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.	)	

PRELIMINARY JURY INSTRUCTIONS

1. PRELIMINARY INSTRUCTIONS

1.1 Introduction

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.

1.2 The Parties And Their Contentions

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. 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. 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.

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.

1.3 Duties Of The Jury

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

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

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

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 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 '363 Patent. 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.

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

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.

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.

1.7 General Guidance Regarding Patents

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;

(3) Whether certain claims of the '363 Patent have been proven by Abraxis by clear and convincing evidence 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

(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 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.

1.8 Conduct Of The Jury

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

1.9 Course Of The Trial

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.

1.11 Glossary Of Patent Terms

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.