent. If the Court requires an instruction on obviousness-type double patenting, Elan consents to the language of Abraxis's proposed instruction.

6. ENFORCEABILITY [DISPUTED]

In addition to claims of invalidity, Abraxis asserts that, under legal theories that I will explain, Elan may not enforce either the '363 Patent or the '025 Patent against Abraxis, because the applicants for the patent acted inequitably when prosecuting their respective patent applications. For reasons that I will explain, Abraxis also asserts that Elan may not enforce the '363 Patent against Abraxis because Elan has unclean hands. Remember that a finding of unenforceability with respect to *any claim* in a patent renders the *entire patent* unenforceable.

Parties' Objections

Abraxis understands that Elan contends that the issue of unenforceability is not to presented to the jury. Abraxis disagrees. *See ISCO Int'l, Inc. v. Conductus, Inc.*, 279 F. Supp. 2d 489, 499-500 (D. Del. 2003), *aff'd*, No. 04-1007, 04-1008, 2005 U.S. App. LEXIS 1709 (Fed. Cir. Feb. 3, 2005).

6.1 Inequitable Conduct [DISPUTED]

Every applicant and inventor for a patent has a duty of candor and good faith in its dealing with the Patent Office and the examiner handling the application. This duty of candor is important because the examiner has only limited information available to determine the state of the art. The time available to the examiner is also limited. Therefore, to prevent an applicant or inventor from obtaining a patent he or she does not deserve, the Patent Office requires full disclosure to the Patent Office of all information which is material to examination of the application.

This duty of honesty and good faith exists from the time the application is filed and continues for the entire time that an application is pending before the Patent Office. It requires that the inventor, the applicant, the applicant's representatives, and others involved in a substantial way with the application fully disclose to the Patent Office all information of which they are aware that is material to examination of the application, including material prior art. I will explain to you in a moment how you may determine whether or not information is material.

Intentional failure to fulfill this duty of honesty and good faith is called inequitable conduct. When inequitable conduct occurs during the court of obtaining a patent, the patent is unenforceable. This means that the patent owner may not prevent others from using the invention covered by the claims of the patent and may not collect damages for patent infringement.

Abraxis has the burden of proving inequitable conduct by the clear and convincing standard. Abraxis must prove that the inventor, the inventor's representative, or someone involved in a substantial way with the application withheld or misrepresented information that

was material to the examination of the '363 Patent application or the '025 Patent application, and that this person acted with an intent to deceive or mislead the patent examiner.

I will now explain to you the requirements of materiality and intent. I will then explain how you should balance any materiality and intent that you find I order for you to determine whether or not there was inequitable conduct.

Source: Federal Circuit Bar Association Model Patent Jury Instructions, § 11 (2002) and the 2008 Federal Circuit Instructions, § 5.1.

Parties' Objections

Abraxis understands that Elan contends that the issue of unenforceability is not to go to the jury. Abraxis disagrees. *See ISCO Int'l, Inc. v. Conductus, Inc.*, 279 F. Supp. 2d 489, 499-500 (D. Del. 2003), *aff'd*, No. 04-1007, 04-1008, 2005 U.S. App. LEXIS 1709 (Fed. Cir. Feb. 3, 2005).

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.

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. On the other hand, whether information is material should be determined before any consideration is given to evidence which may be submitted in support of patentability.

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

Source: 2008 Federal Circuit Instructions, § 5.1; *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); 37 C.F.R. § 1.56(b) ("A *prima facie* case of unpatentability [may be established] …before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability").

Parties' Objections

Abraxis understands that Elan contends that the issue of unenforceability is not to go to the jury. Abraxis disagrees. *See ISCO Int'l, Inc. v. Conductus, Inc.*, 279 F. Supp. 2d 489, 499-

500 (D. Del. 2003), *aff'd*, No. 04-1007, 04-1008, 2005 U.S. App. LEXIS 1709 (Fed. Cir. Feb. 3, 2005).

6.1.2 Intent [DISPUTED]

In order for inequitable conduct to have occurred Abraxis must establish that any failures to disclose material information or false or misleading statements were done with an intent to deceive the examiner. If the failures to disclose material information or false or misleading statements occurred through negligence, oversight, carelessness, or an error in judgment, even if it was grossly negligent, then there was no intent to deceive and there is no inequitable conduct.

Intent may be shown through direct evidence, such as documents or testimony about one's intent to deceive. Intent also may be shown through indirect evidence, or in other words, it may be inferred from conduct. For example, you may infer an intent to mislead from acts substantially certain to accomplish a result, or a combination of conduct and statements. However, you are not required to infer intent. Any inference of intent will necessarily depend upon the totality of the circumstances as you find them to have been, including the nature and level of any culpable conduct you may find and the absence or presence of affirmative evidence of good faith on the Elan's part.

Source: Federal Circuit Bar Association Model Patent Jury Instructions (2008).

Parties' Objections

Abraxis understands that Elan contends that the issue of unenforceability is not to go to the jury. Abraxis disagrees. *See ISCO Int'l, Inc. v. Conductus, Inc.*, 279 F. Supp. 2d 489, 499-500 (D. Del. 2003), *aff'd*, No. 04-1007, 04-1008, 2005 U.S. App. LEXIS 1709 (Fed. Cir. Feb. 3, 2005).

6.1.3 Balancing of Materiality and Intent [DISPUTED]

If you find that Abraxis has proved that material information was withheld or materially misleading statements were made and, further, that these acts or omissions were done with an intent to mislead the examiner, you must then weigh the degree of materiality and the degree of intent to determine whether, on balance, the evidence clearly and convincingly establishes that Elan committed inequitable conduct and the patents should in fairness be declared unenforceable. When performing this balancing, the higher the level of materiality of the withheld information or the false and misleading statements, the lower the level of intent that is required to establish inequitable conduct, and vice versa. Materiality and intent to deceive are separate issues: proof of materiality does not give rise to an inference of intent to deceive, and proof of an intent to deceive does not give rise to an inference of materiality. There must be evidence that establishes materiality and there must be evidence that establishes an intent to deceive. If evidence of either, or both, is missing, there can be no inequitable conduct.

Although the question of whether there has been inequitable conduct is one that I will decide, I will ask for your findings so that I can consider them in making my 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.

Source: Federal Circuit Bar Association Model Patent Jury Instructions (2008).

Parties' Objections

Abraxis understands that Elan contends that the issue of unenforceability is not to go to the jury. Abraxis disagrees. *See ISCO Int'l, Inc. v. Conductus, Inc.*, 279 F. Supp. 2d 489, 499-500 (D. Del. 2003), *aff'd*, No. 04-1007, 04-1008, 2005 U.S. App. LEXIS 1709 (Fed. Cir. Feb. 3, 2005).

6.2 Unclean Hands [DISPUTED]

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.

Source: Federal Circuit Bar Association Model Patent Jury Instructions (2008).

Parties' Objections

Abraxis understands that Elan contends that the issue of unenforceability is not to go to the jury. Abraxis disagrees. *See ISCO Int'l, Inc. v. Conductus, Inc.*, 279 F. Supp. 2d 489, 499-500 (D. Del. 2003), *aff'd*, No. 04-1007, 04-1008, 2005 U.S. App. LEXIS 1709 (Fed. Cir. Feb. 3, 2005).

7. DAMAGES

7.1 Generally [AGREED]

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 [DISPUTED]

Elan's Proposed Instruction

Patent law provides that in the case of infringement of a valid patent claim, the owner of the patent shall be awarded damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer. Damages are compensation for all losses suffered as a result of the infringement.

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 necessary to adequately compensate Elan for Abraxis's infringement. Adequate compensation should return Elan to the position it would have occupied had there been no infringement.

Abraxis's Objections

Abraxis objects to Elan's proposed instruction as the first paragraph and the last sentence of the second paragraph provide an opportunity to claim lost profits under 35 U.S.C. § 284. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1163 (Fed. Cir. 1991); *Proctor & Gamble Co. v. Paragon Trade Brands, Inc.* 989 F. Supp. 547, 600 (D. Del. 1997). Elan, however, makes no claim for lost profits or an established royalty and its interrogatory responses and expert reports allege damages solely in the form of a reasonable royalty. Accordingly, Abraxis objects to Elan's instruction, which instructs the jury to exceed a reasonable royalty. Consequently, Abraxis proposes removal of all language relating to damages other than for a reasonable royalty.

Abraxis's Proposed Instruction

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.

Source: Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware (2004).

Elan's Objection:

Elan objects to Abraxis's instructions as incomplete.

7.3 Burden Of Proof [AGREED]

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 [DISPUTED]

Elan's Proposed Instruction

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

Abraxis's Objections

The parties disagree as to the date damages accrue. Elan contends that damages accrue from January 7, 2005. Abraxis contends that damages may only accrue from October 26, 2007 as the claims of the '363 Patent were invalid for obviousness-type double patenting until a terminal disclaimer was filed on October 25, 2007. If the Court declines to specify a date that damages begin, Abraxis proposes the following instruction.

Abraxis's Proposed Instruction

In this case, the date you begin calculating damages depends on whether you find claims 1, 3, 5, 10, or 11 of the '363 Patent invalid for double patenting in light of the claims of the '684 Patent. If you find any of the claims of the '363 Patent *not invalid for double patenting*, and valid, enforceable, and infringed, then you must begin calculating damages as of January 7, 2005. If you find the claims of the '363 Patent *invalid for double patenting*, but otherwise valid, enforceable, and infringed, then you must begin calculating damages as of October 26, 2007. Regardless of the '363 Patent's validity for double patenting, if you find the claims invalid or unenforceable or not infringed, Elan is not entitled to damages at all. If you find that Elan is entitled to damages, you will be asked to specify the date you begin calculating damages on the jury verdict form.

Elan's Objection:

Elan objects to any reference to the period of damages starting as of October 26, 2007, the ate after Elan filed its terminal disclaimer. The '363 claims would only be finally invalid after expiration of the '684 patent; the correct date for assessing damages is January 7, 2005. Furthermore, Abraxis cites no authority for its complicit intervening rights argument for postponing the damages calculation to October 26, 2007/

7.5 Reasonable Royalty As A Measure Of Damages [DISPUTED]

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 or October 26 2007] 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.

Parties' Objections

With respect to the language in brackets, the parties disagree about the date damages begin. Elan contends that damages accrue from "January 7, 2005," while Abraxis contends that damages may only accrue from "October 26, 2007."

7.6 Factors For Determining Reasonable Royalty [AGREED]

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 elements, 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 [AGREED]

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.]

Parties' Objections

Abraxis proposes the addition of the language in brackets to the instruction from the Uniform Jury Instructions for Patent Cases for the United States District Court for the District of Delaware (2004) to clarify that Elan is not entitled to recover any amounts for any alleged lost profits. Elan objects to the inclusion of the language in brackets.

8. DELIBERATIONS AND VERDICT

8.1 Introduction [AGREED]

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 [AGREED]

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 [AGREED]

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 [AGREED]

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.