UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD; ROCHE DIAGNOSTICS GmbH; and HOFFMANN-LA ROCHE INC., Defendants.	CIVIL ACTION No.: 05-CV-12237WGY

DEFENDANTS' PROPOSED JURY INSTRUCTIONS

Defendants, F. Hoffman-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc., respectfully request that the Court read the attached jury instructions to the jury at the conclusion of trial.

Dated: August 31, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

By their attorneys,

/s/ Julia Huston
Lee Carl Bromberg (BBO# 058480)
Timothy M. Murphy (BBO# 551926)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
Kimberly J. Seluga (BBO# 667655)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
jhuston@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Christopher T. Jagoe (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Julia Huston
Julia Huston

03099/00501 725187.4

DEFENDANTS' PROPOSED JURY INSTRUCTIONS
TABLE OF CONTENTS

1 GENERAL INSTRUCTIONS[1]

1.1 INTRODUCTION

Ladies and Gentlemen of the jury, you have heard the evidence and arguments in this case and the time has come for you to weigh the evidence, deliberate and reach a verdict. Now it is time for me to instruct you about the law that you must follow in deciding this case. I will start by explaining your duties and the general rules that apply in every civil case. Then I will explain some rules that you must use in evaluating particular testimony and evidence. Then I will explain the positions of the parties and the law you will apply. And 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 all of my instructions. Do not pick out any particular part, but consider the instructions as a whole. The fact that I instruct you as to all aspects of the case does not mean that I think anything has been proved or not proved. I must instruct you as to all aspects of the case.

[1] The General Instructions, as well as other substantive Instructions, are adapted from the AIPLA 2005 Model Patent Jury Instructions and the Model Patent Jury Instructions from the District Court of the District of Delaware.

1.2 JURORS' DUTIES

You have two main duties as jurors. The first one is to decide what the facts are from the evidence that you saw and heard here in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way.

Your second duty is to take the law that I give you, apply it to the facts, and decide whether Amgen's asserted patents are valid, whether defendants have infringed them and whether anyone at Amgen or acting on Amgen's behalf misrepresented, omitted or buried material information before the Patent Office in obtaining the asserted patents, with an intent to deceive the Patent Office. It is my job to instruct you about the law, and you are bound by the oath that you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that I gave you before and during the trial and these instructions. All the instructions are important, and you should consider them together as a whole. You are required to apply the law, and to do so you must truly understand it. If you do not understand any of my instructions, you may ask questions. During the recess that follows my instructions, you should write out any question about the law that you believe will help you understand the framework in which you are required to weigh the evidence before you, and I will answer them.

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.

1.3 EVIDENCE DEFINED

You must make your decision based only on the evidence that you saw and heard here in court. Do not let rumors, suspicions, or anything else that you may have seen or heard outside of court influence your decision in any way.

The evidence in this case includes only what the witnesses said while they were testifying under oath, the exhibits that I allowed into evidence, the stipulations that the lawyers agreed to, and the facts that I have judicially noticed.

Nothing else is evidence. The lawyers' statements and arguments are not evidence. Their questions and objections are not evidence. My legal rulings are not evidence. None of my comments or questions is evidence.

During the trial I may have not let you hear the answers to some of the questions that the lawyers asked. I also may have ruled that you could not see some of the exhibits that the lawyers wanted you to see. And sometimes I may have ordered you to disregard things that you saw or heard, or I struck things from the record. You must completely ignore anything that was excluded. Do not even think about them. Do not speculate about what a witness might have said or what an exhibit might have shown. These things are not evidence, and you are bound by your oath not to let them influence your decision in any way.

Make your decision based only on the evidence, as I have defined it here, and nothing else.

1.4 DIRECT AND CIRCUMSTANTIAL EVIDENCE

Now, some of you may have heard the terms "direct evidence" and "circumstantial evidence."

Direct evidence is simply evidence like the testimony of an eyewitness, which, if you believe it, directly proves a fact. If a witness testified that he saw it raining outside, and you believed him, that would be direct evidence that it was raining.

Circumstantial evidence is simply a chain of circumstances that indirectly proves a fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet hat that would be circumstantial evidence from which you could conclude that it was raining.

It is your job to decide how much weight to give the direct and circumstantial evidence. The law makes no distinction between the weight that you should give to either one, nor does it say that one is any better evidence than the other. You should consider all the evidence, both direct and circumstantial, and give it whatever weight you believe it deserves.

1.5 CONSIDERATION OF EVIDENCE

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events, and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion. In considering the evidence and drawing conclusions, you must make reasonable inferences but you must not guess or speculate.

1.6 CREDIBILITY OF WITNESSES

As the jurors, you have the power to use everything you know about the witnesses who will testify on the witness stand. You are entitled to consider how they answered questions on both direct and cross examination. You may decide to believe or disbelieve everything any one of these witnesses has said to you, or you may decide to believe some parts of the witnesses' testimony but not others.

In determining the weight to give to the testimony of a witness, you should ask yourself whether there was evidence tending to prove that the witness testified falsely about some important fact, or, whether there was evidence that at some other time the witness said or did something, or failed to say or do something that was different from the testimony he gave at the trial.

Consider what interest any witness had in testifying as he or she so testified. Is the witness employed by, an advisor to, friendly with, hostile to, or opposed to one or the other parties in the case? In a case like this, it is frequent that some witnesses are employed or engaged by the parties, and that alone does not make their testimony implausible or not believable, but you may consider it.

You should remember that a simple mistake by a witness does not necessarily mean that the witness was not telling the truth. People may tend to forget some things or remember other things inaccurately. On the other hand, if a witness testifies that he or she does not remember something and you do not believe him or her, you should take that into account when determining the witness's credibility. If a witness has made a misstatement or an omission, you must consider whether it was simply an innocent lapse of memory or an intentional falsehood, and that may depend upon whether it concerns an important fact or an unimportant detail.

1.7 NUMBER OF WITNESSES

One more point about the witnesses. Sometimes jurors wonder if the number of witnesses who testified makes any difference.

Do not make any decisions based only on the number of witnesses who testified. What is more important is how believable the witness was, and how much weight you think their testimony deserves. Concentrate on that, not the numbers.

1.8 EXPERT WITNESSES

When knowledge of technical subject matter may be helpful to the jury, a person who has special training or experience in that technical field - he or she is called an expert witness - is permitted to state his or her opinion on those technical matters. You have heard testimony from several scientific experts in this case. These witnesses are just like any other witness, and, as with any other witness, you may choose to believe some, all, or none of their testimony. You are not required to accept any or all of their opinions.

With respect to an expert witness, you will have in mind the opinion testified to—the expert's conclusions—and what data and analysis that opinion is based on. I suggest to you that you consider whether you believe the data is accurate and whether the analysis makes sense to you. If it does, then you decide for yourselves whether the opinions based on those data and analyses persuade you. Consider whether the opinions follow logically. Consider how they compare with other evidence in the case. In short, you may sum up these witnesses' testimony and decide what you believe or what you don't want to believe.

1.9 DOCUMENTS

A number of documents have been admitted as exhibits, and they will be made available to you in the jury room while you deliberate. Like the testimony of witnesses, you may choose to believe some, or all or none of what a document says.

2 THE PARTIES AND THEIR CONTENTIONS

2.1 THE PARTIES

As you now undoubtedly know, the Plaintiff is Amgen Incorporated, hereinafter "Amgen."

The Defendants are Hoffman-LaRoche Ltd., Roche Diagnostics, GmbH, and Hoffman LaRoche Inc., whom I will refer to collectively as "Roche."

2.2 SUMMARY OF PLAINTIFF'S CONTENTIONS

Ladies and Gentlemen of the jury, in the beginning of the case I explained to you the issues that you must decide. I will repeat them for you generally now and will give you more detailed instruction on the law that you must follow in reaching your decision in this case.

Plaintiff Amgen contends that Defendant Roche has imported and is currently importing into the United States a pharmaceutical composition, called MIRCERA® , that Amgen alleges infringes its various patents directed to erythropoietin ("EPO"), a protein used to treat anemia and related blood disorders. As of the filing of this lawsuit and up to today, MIRCERA® has yet to be approved by the FDA and has never been nor is currently on the market. Amgen thus seeks a declaratory judgment that Roche is currently infringing or, upon FDA approval, will infringe claims 1 and 2 of the '868 patent, claims 3, 7-9, 11, 12, and 14 of the '933 patent, claims 6-9 of the '698 patent, claim 7 of the '349 patent and claim 1 of the '422 patent.

2.3 SUMMARY OF DEFENDANTS' CONTENTIONS

Roche contends that it does not infringe any of the asserted claims of Amgen's '868, '933, '698, '349, or '422 patents. Roche also contends that asserting these claims and patents is improper as the patents-in-suit are all invalid.

With regard to non-infringement, Roche contends that it has not infringed and is not infringing any of Amgen's asserted claims, either directly or indirectly, or literally or under the doctrine of equivalents or due to the reverse doctrine of equivalents. Roche further contends that all allegedly infringing activities cannot constitute infringement as a matter of law as such activities are protected under 35 U.S.C. § 271(e)(1). This provision is often referred to as the "safe harbor provision." It allows otherwise infringing activities to be exempt from liability if said activities are pursuant to clinical trials pursuant to gaining FDA approval.

With regard to invalidity, Roche contends that various claims of the asserted patents are invalid because they fail to satisfy the legal conditions for patentability, including non-anticipation, non-obviousness, adequate written description, enablement, and definiteness. Roche further contends that some of the asserted patents are invalid as they cover the same subject matter for which Amgen holds other patents, namely the expired '008 patent, the '868 patent and the '698 patent. Roche contends that the asserted patents are an improper attempt at prolonging a monopoly whose time has lapsed.

Additionally, Roche contends that the patents-in-suit are not enforceable, in whole or in part, due to Amgen's wrongful and improper conduct in attaining the patents-in-suit.

2.4 SUMMARY OF PARTIES' ISSUES

I will now summarize the issues that you must decide, as I instructed you in the beginning of the case, and for which I will provide further instructions on the law to guide your deliberations. You must decide the following issues:

For the issue of **invalidity,** you must determine:

- whether references in the prior art anticipate the asserted patents
- whether the subject matter of an asserted claim was used publicly more than a year before the patent for the asserted claim was filed
- whether the subject matter of an asserted claim was invented by another before Lin invented the subject matter of the asserted claims
- whether the subject matter of an asserted claim was known publicly more than a year before the patent for the asserted claim was filed
- whether the subject matter of an asserted claim was sold in the U.S. more than a year before the patent for the asserted claim was filed
- whether the subject matter of an asserted claim was patented in the U.S. or a foreign country more than a year before the patent for the asserted claim was filed
- whether the asserted claims would have been obvious to one of ordinary skill in the art at the time of filing
- whether the asserted claims were enabled at the time of filing, such that one skilled in the field of the invention could make and use the claimed invention
- whether the asserted claims were described adequately in the patents-in-suit
- whether the asserted claims were definite such that one skilled in the art could determine the precise limits of the claimed invention
- whether some of the claims-in-suit are mere obvious variations of Amgen's expired '008 patent , the '868 patent, or the '698 patent

- whether, during the prosecution of the patent application that led to the '349 patent, Amgen elected to proceed under 35 U.S.C. Sec. 103(b), and thus the '349 patent should have expired when the '008 patent expired

For the issue of **infringement**, you must determine:

- whether Roche directly infringed the patents-in-suit
- whether Roche induced infringement on the patents-in-suit
- whether Roche literally infringed the patents-in-suit
- whether Amgen has proven that products imported by Roche allegedly infringing the asserted process claims were not materially changed such that they do not infringe any of the asserted claims
- whether Roche infringed the patents-in-suit by the doctrine of equivalents
- whether the doctrine of equivalents should not apply due to limitations in the prior art, prosecution history estoppel, or subject matter dedicated to the public
- whether Roche has proven by the reverse doctrine of equivalents that its products and processes are so different from the asserted claims that they are non-infringing
- whether all of Roche's allegedly infringing activity is protected under the safe harbor exemption

For the issue of **unenforceability**, you must determine:

- whether information material to the Lin patents was misrepresented, omitted, and/or buried to the United States Patent and Trademark Office (USPTO)
- whether any person substantially involved in the prosecution of the Lin patents had the intent to mislead the USPTO
- whether Amgen committed fraud on the USPTO to obtain the Lin patents.

2.5 ISSUES ESTABLISHED BY PRIOR LITIGATIONS

In the law, once a party has had the opportunity to litigate an issue fully and that issue has been conclusively decided, that party may not relitigate that same issue. The legal term for this rule is "issue preclusion."[2]

In this case, I have determined that there are certain issues that have been established in prior litigation involving Amgen and are not appropriately reconsidered as open issues in this case.

I therefore instruct you to consider the following facts as conclusively established:

1. Recombinant erythropoietin cannot be distinguished from urinary erythropoietin on the basis of glycosylation.[3]

2. The claims of the patents-in-suit cannot cover analogs beyond the handful disclosed in the specification.[4]

---

[2] Issue preclusion is invoked when the following four-part test is satisfied:

1. the issue is identical to one decided in the first action;
2. the issue was actually litigated in the first action;
3. resolution of the issue was essential to a final judgment in the first action; and
4. the party against whom estoppel is invoked had a full and fair opportunity to litigate the issue in the first action

Amgen, Inc. v. F. Hoffman-La Roche Ltd., ---F.Supp.2d---, 2007 WL 1893058 *2 (D. Mass. 2007) (citing *Innovad Inc. v. Microsoft Corp.*, 260 F.3d 1326, 1334 (Fed. Cir. 2001)).

[3] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1341 (Fed. Cir. 2003) ("In its discussion characterizing recombinant glycoprotein products, the specification of the '933 patent does not direct those of ordinary skill in the art to a standard by which the appropriate comparison can be made."); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 155-56, 165 (D. Mass. 2001) ("The glycosylation of human urinary erythropoietin is a standardless standard... As a result, making comparisons between the glycosylation of recombinant EPO and that of human urinary EPO is virtually impossible."); ("Dr. Lin's specification falters ... because it fails to enable one of ordinary skill in the art to compare the glycoyslation of the recombinant EPO product with that of human urinary erythropoietin."); *see also* Exhibit A to Defendants' Memorandum of Law in Support of Motion In Limine to Invoke Issue Preclusion as to Findings from Prior Litigation (D.N. 821-2) (quoting numerous additional statements).

[4] *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1213-14 (Fed. Cir. 1991)* ("Details for preparing only a few EPO analog genes are disclosed" in the patents-in-suit.);

Because these facts are considered conclusively established, you may not consider any argument, testimony or evidence to the contrary.

("There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them."); ("Considering the structural complexity of the EPO gene, the manifold possibilities for change in its structure, with attendant uncertainty as to what utility will be possessed by these analogs, ... more is needed concerning identifying the various analogs that are within the scope of the claim, methods for making them, and structural requirements for producing compounds with EPO-like activity. It is not sufficient, having made the gene and a handful of analogs whose activity has not been clearly ascertained, to claim all possible genetic sequences that have EPO-like activity."); *see also* Exhibit A to Defendants' Memorandum of Law in Support of Motion In Limine to Invoke Issue Preclusion as to Findings from Prior Litigation (D.N. 821-2)(quoting numerous additional statements).

3 BURDEN OF PROOF

I will instruct you now of the burdens of proof associated with the issues presented to you. As I instructed you earlier, Amgen bears the burden of proving that Roche has infringed. Amgen must meet this burden by what is called a preponderance of the evidence. That means that Amgen has to produce evidence which, when considered in light of all the facts, leads you to believe that what Amgen claims is more likely true than not. To put it differently, if you were to put the plaintiff's and the defendant's evidence on opposite sides of a scale, the evidence supporting the plaintiff's claims would have to make the scales tip on the plaintiff's side.

Additionally, defendant urges that plaintiff's patents are invalid. A patent is presumed to be valid. Accordingly, defendant has the burden of proving that the patents-in-suit are invalid 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; it is a higher burden than proof by a preponderance of the evidence.

Those of who you are familiar with criminal cases will have heard the term "proof beyond a reasonable doubt." That burden does not apply in a civil case and you should, therefore, put it out of your mind in considering whether or not the plaintiff or defendant has met its burden of proof.

4 VALIDITY DEFENSES

Roche contends that the asserted claims of the patents-in-suit are invalid, as well as claims 4 and 5 of the '698 patent. Roche has the burden of proving by clear and convincing evidence that each is invalid.

Roche contends that the asserted claims are invalid for the following reasons:

- references in the prior art anticipate the asserted patents
- the subject matter of asserted claims were used publicly before November 30, 1983
- the subject matter of asserted claims were invented by another before Dr. Lin invented the subject matter of the asserted claims
- the subject matter of asserted claims were known before November 30, 1983
- the subject matter of asserted claims were sold in the U.S. before November 30, 1983
- the subject matter of asserted claims were patented in the U.S. or a foreign country before November 30, 1983
- the asserted claims would have been obvious to one of ordinary skill in the art
- Dr. Lin derived enough of the subject matter of the asserted claims to render the rest of the claimed subject matter obvious
- the asserted claims were not fully enabled at the time of filing, such that one of ordinary skill in the art could make and use the claimed invention
- the full scope of the asserted claims were not adequately described in the patents-in-suit
- the asserted claims were indefinite such that one of ordinary skill in the art could not determine the precise limits of the claimed invention
- the claims-in-suit are obvious variations of the claims of Amgen's expired '008 patent, or the '868 patent and the '698 patent
- Amgen elected to proceed under 35 U.S.C. Sec. 103(b), and thus the '349 patent should have expired when the '008 patent expired

4.1 PRIOR ART DEFINED

In this case, prior art includes any of the following items received into evidence during trial:[5]

1. any product or method that was publicly known or used by others in the United States before Amgen's invention date;

2. patents that issued before Amgen's date of invention, or before November 30, 1983;

3. publications having a date before Amgen's date of invention, or before November 30, 1983;

4. any product or method that was in public use or on sale in the United States before November 30, 1983;

5. any product or method that was invented by anyone before Amgen's date of invention, where the product or method was not abandoned, suppressed, or concealed; and

6. any disclosure to Dr. Lin before Amgen's date of invention, by another who is not a named inventor on the asserted patents.

[5] 35 U.S.C. § 102.

4.2 ANTICIPATION [6]

A person cannot obtain a patent if someone else already has made an identical invention. Simply put, the invention must be new. An invention that is not new or novel is said to be "anticipated" by the prior art. To prove anticipation, Roche must present clear and convincing evidence showing that each and every element in the claim is present in a single prior art reference.[7]

In this case, Roche contends that claims of the '933 and '422 patents are anticipated. Specifically, Roche contends for claims 3, 7, and 8 of the '933 patent:

- a substance satisfying the elements of these claims was known or used before Amgen's date of invention
- a substance satisfying the elements of these claims was patented or described in a printed publication before Amgen's date of invention, or before November 30, 1983
- a substance satisfying the elements of these claims was in public use or on sale in the U.S. before November 30, 1983
- a substance satisfying the elements of these claims was made in the U.S. by another inventor before Amgen's date of invention
- a substance satisfying the elements of these claims was described in a patent granted on an application for patent by another, filed in the U.S. before Amgen's date of invention

For claims 9 and 12 of the '933 patent and claim 1 of the '422 patent, Roche contends:

- a pharmaceutical composition satisfying the elements of these claims was known or used before Amgen's date of invention

---

6 35 U.S.C. § 102; AIPLA 2005 Model Patent Jury Instructions, 6.0.

7 *IPXL Holdings, LLC v. Amazon.com, Inc.,* 430 F.3d 1377, 1381 (Fed. Cir. 2005), (quoting *Brisol-Myers Squibb Co. v. Ben Venue Labs., Inc.,* 246 F.3d 1368, 1373 (Fed. Cir. 2001)).

- a pharmaceutical composition satisfying the elements of these claims was patented or described in a printed publication before Amgen's date of invention or before November 30, 1983
- a pharmaceutical composition satisfying the elements of these claims was publicly used or sold in the U.S. before November 30, 1983
- a pharmaceutical composition satisfying the elements of these claims was made in the U.S. by another inventor before Amgen's date of invention
- a pharmaceutical composition satisfying the elements of these claims was described in a patent granted on an application by another filed in the U.S. before Amgen's date of invention

In determining whether all the elements of the claimed invention is found in the prior art reference, you should take into account what a person of ordinary skill in the art would have understood from his or her examination of the particular item of prior art. If the prior art reference was properly before the PTO at the time of issuance, a patent nevertheless may be found to be anticipated on the basis of that reference.[8] If, on the other hand, the prior art reference was not before the PTO, the presumption of validity of the patent is weakened because the rationale underlying the presumption -- that the PTO, using its expertise, had approved the claim -- is diminished.[9]

A product-by-process claim covers the product, not the process. Amgen's product-by-process claims are anticipated if the products of those claims existed in the prior art. Whether such prior art products were produced by a process different from the process employed by Amgen, or are from a different source, is immaterial when determining the validity of Amgen's

---

[8] *IPXL Holdings, LLC. v. Amazon.com, Inc.*, 430 F.3d 1377, 1381 (Fed. Cir. 2005).

[9] *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1745 (2007).

product-by-process claims. For that determination, the focus remains at all times on Amgen's claimed product and the products of the prior art..[10]

In determining whether the single item of prior art anticipates a patent claim, you should take into consideration not only what is expressly disclosed in the particular item but also what inherently occurred as a natural result of its practice. This is called "inherency." A party claiming inherency must prove it by clear and convincing evidence. To establish inherency, the evidence must make clear that the missing descriptive matter is necessarily present in the reference. Inherency, however, does not require that a person of ordinary skill in the art at the time of the disclosure or occurrence of the anticipating subject matter would have recognized the inherent disclosure.[11] Thus, the prior use of the patented invention that was accidental or unrecognized and unappreciated can still be an invalidating anticipation.

You must keep these requirements in mind and apply them to each kind of anticipation you consider in this case.

---

[10] *SmithKline Beecham Corp. v. Apotex Corp.,* 439 F.3d 1312, 1317 (Fed. Cir. 2006); *Amgen Inc. v. Hoechst Marion Roussel, Inc.,* 314 F.3d 1313, 1354 n.20 (Fed. Cir. 2003); *Gen. Elec. Co. v. Wabash Appliance Corp.,* 304 U.S. 364, 373 (1938); *Diamond v. Chakrabarty,* 447 U.S. 303, 309-10 (1980).

[11] *See Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1321 (Fed. Cir. 2004).

4.3 EFFECTIVE FILING DATE AND DATE OF INVENTION

The effective filing date of the asserted claims is November 30, 1984. Amgen's date of invention is the effective filing date -- November 30, 1984 -- unless you find that Amgen has proven the conception and actual reduction to practice of the invention earlier than that.

4.4 PRIOR PUBLIC USE

Roche contends that claims 3, 7, 8, 9 and 12 of the '933 patent and claim 1 of the '422 patent were anticipated because the invention defined in those claims were publicly used in the United States before Amgen's date of invention, or before November 30, 1983.

An invention is publicly used if it is used by the inventor or by a person who is not under any limitation, restriction, or obligation of secrecy to the inventor.

4.5 PRIOR INVENTION

Roche contends that claims 3, 7, 8, 9 and 12 of the '933 patent and claim 1 of the '422 patent were anticipated because the inventions defined in those claims were invented by another person before Amgen's date of invention.

Roche must show by clear and convincing evidence either (1) before Amgen's date of invention, a third party reduced to practice a product or method that includes all of the elements of the relevant claims or (2) that a third party was the first to conceive of the invention and that he exercised reasonable diligence in later reducing the invention to practice. In addition, Roche must show that the third party's invention was sufficiently developed that one skilled in the art would have recognized that it would work for its intended purpose.

If the prior invention was abandoned, suppressed, or concealed, it does not anticipate Amgen's patent.

An invention was not abandoned, suppressed, or concealed if the invention was made public, sold, or offered for sale, or otherwise used for a commercial purpose. A period of delay does not constitute abandonment, suppression, or concealment if the prior inventor was engaged in reasonable efforts to bring the invention to market.[12]

---

[12] AIPLA Model Patent Jury Instruction 6.5; 35 U.S.C. § 102; *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373 (Fed. Cir. 2002); *Monsanto Co. v. Mycogen Plant Sci., Inc.*, 261 F.3d 1356 (Fed. Cir. 2001); *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031 (Fed. Cir. 2001); *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056 (Fed. Cir. 1989); *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430 (Fed. Cir.1988); *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437 (Fed. Cir. 1984); *Gen. Motors Corp. v. Toyota Motor Co.*, 467 F. Supp. 1142 (S.D. Ohio1979), *aff'd in part & rev'd in part*, 667 F.2d 504 (6th Cir. 1981).

4.6 PRIOR PUBLIC KNOWLEDGE

Roche contends that claims 3, 7, 8, 9 and 12 of the '933 patent and claim 1 of the '422 patent were anticipated because the inventions defined in those claims were publicly known in the United States before Amgen's date of invention.

Private or secret knowledge does not invalidate a patent claim. Similarly, if something is only publicly known outside of the United States, this is not invalidating public knowledge.[13]

[13] 35 U.S.C. § 102; *Rosemount, Inc. v. Beckman Instruments, Inc.,* 727 F.2d 1540 (Fed. Cir. 1984); *Trend Prods. Co. v. Metro Indus., Inc.,* 10 U.S.P.Q. 2d 1531 (C.D. Cal. 1989).

4.7 PRINTED PUBLICATION

Roche contends that claims 3, 7, 8, 9 and 12 of the '933 patent and claim 1 of the '422 patent were anticipated because the invention defined in those claims were described in a printed publication Amgen's date of invention, or before November 30, 1983.

A printed publication must be reasonably accessible to those members of the public who would be interested in its contents. It is not necessary that the printed publication be available to every member of the public. An issued patent is a printed publication. A published patent application is a printed publication as of its publication date.

For a printed publication to anticipate a patent claim, it must, when read by a person of ordinary skill in the art, expressly or inherently disclose each element of the claimed invention to the reader, and must be complete enough to enable one of ordinary skill in the art to practice the invention without undue experimentation. In determining whether the disclosure is enabling, you should take into account what would have been within the knowledge of a person of ordinary skill in the art one year before the application for the patent was filed and/or at the time the invention of the patents were made; you may consider evidence that sheds light on the knowledge such a person would have had.[14]

---

[14] AIPLA Model Jury Instruction 6.4; 35 U.S.C. § 102; *In re Carol F. Klopfenstein*, 380 F.3d 1345, 1352 (Fed. Cir. 2004); *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.,* 45 F.3d 1550 (Fed. Cir. 1995); *Scripps Clinic & Research Found. v. Genentech, Inc.,* 927 F.2d 1565 (Fed. Cir.), *clarif. on recon.*, 927 F.2d 1565 (Fed. Cir. 1991); *Constant v. Advanced Micro-Devices, Inc.,* 848 F.2d 1560 (Fed. Cir. 1988); *Akzo N.V. v. U.S. Int'l Trade Comm'n,* 808 F.2d 1471 (Fed. Cir. 1986); *In re Hall,* 781 F.2d 897 (Fed. Cir. 1986); *In re Donohue,* 766 F.2d 531 (Fed. Cir. 1985); *Studiengesellschaft Kohle mbH v. Dart Indus., Inc.,* 726 F.2d 724 (Fed. Cir. 1984); *In re Wyer,* 655 F.2d 221 (C.C.P.A. 1981); *In re Donohue,* 632 F.2d 123 (C.C.P.A. 1980); *In re Samour,* 571 F.2d 559 (C.C.P.A. 1978); *In re Coker,* 463 F.2d 1344 (C.C.P.A. 1972); *Deep Welding, Inc. v. Sciaky Bros., Inc.,* 417 F.2d 1227 (7th Cir. 1969); *Phillips Petroleum Co. v. Ladd,* 219 F. Supp. 366 (D.D.C. 1963); *Garrett Corp. v. United States,* 422 F.2d 874 (Ct. Cl. 1970); *Honeywell, Inc. v. Sperry Rand Corp.,* 180 U.S.P.Q. 673 (D. Minn. 1973); *Tyler Refrigeration Corp. v. Kysor Indus. Corp.,* 553 F. Supp. 279 (D. Del. 1982).

4.8 PRIOR PATENT

Roche contends that claims 3, 7, 8, 9 and 12 of the '933 patent and claim 1 of the '422 patent were anticipated because the invention defined in those claims were patented by a third party.

To show anticipation of the patented invention, Roche must show by clear and convincing evidence that a third party patented an invention anywhere in the world that included all of the elements of the claims above, before Amgen's date of invention, or before November 30, 1983.[15]

A prior patent is presumed to be enabled as to both its claims and its unclaimed disclosures.[16]

---

[15] AIPLA Model Jury Instruction 6.6; 35 U.S.C. § 102; *In re Monks,* 588 F.2d 308 (C.C.P.A. 1978); *In re Fuge,* 272 F.2d 954 (C.C.P.A. 1959); *In re Ekenstam,* 256 F.2d 321 (C.C.P.A. 1958); *Bendix Corp. v. Balax, Inc.,* 421 F.2d 809 (7th Cir. 1970).

[16] *Amgen v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1307 (Fed. Cir. 2006).

4.9 OBVIOUSNESS

Roche contends that the claims of all of the asserted patents are invalid because the claimed subject matter would have been obvious to one of ordinary skill in the art at the time the invention was made.[17] Roche bears the burden of proving this defense by clear and convincing evidence. Each claim must be considered separately.

For obviousness, a person of ordinary skill in the art may combine two or more items of prior art. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.[18] When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.[19] You must consider all of the prior art references and evaluate obviousness from the perspective of one of ordinary skill in the art at the time the invention was filed (not from the perspective of a layman or a genius in the art). However, "A person of ordinary skill is also a person of ordinary creativity, not an automaton."[20]

Before determining whether or not Roche has established obviousness of the claimed invention, you must determine the following factual matters:

1. The scope and content of the prior art relied upon by Roche;

2. The difference or differences, if any, between each claim of the asserted patents and the prior art; and

---

17 *See* 35 U.S.C. § 103

18 *KSR Intern. Co. v. Teleflex Inc.,* 127 S. Ct. 1727, 1739 (2007); *see also Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.,* 485 F.3d 1157, 1161 (Fed. Cir. 2007).

19 *KSR Intern. Co. v. Teleflex Inc.,* 127 S. Ct. 1727, 1740 (2007) (quoting *Sakraida v. Ag Pro, Inc.* 425 U.S. 273, 282 (1976)).

20 *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (2007).

3. The level of ordinary skill in the art at the time the inventions of the asserted patents were made.

4. Objective factors indicating non-obviousness, including commercial success, long-felt need, failure of others, copying, unexpected results, acceptance of licenses.

Against this background of facts, you will then make your conclusion whether or not the claimed subject matter would have been obvious to a person of ordinary skill in the art at the time the invention was made.[21]

Just because there is unpredictability in the applicable art, that doesn't mean that obviousness is necessarily avoided. As long as there is reasonable probability of success, a finding of obviousness is proper.[22] Many techniques that require extensive time, money, and effort to carry out may nevertheless be arguably routine to one of ordinary skill in the art and do not equate to a conclusion that an expectation of success was unlikely.[23]

---

[21] AIPLA Model Jury Instruction 7.0; *Graham v. John Deere Co.,* 383 U.S. 1 (1966); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654 (Fed. Cir. 2000); *Arkies Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953 (Fed. Cir. 1997); *Ryko Mfg. Co. v. Nu-Star, Inc.,* 950 F.2d 714, 716 (Fed. Cir. 1991); *Nutrition 21 v. United States,* 930 F.2d 867, 871 n.2 (Fed. Cir. 1991); *Newell Cos. v. Kenney Mfg. Co.,* 864 F.2d 757, 764 (Fed. Cir. 1988); *Structural Rubber Prods. Co. v. Park Rubber Co.,* 749 F.2d 707 (Fed. Cir. 1984); *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.,* 707 F.2d 1376 (Fed. Cir. 1983); *Stratoflex, Inc. v. Aeroquip Corp.,* 713 F.2d 1530 (Fed. Cir. 1983).

[22] *Pfizer v. Apotex, Inc.,* 480 F.3d 1348, 1364 (Fed. Cir. 2007); (*citing In re Corkill,* 771 F.2d 1496, 1500 (Fed. Cir. 1985) *Brown v. Williamson Tobacco Corp. v. Philip Morris Inc.,* 229 F.3d 1120, 1125 (Fed. Cir. 2000); *Merck & Co. v. Biocraft Labs., Inc.,* 874 F.2d 804, 809 (Fed. Cir. 1989); *In re Merck & Co., Inc.,* 800 F.2d 1091, 1097 (Fed. Cir. 1986).

[23] *Pfizer Inc. v. Apotex, Inc.,* 480 F.3d 1348, 1367-68 (Fed. Cir. 2007); *Velander v. Garner,* 348 F.3d 1359, 1368 (Fed. Cir. 2003).

4.10 OBVIOUSNESS DECISION

In determining whether the invention of the asserted patents would have been obvious to a person of ordinary skill in the art, you must presume that person would have known about all relevant prior art.

In examining the prior publication, inventions, etc., you should take into account not only what they expressly disclose, but also anything that inherently occurred as a result of practicing what was expressly disclosed in that prior art.[24]

In a determination of whether a claimed invention is obvious it is proper to consider "the effects of demands known to the design community or present in the marketplace; the background knowledge possessed by a person having ordinary skill in the art; and the inferences and creative steps that a person of ordinary skill in the art would employ."[25] It often may be the case that market demand, rather than scientific literature, will provide the motivation to create a particular combination that renders the claimed invention obvious.[26]

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious and therefore invalid.[27]

---

[24] *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

[25] *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740-41 (2007).

[26] *Id.*

[27] *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (2007).

4.11 SCOPE AND CONTENT OF THE PRIOR ART

The prior art that you considered previously for anticipation purposes is also prior art for obviousness purposes. As with anticipation, you should take into consideration not only what is expressly disclosed in the particular item but also what inherently occurred as a natural result of its practice.[28] Remember, however, that for obviousness inquiries, you may consider multiple pieces of prior art simultaneously.

[28] *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

4.12 OBJECTIVE FACTORS

You must also consider, where they exist, the objective factors I mentioned before, including commercial success, long-felt need, failure of others, copying, unexpected results, and/or the acceptance of licenses support a finding of non-obviousness.

Amgen must demonstrate a nexus between the merits of invention and evidence of objective factors. Thus, in the context of objective factors of non-obviousness, praise by others for the inventors' work must be directly tied to an actual inventive contribution rather than confirmation of what the state of knowledge in the art was already indicating.[29]

[29] *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 2007 WL 1964863, *20 (Fed. Cir. 2007).

4.13 LEVEL OF ORDINARY SKILL IN THE ART

In reaching your determination as to whether or not the claimed invention would have been obvious, you should consider the level of ordinary skill in the pertinent art. When determining the level of ordinary skill in the art, you should consider all the evidence submitted by Amgen and Roche to show:

1. the level of education and experience of persons actively working in the field at the time of the invention;

2. the types of problems encountered in the art at the time of the invention;

3. the prior art patents and publications;

4. the activities of others;

5. prior art solutions to the problems; and

6. the sophistication of the technology.

Based on the factors listed and the evidence presented, you must determine the level of ordinary skill in the art at the time of the invention.

When you decide the issue of obviousness, you must decide whether or not the invention would have been obvious to one having this ordinary level of skill in the fields of molecular biology, biotechnology, protein chemistry or nephrology.[30]

[30] AIPLA Model Jury Instruction 7.4; *Graham v. John Deere Co.,* 383 U.S. 1 (1966); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654 (Fed. Cir. 2000); *Orthopedic Equip. Co. v. United States,* 702 F.2d 1005 (Fed. Cir. 1983); *Envtl. Designs, Ltd. v. Union Oil Co.,* 713 F.2d 693 (Fed. Cir. 1983).

4.14 FACTORS INDICATING OBVIOUSNESS

Additionally, other objective evidence may favor a finding of obviousness. For example the simultaneous or near simultaneous invention by others of the patented subject matter is a secondary consideration supporting a conclusion of obviousness. Just as the failure of others to make the invention may be evidence that an invention would not have been obvious, independent making of the invention by persons other than the inventor at about the same time may be evidence that the invention would have been obvious, depending on the circumstances.[31]

[31] AIPLA Model Jury Instruction 7.8; *Ecolochem, Inc. v. S. Cal. Edison Co*, 227 F.3d 1361, 1379 (Fed. Cir. 2000); *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 883-84 (Fed. Cir. 1998); *Stewart-Warner Corp. v. City of Pontiac,* 767 F.2d 1563 (Fed. Cir. 1985); *Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co.,* 730 F.2d 1452 (Fed. Cir. 1984); *In re Farrenkopf,* 713 F.2d 714 (Fed. Cir. 1983); *Orthopedic Equip. Co. v. United States,* 702 F.2d 1005 (Fed. Cir. 1983); *Simmonds Precision Prods., Inc. v. United States,* 153 U.S.P.Q. 465 (Ct. Cl. 1967).

4.15 DERIVATION OF INVENTION

You may also find the asserted patents to be invalid for derivation of invention if Roche proves that Dr. Lin acquired knowledge of the claimed invention from another, or so much of the claimed invention as would have made it obvious to one of ordinary skill in the art.[32]

[32] *Oddzon Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1403-04 (Fed. Cir. 1997); *New England Braiding Co., Inc. v. A.W. Chesterson Co.*, 970 F.2d 878, 883 (Fed. Cir. 1992).

4.16 ENABLEMENT

The written description set forth in a patent must disclose sufficient information to enable or teach one skilled in the field of the invention to make and use the full scope of claimed invention. This requirement is known as the enablement requirement. If a patent claim is not enabled, it is invalid.

A patent is enabling if its disclosure is sufficient to enable a person of ordinary skill in the art to make and use the claimed invention. Roche bears the burden of establishing lack of enablement by clear and convincing evidence.

Roche contends that the '422, '933, '698, '868 and '349 patents are invalid for lack of enablement. The fact that some experimentation may be required for a skilled person to practice the full scope of the claimed invention does not mean that a patent's written description fails to meet the enablement requirement. Factors that you may consider in determining whether the written description would require undue experimentation include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability of the art; and (8) the breadth of the claims.[33]

---

[33] AIPLA Model Jury Instruction 8; *Durel Corp. v. Osram Sylvania Inc.,* 256 F.3d 1298, 1306 (Fed. Cir. 2001); *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 690-92 (Fed. Cir. 2001); *Ajinomoto Co. v. Archer-Daniels-Midland Co*., 228 F.3d 1338, 1345-46 (Fed. Cir. 2000); *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195-98 (Fed. Cir. 1999); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir.1987); *Hybritech Inc. v. Monolonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986); *Ralston Purina Co. v. Far-Mar Co.*, 772 F.2d 1570, 1573-74 (Fed. Cir. 1985); *Linedmann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1463 (Fed. Cir. 1984); *White Consol. Indus., Inc. v. Vega Servo Control, Inc.*, 713 F.2d 788, 791 (Fed. Cir. 1983).

In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the more unpredictable the area of technology, the more the patentee must disclose.[34]

[34] *In re Fisher,* 427 F.2d 833, 839 (C.C.P.A. 1970).

4.17 WRITTEN DESCRIPTION

A patent must contain a written description of the product or method claimed in the patent. The written description is the "technologic disclosure of the invention."[35] Roche can meet its burden of proving that a patent claim is invalid by showing that the patent does not contain an adequate written description of the full scope of claimed invention.

Roche contends that the '422, '933, '698, '868 and '349 patents are invalid for failure to satisfy the written description requirement. Roche bears the burden of establishing lack of written description by clear and convincing evidence.

The written description must show that the applicant was in full possession of the claimed subject matter on the application filing date and to allow other inventors to develop and obtain patent protection for later improvements and subservient inventions that build on applicant's teachings.[36]

To satisfy the written description requirement, the patent must describe each and every limitation of a patent claim, although the exact words found in the claim need not be used. The written description requirement is not satisfied if a person of ordinary skill in the field, reading the patent application as originally filed, would not recognize that the patent application described the invention as finally claimed in the patent.[37]

---

35 *Space Sys/Loral, Inc. v. Lockheed Martin Corp.*, 405 F.3d 985 (Fed. Cir. 2005).

36 35 U.S.C § 112(1) and (2); 3 Donald S. Chisum, Chisum on Patents § 7.04 (2007) (internal citations omitted); Northern District of California Model Jury Instruction No. 4.2a (September 20, 2004); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478-80 (Fed. Cir. 1998); *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319-20 (Fed. Cir. 2003).

37 *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) ("…one skilled in the art, reading the disclosure, must immediately discern the limitation at issue in the claims.")

If you find that Roche has proved that the claims of the above patents do not contain a complete written description of the invention covered by any of its claims, then you must find that the claim is invalid.[38]

When I construed the claims at issue, I did not make any decision as to whether or not the claims were adequately described.

---

[38] AIPLA Model Jury Instruction 9; *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004); *Turbocare Div. of Demag Delaval Turbomach. Corp., v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2002); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002) (en banc); *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320 (Fed. Cir. 2000); *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345-46 (Fed. Cir. 2000); *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 20 F.3d 989, 996-1001 (Fed. Cir. 2000); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478-90 (Fed. Cir. 1998); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991).

4.18 INDEFINITENESS

The claims of a patent to be sufficiently definite that one skilled in the art could determine the precise limits of the claimed invention. If a claim is found to be indefinite the claim is invalid.

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's disclosure. Roche contends that the '422, '933, '698, '868 and '349 patents are invalid for indefiniteness. You must decide if the claims of these patents, read in light of the disclosure, reasonably apprised those skilled in the art of the proper scope of the invention, and if the language is as precise as the subject matter permits. If they did not, the claims are indefinite.

Simply because some claim language may not be precise does not automatically render a claim invalid. When a word or phrase of degree such as "substantially equal to" is used, you must determine whether the patent disclosure provides some standard for measuring that degree. You must then determine whether one of ordinary skill in the art would understand what is covered when the claim is read in light of the disclosure.[39] The primary purpose of this requirement is to ensure that the claims are written in a way that the public is given notice of the extent of the legal protection afforded by the patent so that interested parties can determine whether or not they infringe.[40]

When I construed the claims at issue, I did not make any decision as to whether or not the claims were definite.

---

[39] Delaware Model Jury Instruction 4.1; *Seattle Box Co. v. Indus. Crating & Packing, Inc.,* 731 F.2d 818, 826 (Fed. Cir. 1984).

[40] *Default Proof Credit Card Sys., Inc. v. Home Depot U.S.A., Inc.,* 412 F.3d 1291, 1302-03 (Fed. Cir. 2005) (*quoting All Dental Prodx, LLC v. Advantage Dental Prods., Inc.,* 309 F.3d 774, 779-80 (Fed. Cir. 2002).

4.19 INVALIDITY FOR DOUBLE PATENTING

In order to curb the improper prolongation of patent monopolies, courts have created a doctrine called obviousness-type double patenting. This doctrine prevents extension of patent rights beyond their terms by barring claims that are different, but not patentably distinct, from claims in an earlier-issued, commonly owned patent.[41] Roche contends that the '868 and '698 patents are invalid for "obviousness-type double patenting" over Amgen's expired '008 patent, and that the '349, '933 and '422 patents are invalid for double patenting over the '868 and '698 patents. A claim is not patentably distinct from an earlier claim if it is obvious in light of the earlier claim, or is merely an obvious variation of what is disclosed in the earlier claim.[42] The critical inquiry is whether Amgen's asserted claims define an obvious variation of the invention claimed in the prior patents.[43] If they do, the asserted patents must be found invalid for obviousness-type double patenting.

In evaluating obviousness of the claims-in-suit, you may consider Amgen's assertions in previous proceedings regarding the similarities between the asserted claims that are subject to a double patenting challenge and the previously issued claims of the '008, '868 and '698 patents.

---

41 *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985).

42 *Application of Vogel,* 422 F.2d 438, 441-42 (CCPA 1970).

43 *In re Metoprolol Succinate Patent Litigation*, 2007 WL 2080390, *5 (Fed. Cir. 2006) (*citing In re Emert*, 124 F.3d 1458, 1461-62 (Fed. Cir. 1997).

4.20 BIOTECHNOLOGICAL PROCESS ELECTION

Roche contends that claim 7 of the '349 patent is invalid and/or unenforceable because Amgen elected to proceed under Section 103(b) of the patent statute, and therefore the claim expired at the same time that the '008 patent expired. Roche bears the burden of proving this defense by clear and convincing evidence.

Under 35 U.S.C. § 103(b), when a composition of matter is found upon examination to be patentable, a process of using that composition of matter shall likewise be found to be patentable when the patent applicant elects to link the examination of the process claim to the examination of the composition of matter claim. When there is one patent issued for the composition of matter claim and another patent issued for the process claim relating to the composition of matter, the patent for the process must expire on the same date as the patent on the composition of matter.

To show that claim 7 of the '349 patent is invalid and/or unenforceable, Roche must show by clear and convincing evidence that Amgen made such an election in the '349 patent.

5 CONSTRUCTION OF CLAIMS

5.1 GENERAL PRINCIPLES

Before you decide the issue of infringement you will have to understand the "claims" of the patents-in-suit and what they require. It is my job as Judge to determine what the patent claims mean and to instruct you about that meaning. You must apply the meanings I give you in determining whether or not the patents are infringed and also in determining whether or not they are invalid.[44] A copy will be available to you in the jury room if you require them.

You should give the rest of the words in the claims their ordinary meaning in the context of the patent specification and prosecution history.

It is often difficult to describe an invention in scientifically precise terms. For that reason, the patent law allows the inventor to use his own terms in describing his invention. Thus, the meaning of a claim can be construed in connection with the patent specification, the patent's prosecution history, and prior art to determine what the inventor intended to cover by the claims of the patent.

---

[44] *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005); *Markman v. Westview Instruments, Inc.,* 52 F.3d 967 (Fed. Cir. 1995) (en banc).

5.2 DEPENDENT AND INDEPENDENT CLAIMS

There are two different types of claims in the patents-in-suit. The first type is called an independent claim. An independent claim does not refer to any other claim of the patent. An independent claim is read separately to determine its scope.

On the other hand, a dependent claim refers to at least one other claim in the patent and thus incorporates all the elements of that other claim, plus additional elements. Accordingly, to determine what a dependent claim covers, you must read both the dependent claim and the claim or claims to which it refers.

For example, claim 1 of the '868 patent is an independent claim. You know this because this claim mentions no other claim. Accordingly, the words of this claim are read by themselves in order to determine what the claim covers.

Claim 2 of the '868 patent, on the other hand, is a dependent claim; specifically, claim 2 depends from claim 1. Accordingly, claim 2 is read to include all elements of claim 1 of the '868 patent plus the additional elements stated in the claim. Thus, claims 1 and 2 must be read together in order to determine what the dependent claim, claim 2, covers.

Some claims of the patents in suit are broader than other claims. You are not to imply the limitations or words of the narrower or dependent claim into a broader or independent claim if the broader claim does not include the same limitations.[45]

---

[45] 35 U.S.C. § 112. *Fromson v. Advance Offset Plate, Inc.,* 720 F.2d 1565, 219 U.S.P.Q. 1137 (Fed. Cir. 1983).

5.3 MARKUSH GROUPS

Claim 1 of the '422 patent and claims 9 and 12 of the '933 patent contain something in patent law called a "Markush group." A Markush group is a listing of specified alternatives of a group typically expressed in the form: "a member selected from the group consisting of A, B, and C." However, claim language in the format "A, B, C, or D" is equally acceptable for Markush claiming. All of the claims above share the following language: "A pharmaceutical composition **comprising** . . . a pharmaceutically acceptable **diluent, adjuvant or carrier**."[46]

Each member of the above Markush group (diluent, adjuvant, or carrier) is used *singly*. In other words, the above language would not encompass a pharmaceutical composition comprising a pharmaceutically acceptable diluent *and* a pharmaceutically acceptable adjuvant. If a patentee desires mixtures of combinations of the members of the Markush group, the patentee would need to add qualifying language while drafting the claim, such as: "and mixtures thereof" or "at least one member of the group" Without expressly indicating the selection of multiple members of a Markush grouping, a patentee does not claim anything other than the plain reading of the closed claim language.[47]

---

[46] Emphasis added.

[47] *Abbott Labs. v. Baxter Pharm. Prods., Inc.,* 334 F.3d 1274, 1280-81 (Fed. Cir. 2003).

6 INFRINGEMENT

6.1 GENERAL PRINCIPLES

A patent owner may enforce his right to exclude others from making, using or selling the patented invention by filing a lawsuit for patent infringement. Here, Amgen, the patent owner, has sued Roche, the accused infringer, and has alleged that Roche's product and method for producing its product infringes the following claims in the patents-in-suit: claims 1 and 2 of the '868 patent, claims 3, 7, 8, 9, 11, 12, and 14 of the '933 patent, claims 6-9 of the '698 patent, claim 7 of the '349 patent and claim 1 of the '422 patent.

Patent law provides that any person or business entity which makes, uses or sells, without the patent owner's permission, any product, apparatus or method legally protected by at least one claim of a patent within the United States before the patent expires, infringes the patent.

6.2 DIRECT INFRINGEMENT - KNOWLEDGE OF PATENT OR INTENT TO INFRINGE IS IMMATERIAL

Roche would be liable for directly infringing Amgen's patents only if you find that Amgen has proven that it is more likely than not that Roche has made, used or sold the invention defined in at least one claim of plaintiff's patents.[48] It is not enough if Amgen has shown only that the evidence allows for two equal but opposite conclusions.

A person may directly infringe a patent without knowledge that what he is doing is an infringement of the patent. He may also infringe even though in good faith he believes that what he is doing is not an infringement of any patent.[49]

---

[48] 35 U.S.C. § 271(a).

[49] Delaware Model Patent Jury Instructions, 3.5; *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470,478 (1974); *Filmways Pictures, Inc. v. Marks Polarized Corp.*, 552 F. Supp. 863,868,220 U.S.P.Q. 870 (S.D.N.Y. 1982).

6.3 INDUCING PATENT INFRINGEMENT

Amgen asserts that Roche has actively induced patients to infringe the asserted method claims of the '933 patent, specifically claims 11 and 14 of this patent. To show induced infringement, Amgen must prove that it is more likely than not that someone has directly infringed the asserted claims of the '933 patent and that Roche has actively and knowingly encouraged that direct infringement.[50] If Roche provided instructions and directions to perform the infringing act through labels, advertising, or other sales methods or by supplying the components used in an infringing product or method with the knowledge and intent that its customer would use the components to make, use, or sell the patented invention, this may be evidence of inducement to infringe.[51]

The intent element of inducement, however, requires more than just intent to cause the acts that produce direct infringement. The inducer must have knowingly and with specific intent encouraged another's infringement.[52] Inducement is not present if the alleged inducer merely had knowledge of the direct infringer's activities.[53] Additionally, if you find that Roche did not believe they were infringing Amgen's patents-in-suit based on good faith evidence such as the

---

50 *DSU Med. Corp. v. JMS Co., Ltd.,* 471 F.3d, 1293, 1304 (Fed. Cir. 2006) (en banc) (quoting *Water Tech. Corp. v. Calco Ltd.,* 850 F.2d 660, 668 (Fed. Cir. 1988).

51 35 U.S.C. § 271(b); *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1342 (Fed. Cir. 2003); *C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.,* 911 F.2d 670, 674 (Fed. Cir. 1990); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990); AIPLA 2005 Model Patent Jury Instructions, 3.2.

52 *DSU,* 471 F.3d at 1304 (internal citations omitted) (quoting *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.,* 420 F.3d 1369, 1378 (Fed. Cir. 2005); *Minn. Mining & Mfg. Co v. Chemque, Inc.,* 303 F.3d 1294, 1304-05 (Fed. Cir. 2002).

53 *DSU,* 471 F.3d at 1306; *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.,* 125 S.Ct. 2764, 2780 (2005); *Manville Sales Corp. v. Paramount Sys., Inc.,* 917 F.2d 544, 553 (Fed. Cir. 1990).

opinion of its counsel, you may use this information to negate the finding necessary for inducement of infringement.[54]

[54] *DSU,* 471 F.3d at 1307.

6.4 LITERAL INFRINGEMENT

There are two ways in which a patent claim may be directly infringed. First, a claim may be literally infringed.[55] Second, a claim may be infringed under what is called the "doctrine of equivalents," which I will address shortly.[56]

You must determine literal infringement with respect to each patent claim individually. A patent claim is literally infringed only if Roche's product or method includes each and every element or method step in a given asserted claim.[57] If Roche's product or method is missing just one of the elements or method steps recited in a claim, then you may not find that Roche literally infringes that claim.

Remember, the question is whether Roche's product or method infringes any claim of Amgen's patents-in-suit, and not whether Roche's product is similar or even identical to a product made by Amgen.[58] Accordingly, you must be certain to compare Roche's accused product or method with the claim it is alleged to infringe and not with any product made by Amgen.[59] For Amgen's product-by-process claims, Amgen must prove that Roche's product possesses the same material structural and functional characteristics as the claimed product by

---

55 35 U.S.C. § 271; *Cybor Corp. v. FAS Tech., Inc.,* 138 F.3d 1448 (Fed. Cir. 1998) (en banc).

56 35 U.S.C. § 271; *Warner Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17 (1997).

57 *Terlep v. Brinkmann Corp.,* 418 F.3d 1379, 1384 (Fed. Cir. 2005); *Mass. Inst. of Tech. v. Lockheed Martin Global Telecomms., Inc.,* 251 F. Supp. 2d 1006, 1010 (D. Mass. 2003).

58 *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.,* 19 F.3d 1418, 1423 (Fed. Cir. 1994).

59 Delaware Model Patent Jury Instructions, 3.9; *Martin v. Barber,* 755 F.2d 1564, 1567, 225 U.S.P.Q. 233 (Fed. Cir. 1985).

process and also is made by a process employing each and every one of the steps recited in the claims.[60]

6.5 INFRINGEMENT OF DEPENDENT CLAIMS[61]

To establish literal infringement of a dependent claim, Amgen must show that it is more likely than not that Roche's product or process includes each and every element of the dependent claim. Asserted dependent claims include: claim 2 of the '868 patent, claims 7, 8, 9, 11, 12, and 14 of the '933 patent, claims 7, 8, and 9 of the '698 patent, and claim 7 of the '349 patent.

If, however, you find that the independent claim from which a dependent claim depends is not literally infringed, then you cannot find that the dependent claim is literally infringed.

---

60 *Scripps Clinic v. Research Found. v. Genentech, Inc.,* 927 F.2d 1565, 1580 (Fed. Cir. 1991); *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.,* 970 F.2d 834, 846-47 (Fed. Cir. 1992).

61 AIPLA's Model Patent Jury Instructions 3.6; *Wolverine World Wide v. Nike Inc.,* 38 F.3d 1192, 1199 (Fed. Cir. 1994); *Wilson Sporting Goods v. David Geoffrey & Assocs.,* 904 F.2d 677 (Fed. Cir. 1990); *Wahpeton Canvas Co., Inc. v. Frontier, Inc.,* 870 F.2d 1546, 1553 nn.9&10 (Fed. Cir. 1989).

6.6 MATERIAL CHANGE

In the United States, one is allowed to import items into the country even if they are derived from a product made by a patented process as long as the product is "materially changed" in the course of its conversion into the imported item.[62] Such importation does not constitute infringement. With regard to whether or not the imported product is "materially changed," Amgen bears the burden of proof.[63] In other words, Amgen, in its assertion of various process claims, must prove that any imported product allegedly infringing those claims was not materially changed. Specifically, Amgen has asserted that Roche infringes the process claims of the '868, '698, or '349 patents; thus, if Roche performs any elements of these process claims in Europe, Amgen must prove that the resulting product is not "materially changed" from the product defined by the patented process.

To determine material change, one must look to the substantiality of the change between the product of the patented process and the imported product.[64] In the chemical context, a material change in a compound is most naturally viewed as a significant change in the compound's structure and properties.[65] It is also possible that additional process steps done after a patented process can support a finding of material change. The following factors support a finding of material change:[66]

---

62 35 U.S.C. § 271(g); *Eli Lilly & Co. v. Am. Cyanamid Co.,* 82 F.3d 1568, 1572 (Fed. Cir. 1996).

63 *Genentech, Inc. v. Boehringer Mannheim GmbH,* 47 F. Supp. 2d 91, 108 (D. Mass. 1999).

64 *Eli Lilly,* 82 F.3d at 1568, *Genentech, Inc.,* 47 F. Supp. 2d at 107, *Eli Lilly and Co. v. American Cyanamid Co.,* 896 F. Supp. 851 (S.D. Ind. 1995).

65 *Eli Lilly,* 82 F.3d at 1573.

66 *Eli Lilly and Co. v. Am. Cyanamid Co.,* 66 F. Supp. 2d 924, 932 (S.D. Ind. 1999).

- that subsequent processes confer an additional, distinct, and valuable property to the product of the patented process
- that subsequent processes confer superior properties relating to the basic utility of the product of the patented process, *e.g.,* increased potency
- that subsequent processes confer significant structural differences to the product of the patented processes such as the removal and/or addition of certain chemical groups of a compound
- that subsequent processes applied to the product of a patented process are complex and involve multiple steps

Additionally, even if individual steps of subsequent processes administered to the product of a patented process involve relatively routine chemical reactions, that does not preclude a finding of material change.[67]

[67] *Eli Lilly,* 82 F.3d at 1572-73.

6.7 INFRINGEMENT BY DOCTRINE OF EQUIVALENTS

If you do not find literal infringement you may consider infringement under the "doctrine of equivalents." Amgen contends that every patent claim it asserts is infringed literally is also infringed under the doctrine of equivalents. I have referred to the "doctrine of equivalents" before. Now it is time to explain this term. In exceptional circumstances, you may find that defendant's products or processes infringe Amgen's asserted claims even if not all of the components or method steps of the claim are present in defendant's product or method. You may find infringement in such circumstances if, for the missing components or method steps in defendant's product or method, there are equivalent components or method steps.[68] This is called the doctrine of equivalents.[69]

Again, however, application of the doctrine of equivalents is the exception, not the rule. Patent claims must be clear enough so that the public has fair notice of what was patented. Notice permits other parties to avoid actions which infringe the patent and to design around the patent. On the other hand, the patent owner should not be deprived of the benefits of his patent by competitors who appropriate the essence of an invention while barely avoiding the literal language of the patent claims.[70]

The evidence in support of a finding of equivalency must be specific and precise. Generalized testimony as to an overall similarity between the claims and Roche's product or process will not suffice.[71] That is to say, you cannot find infringement by the doctrine of

---

[68] 35 U.S.C. § 271(a); *Warner Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17 (1997).

[69] *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.,* 339 U.S. 605, 70 S.Ct. 854, 94 L.Ed. 1097 (1950).

[70] *London v. Carson Pirie Scott & Co.,* 946 F.2d 1534, 1538, 20 U.S.P.Q. 1456, 1458 (Fed. Cir. 1991).

[71] *Texas Instruments Inc. v. Cypress Semiconductor Corp.,* 90 F.3d 1558, 1567 (Fed. Cir. 1996).

equivalents if Roche's product comes close to one of Amgen's claims. The doctrine of equivalents must be applied to individual elements of the claim, not to the claimed product or process as a whole.[72]

The test to determine equivalents of an individual element under the doctrine of equivalents is whether the allegedly equivalent element in defendant's product or method performs substantially the same function in substantially the same way to obtain substantially the same result as the claimed individual element.[73]

The question of whether Roche's product or method and its components or method steps are equivalent to that defined in Amgen's claims is to be determined as of the time of the alleged infringement.[74]

---

[72] *E-Pass Techs., Inc. v. 3Com Corp.*, 473 F.3d 1213, 1221 (Fed. Cir. 2007).

[73] *Warner Jenkinson Co.*, 520 U.S. at 39-40; *Graver Tank,* 339 U.S. at 608.

[74] *Amgen v. Hoechst Marion Roussel, Inc.,* 339 F. Supp. 2d 202, 297 (D. Mass. 2004).

6.8 LIMITATIONS ON DOCTRINE OF EQUIVALENTS - PRIOR ART

Resort to the doctrine of equivalents to find infringement is not permitted if you find that the defendant is merely practicing what was in the prior art prior to the patented invention or that which would have been obvious in light of what was in the prior art. This is because a patent owner should not obtain, under the doctrine of equivalents, coverage which he could not have lawfully obtained from the Patent Office. Accordingly, to find infringement under the doctrine of equivalents you must find that Amgen has proven that it could have obtained from the Patent Office hypothetical claims similar to the asserted claims at issue, but broad enough to literally cover the accused product and method.[75]

[75] *Wilson Sporting Goods v. David Geoffrey & Assocs.,* 904 F.2d 677, 685 (Fed. Cir. 1990), *cert denied,* 111 S. Ct. 537 (1990).

6.9 LIMITATIONS ON DOCTRINE OF EQUIVALENTS - PROSECUTION HISTORY ESTOPPEL

As you have already heard, during prosecution of patents, the patent applicant often makes arguments and amendments in an attempt to convince the PTO examiner to grant the patent. The party seeking to obtain a patent may amend his patent claims or submit arguments in order to define or narrow the meaning of the claims to obtain the patents. Once he has done so, he is not entitled to patent coverage under the doctrine of equivalents that would be so broad that it would cover the same feature that was used to distinguish the invention during patent prosecution.[76] In other words, if Amgen, when in the process of obtaining the patents-in-suit, limited them in some way in order to argue that they were different from what was in the public domain, then Amgen is not now free to use the doctrine of equivalents to recapture what it already surrendered.[77]

---

[76] AIPLA's Model Patent Jury Instructions 3.10; Delaware Model Patent Jury Instruction 3.2; *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 30 (1997); *DeMarini Sports v. Worth, Inc.,* 239 F.3d 1314, 1332 (Fed Cir. 1997).

[77] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 535 U.S. 722, 737 (2002).

6.10 LIMITATIONS ON DOCTRINE OF EQUIVALENTS -- CLAIM ELEMENTS MAY NOT BE READ OUT OF EXISTENCE

The doctrine of equivalents may not be used to eliminate an element from a patent claim. Because of this rule, some claim limitations may be written in such a way as to have no equivalents. If a claim limitation is written in such a way that applying the doctrine of equivalents would make a claim limitation ineffective, then there are no equivalents for that element.[78]

[78] *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997); *Novartis Pharms. Corp. v. Abbott Labs.,* 375 F.3d 1328, 1339 (Fed. Cir. 2004).

6.11 LIMITATIONS ON DOCTRINE OF EQUIVALENTS - APPLIED ON AN ELEMENT BY ELEMENT BASIS

Each element of a claim is important to the claimed invention. Accordingly, the Doctrine of Equivalents must be applied on an element by element basis, not to the claimed process or product as a whole. Thus, to find that a claim is infringed under the Doctrine of Equivalents, you must find that each element of the claim that is not infringed literally has an equivalent structure or step in the accused product or process. If any single element of a claim is not present in the accused product or process either literally or by equivalents, then the claim cannot be infringed.[79]

[79] *E-Pass Technologies, Inc. v. 3Com Corp.*, 473 F.3d 1213, 1221 (Fed. Cir. 2007)

6.12 LIMITATIONS ON THE DOCTRINE OF EQUIVALENTS - SUBJECT MATTER DEDICATED TO THE PUBLIC[80]

When a patent discloses subject matter but does not claim it, the patent has dedicated that unclaimed subject matter to the public. If you find that the patent discloses, but does not claim, subject matter alleged to be equivalent to an element of the asserted patent claims, then you cannot find that allegedly equivalent component or step in Roche's product or method to be equivalent to that element of the patent claim. This is true even if the failure to claim the subject matter was wholly unintentional.

---

[80] AIPLA's Model Patent Jury Instructions 3.11; *Toro Co. v. White Consol. Indus., Inc.,* 383 F.3d 1326 (Fed. Cir. 2004); *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.,* 285 F.3d 1046-1054-55 (Fed Cir. 2002) (en banc).

6.13 REVERSE DOCTRINE OF EQUIVALENTS

The doctrine of equivalents for finding infringement has a counterpart called the reverse doctrine of equivalents which supports a finding of non-infringement. Therefore, even if Amgen's claims are found to be literally infringed, Roche may still avoid infringement under the reverse doctrine of equivalents. The reverse doctrine of equivalents is a fairness doctrine that may be applied when a product or process is so fundamentally different from the patented invention that a judgment of infringement would constitute an unwarranted extension of the claims beyond a fair scope of the invention. A product or process is fundamentally different if it performs the same or a similar function in a substantially different way. This determination is made by considering the original intended scope of the patent and the "spirit and intent" of the claims, keeping in mind the particular context of the patent, the prior art, and the particular circumstances of the case. A new product or process that uses a new technology that makes a real difference in how the process works or what is produced would not infringe under the reverse doctrine of equivalents (e.g. changes to a drug's biologic or therapeutic effects).[81] A prima facie (on its face) case of reverse doctrine of equivalents exists where the alleged infringer has a patent on the accused product or process.[82]

---

[81] *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 283-303 (D. Mass. 2004); *Union Carbide Corp. v. Tarancon Corp.*, 682 F. Supp. 535, 541 (N.D. Ga. 1988), quoting *SRI Int'l v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1116 (Fed. Cir. 1985); *Precision Metal Fabricators, Inc. v. Jetstream Sys. Co., Div. of Oerlikon Motch Corp.*, 693 F. Supp. 814, 819 (N.D. Cal. 1988), quoting *Graver Mfg. Co v. Linde Co.*, 339 U.S. 605, 607-08 (1949); *Brenner v. Recognition Equip. Inc.*, 593 F. Supp. 1275, 1278 (D.C.N.Y. 1984).

[82] *Jewish Hosp. of St. Louis v. IDEXX Labs.,* 973 F. Supp. 24, 28 (D. Me. 1997).

6.14 SAFE HARBOR EXEMPTION

Recognizing that new drugs require extensive clinical testing before being deemed safe enough to enter the market, U.S. law provides what is called a "safe harbor," allowing what would otherwise constitute infringement of a patent to occur in the United States so long as the activity is reasonably related to the development and submission of information to the FDA, the federal agency by which all U.S. drugs must get approval.[83] The safe harbor includes preclinical studies of patented compounds done pursuant to getting FDA approval.[84] That being said, the FDA exemption is not strictly confined to such activities, and the safe harbor does not categorically exclude (1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA. If it is reasonable to believe that the experiments at issue will produce the types of information that are relevant to a new drug application, then the FDA Exemption applies.[85]

---

83 § 271(e)(1); *Integra Lifesciences I, Ltd. v. Merck KgaA,* --- F.3d ---, 2007 WL 2142878 (Fed. Cir. 2007); *Merck KgaA v. Integra Lifesciences I., Ltd.,* 545 U.S. 193 (2005).

84 *Merck KgaA,* 545 U.S. at 202.

85 *Integra Lifesciences,* 2007 WL 2142878 at *5.

6.15 SPECIFIC CLAIM INSTRUCTIONS

Now I will tell you specifically, for every claim that Amgen has asserted against Roche, the elements that Amgen must prove in order for you to find that Roche infringes each claim.

6.15.1 INFRINGEMENT OF U.S. PATENT NO. 5,441,868

In order for you to find that claim 1 of the '868 patent is infringed, Amgen must prove that it is more likely than not that Roche's process in producing its MIRCERA® ® product contains, literally or under the doctrine of equivalents, each of the following elements:

- *A process for producing a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of*
- *Growing, under suitable nutrient conditions, mammalian host cells*
- *Where the mammalian host cells are transformed or transfected with an isolated DNA sequence encoding human erythropoietin*
- *Isolating said glycosylated erythropoietin polypeptide therefrom*

For purposes of this claim, "comprising" means "containing the named elements," and "mammalian host cells" means "cells that have been genetically modified with isolated DNA containing genetic instructions for human erythropoietin or later generations of these cells that have inherited those instructions."[86]

Further, if you have found that Roche's process contains all of these steps, and if any of these steps occurs outside the United States, Amgen must further prove that the product that Roche imports into the United States is not materially changed from the product defined by the patented process. Otherwise, you cannot find that Roche infringes this claim.

In order for you to find that claim 2 of the '868 patent is infringed by Roche's process, all of the previously listed elements of claim 1 must be present, literally or under the doctrine of equivalents, in Roche's process, as well as the following further limitation:

---

[86] Memorandum and Order of July 3, 2007 (DN 613). Roche reserves its right to object and/or appeal the Court's claim constructions.

- *The mammalian host cells are CHO cells*

For purposes of this claim, the court has defined a CHO cells as "A cell from the ovary of a Chinese hamster."[87]

Further, if you have found that Roche's process contains all of these steps, and if any of these steps occurs outside the United States, Amgen must further prove that the product that Roche imports into the United States is not materially changed from the product defined by the patented process. Otherwise, you cannot find that Roche infringes this claim.

[87] Memorandum and Order of July 3, 2007 (DN 613).

6.15.2 INFRINGEMENT OF U.S. PATENT NO. 5,547,933

In order for you to find that Roche has infringed claim 3 of U.S. Patent 5,547,933, Amgen must prove that it is more likely than not that Roche's MIRCERA® product contains, literally or under the doctrine of equivalents, every one of the following elements:

- *Non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin*
- *Said product possessing the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells*

For purposes of this claim, "non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin" means "a glycoprotein (not occurring in nature) that is the product of the expression in a mammalian host cell of a DNA sequence that does not originate in the genome of the host, and which contains the genetic instructions (or a DNA sequence) encoding human erythropoietin."[88]

In order for you to find that Roche has literally infringed claim 7 of the '933 patent, Amgen must show that it is more likely than not that MIRCERA® ® contains, literally or under the doctrine of equivalents, every one of the elements listed for claim 3, plus the following additional element:

- *The host cell is a non-human mammalian cell*

---

[88] Memorandum and Order of July 3, 2007 (DN 613). Roche reserves its right to object and/or appeal the Court's claim constructions.

In order for you to find that Roche has literally infringed claim 8 of the '933 patent, Amgen must show that MIRCERA® contains, literally or under the doctrine of equivalents, all the elements listed for claim 3 and claim 7, plus the following additional element:

- *The non-human mammalian is a CHO cell*

For purposes of this claim, CHO cell means "A cell from the ovary of a Chinese hamster."[89]

In order to find that Roche has literally infringed claim 9 of the '933 patent, Amgen must show that MIRCERA® ® is a pharmaceutical composition containing, literally or under the doctrine of equivalents, every element listed for claim 3, plus the following elements:

- *A pharmaceutical composition comprising an effective amount a glycoprotein product effective for erythropoietin therapy*
- *A pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant or carrier*

For purposes of this claim, "an effective amount a glycoprotein product effective for erythropoietin therapy" means an amount "that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO,such as . . . stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and . . . increasing hematocrit levels in mammals." Further, a "pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant or carrier" means "a composition suitable for administration to humans, containing a diluent, adjuvant or carrier."[90]

---

89 Memorandum and Order of July 3, 2007 (DN 613).

90 Memorandum and Order of July 3, 2007 (DN 613). Roche reserves its right to object and/or appeal the Court's claim constructions.

In order for you to find that Roche infringes claim 11 of the '933 patent, Amgen must prove that it is more likely than not that Roche practices a method having the following elements, literally or under the doctrine of equivalents:

- *A method for treating a kidney dialysis patient which comprises*
- *administering a pharmaceutical composition [having every one of the elements listed for claim 9]*
- *in an amount effective to increase the hematocrit level of said patient*

If Roche does not itself perform these steps, Roche cannot be liable for direct infringement. If you determine, however, that some elements of this method were performed by others, then in order to find that Roche induced infringement of this claim, Amgen must prove that it is more likely than not that someone has directly infringed this claim, and that Roche has actively and knowingly encouraged that direct infringement.

In order to find that Roche infringes claim 12 of the '933 patent, Amgen must prove that it is more likely than not that Roche produces a pharmaceutical composition having all the elements of claim 7, literally or under the doctrine of equivalents, plus the following elements:

- *An effective amount of a glycoprotein product effective for erythropoietin therapy*

For purposes of this claim, an "effective amount of a glycoprotein product effective for erythropoietin therapy" is one "that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO, such as . . . stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and . . . increasing hematocrit levels in mammals."[91]

[91] Memorandum and Order of July 3, 2007 (DN 613). Roche reserves its right to object and/or appeal the Court's claim constructions.

In order to find that Roche infringes claim 14 of the '933 patent, Amgen must prove that it is more likely than not that Roche practices a method of treating a kidney dialysis having, literally or under the doctrine of equivalents, the following elements:

- *A method for treating a kidney dialysis patient which comprises*
- *administering a pharmaceutical composition [having every one of the elements listed for claim 12]*
- *in an amount effective to increase the hematocrit level of said patient*

If Roche does not itself perform these steps, Roche cannot be liable for direct infringement. If you determine, however, that some elements of this method were performed by others, in order to find that Roche induced infringement of this claim, that it is more likely than not that someone has directly infringed this claim, and that Roche has actively and knowingly encouraged that direct infringement.

6.15.3 INFRINGEMENT OF U.S. PATENT NO. 5,618,698

In order to find that Roche infringes claim 6 of U.S. Patent No. 5,618,698, Amgen must prove that it is more likely than not that Roche practices every element, literally or under the doctrine of equivalents, of the following process:

- *Process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of*
- *Growing, under suitable nutrient conditions, vertebrate cells comprising amplified DNA encoding the mature erythropoietin amino acid sequence of FIG. 6*
- *Isolating said glycosylated erythropoietin polypeptide expressed by said cells*

For purposes of this claim, "comprising" means "containing the named elements."[92]

Further, if you have found that Roche's process contains all of these steps, and if any of these steps occurs outside the United States, Amgen must further prove that the product that Roche imports into the United States is not materially changed from the product defined by the patented process. Otherwise, you cannot find that Roche infringes this claim.

In order for you to find that Roche infringes claim 7 of U.S. Patent No. 5,618,698, Amgen must prove that it is more likely than not that Roche practices all elements, literally or under the doctrine of equivalents, of claim 6 plus the following element:

- Said vertebrate cells further comprise amplified marker gene DNA

Further, if you have found that Roche's process contains all of these steps, and if any of these steps occurs outside the United States, Amgen must further prove that the product that Roche imports into the United States is not materially changed from the product defined by the patented process. Otherwise, you cannot find that Roche infringes this claim.

---

[92] Memorandum and Order of July 3, 2007 (DN 613). Roche reserves its right to object and/or appeal the Court's claim constructions.

In order for you to find that Roche infringes claim 8 of U.S. Patent No. 5,618,698, Amgen must prove that it is more likely than not that Roche practices all elements, literally or under the doctrine of equivalents, of claims 6 and 7 plus the following element:

- *Said amplified marker gene DNA is Dihydrofolate reductase (DHFR) gene DNA*

Further, if you have found that Roche's process contains all of these steps, and if any of these steps occurs outside the United States, Amgen must further prove that the product that Roche imports into the United States is not materially changed from the product defined by the patented process. Otherwise, you cannot find that Roche infringes this claim.

In order for you to find that Roche infringes claim 9 of U.S. Patent No. 5,618,698, Amgen must prove that it is more likely than not that Roche practices all elements, literally or under the doctrine of equivalents, of claims 6, 7 and 8 plus the following element:

- *Said cells are mammalian cells*

Further, if you have found that Roche's process contains all of these steps, and if any of these steps occurs outside the United States, Amgen must further prove that the product that Roche imports into the United States is not materially changed from the product defined by the patented process. Otherwise, you cannot find that Roche infringes this claim.

6.15.4 INFRINGEMENT OF U.S. PATENT NO. 5,756,349

In order for you to find that Roche infringes claim 7 of U.S. Patent No. 5,756,349, Amgen must prove that it is more likely than not that Roche practices, literally or under the doctrine of equivalents, every one of the following steps:

- *Producing erythropoietin comprising the step of:*
- *culturing, under suitable nutrient conditions:*
- *Vertebrate cells which can be propagated in vitro*
- *Vertebrate cells . . . which are capable upon growth in culture of producing erythropoietin in the medium of their growth in excess of 100 U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay*
- *Said cells comprising non-human DNA sequences which control transcription of DNA encoding human erythropoietin*

For purposes of this claim, "comprising" means "containing the named elements."[93]

Further, if you have found that Roche's process contains all of these steps, and if any of these steps occurs outside the United States, Amgen must further prove that the product that Roche imports into the United States is not materially changed from the product defined by the patented process. Otherwise, you cannot find that Roche infringes this claim.

[93] Memorandum and Order of July 3, 2007 (DN 613). Roche reserves its right to object and/or appeal the Court's claim constructions.

6.15.5 INFRINGEMENT OF U.S. PATENT NO. 5,955,422

In order for you to find that Roche infringes claim 1 of U.S. Patent No. 5,955,422, you do not need to go through all the steps that I described with respect to the other patents. For this claim only, you need only determine whether Roche's practice of the elements of this claim fall within the safe harbor about which I instructed you previously.[94] If the safe harbor applies, there can be no infringement. The elements of this claim are :

- *A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin*
- A *pharmaceutical composition comprising . . . human erythropoietin*
- *A pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant or carrier*
- *Said erythropoietin is purified from mammalian cells grown in culture*

For purposes of this claim, a "therapeutically effective amount" is "one that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO,such as . . . stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and . . . increasing hematocrit levels in mammals." "Human erythropoietin" means "a protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine." "A pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant or carrier" means "a composition suitable for administration to humans, containing a diluent, adjuvant or carrier." "Purified from mammalian cells grown in culture" means "obtained in substantially homogeneous form from the mammalian cells, using the word from in the sense that it originates in the mammalian cells,

[94] Court Order dated August 28, 2007, granting in part [509] Amgen's motion for summary judgment as to infringement of the '422 patent (but not addressing safe harbor issue). Roche reserves the right to object to and/or appeal the Court's ruling.

without limitation to it only taking it directly out of the interior of the cells, which have been grown in the in vitro culture."

7 UNENFORCEABILITY (INEQUITABLE CONDUCT)

7.1 INEQUITABLE CONDUCT - GENERALLY

After a patent application is filed, it is assigned to an Examiner, who examines the application and attempts to determine whether or not the application and the claims meet all of the requirements of the patent laws. In conducting this examination, the Examiner must consider the description of the invention in the application, which may involve highly technical subject matter, and search for and consider the prior art. The Examiner has only a limited amount of time and resources available and, therefore, must rely on information provided by the applicant with respect to the technical field of the invention and the prior art.

Because the United States Patent and Trademark Office ("PTO") must rely on the patent application for information, applicants are required to prosecute patent applications with candor, good faith, and honesty. This duty of candor and good faith extends to all inventors named on a patent application, all attorneys and agents involved in preparing and prosecuting the application, and every other person involved with the prosecution of the patent application. Each individual with such a duty must disclose directly to the Examiner all information known to that individual to be material.[95] The term "information" can include prior art and factual representations made

[95] 37 C.F.R. 1.4(b) ("Since each file must be complete in itself, a separate copy of every paper to be filed in a patent application, patent file, or other proceeding must be furnished for each file to which the paper pertains, even though the contents of the papers filed in two or more files may be identical."); 37 C.F.R. 1.4(c) ("Since different matters may be considered by different branches or sections of the United States Patent and Trademark Office, each distinct subject, inquiry or order must be contained in a separate paper to avoid confusion and delay in answering papers dealing with different subjects."); *A.B. Dick Co. v. Burroughs Corp.*, 617 F.Supp. 1382, 1395 (N.D. Ill. 1985) ("the PTO cannot realistically be thought of as the equivalent (say) of a small law office, in which notice to one person may fairly be deemed notice to all. It is not necessarily true that the PTO Examining Division will have access to proofs filed in the course of an interference.") *aff'd*, 798 F.2d 1392 (Fed. Cir. 1986); *General Electric Co. v. United States*, 206 U.S.P.Q. 260, 278 (Ct. Cl. 1979) ("Even if [the applicant] had reason to believe that the Patent Examiner might review the interference record, it was incumbent upon counsel . . .

by each individual to the Examiner. Moreover, the duty of candor and good faith requires more than just disclosing material information.[96] For example, if an applicant knowingly takes advantage of an error by the Examiner, then it would not fulfill its duty of candor and good faith.[97] Similarly, the mere submission of information does not satisfy the duty of candor and good faith where an applicant buries material information or presents the information in a manner so that the examiner would be likely to ignore it and permit the application to issue as a patent.[98]

Roche contends that Amgen may not enforce its patents against Roche because Amgen engaged in inequitable conduct during the prosecution of its patents. "Inequitable conduct" refers to the failure to meet this duty of candor and good faith.

Roche contends that information material to the Lin patents was misrepresented, omitted, and/or buried in Amgen's communications with the Examiner; that persons substantively involved in the prosecution of the Lin patents had the intent to mislead the Examiner; and that Amgen committed fraud to obtain the Lin patents.

---

to call to his attention any evidence which might bear on the issue of patentability of the claims.")

96 Manual of Patent Examining Procedure ("MPEP") § 2001.04 (5th Ed. Rev. 14, Nov. 1992); MPEP § 2001.04 (8th Ed. Rev. 5, Aug. 2006); *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983).

97 *KangaROOS USA, Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1576 (Fed. Cir. 1985).

98 *See eSpeed Inc. v. BrokerTec USA LLC*, 417 F. Supp. 2d 580, 598 (D. Del. 2006) (submission made amidst more than two thousand pages of materials was a "blizzard of paper" characterized as "consistent with an intent to hide" and supporting a finding of inequitable conduct), *aff'd,* 480 F.3d 1129 (Fed. Cir. 2007); *Golden Valley Microwave Foods Inc. v. Weaver Popcorn Co., Inc.*, 837 F. Supp. 1444, 1477 (N.D. Ind. 1992) (holding duty of candor violated where applicant or attorney discloses reference "in such a way as to 'bury' it or its disclosure in a series of disclosures of less relevant prior art references, so that the examiner would be likely to ignore the entire list and permit the application to issue"), *aff'd*, 11 F.3d 1072 (Fed.Cir. 1993); *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F.Supp. 948, 965 (S.D. Fla. 1972), *aff'd* 479 F.2d 1328 (5th Cir. 1973); MPEP § 2001.04 (8th ed. Rev. 5, Aug. 2006).

Roche bears the burden of establishing inequitable conduct by clear and convincing evidence. To determine whether the Amgen patents were obtained through inequitable conduct, you must determine that Amgen, its representatives, or someone involved in a substantial way with the prosecution of the application, withheld or misrepresented information that was material to the examination of the patent application, and that this individual or individuals acted with an intent to deceive or mislead the Examiner.[99]

[99] AIPLA model jury instruction 11.0; *Bristol-Myers Squibb Co. v. Phone-Poulence Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268 (Fed. Cir. 2001); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997).

7.2 MATERIALITY

You must first determine whether Amgen withheld or misrepresented any information at all and, if so, whether that information was indeed material. An applicant can be deemed to have withheld or misrepresented information if such information is buried within a series of disclosures of less relevant information or within a lengthy disclosure of information.

Information is material if it establishes, either alone or in combination with other information, that a claim of the patent application would more likely than not meet one of the requirements for a patent, such as the requirements that the invention be new, useful, and non-obvious. Information is material where there is a likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. Information is also material if it refutes or is inconsistent with the information provided or arguments made by Amgen to persuade the Examiner that the invention is entitled to patent protection. Information is material if the reference "more explicitly and clearly" discloses limitations also found in submitted prior art.[100]

Roche contends that Amgen withheld or misrepresented various facts, declarations, agreements, judicial decisions, publications, experiments, prior art, and studies during the prosecution of its patents with the intent to mislead or deceive the Examiner. Roche contends that the Lin Patents would not have issued but for Amgen's inequitable conduct.

If you determine that there was a withholding or misrepresentation of information and that the information was material, then you must consider the element of intent. If, on the other hand, you find that Roche has failed to prove by clear and convincing evidence that Amgen or its

---

[100] *See McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 909 (Fed. Cir. 2007)

attorneys withheld or misrepresented any material information, then you must find that there was no inequitable conduct.[101]

[101] Delaware Model Jury Instruction 5.2; AIPLA Model Jury Instruction 11.1(B) (Post-1992 standard); *JP Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553 (Fed. Cir. 1984), *cert. denied*, 474 U.S. 822 (1985).

7.3 INTENT

If you determine that material information was withheld or misrepresented to the PTO, you must next determine whether such information was withheld or misrepresented with the intent to deceive or mislead the Examiner, or buried within a mass of less relevant information. Intent to deceive the Examiner may be found from direct evidence of such intent. Such direct evidence is rare, however, and as a result, the law allows deceptive intent to be inferred from the facts and surrounding circumstances. In determining whether or not there was intent to deceive or mislead the PTO, you should consider the totality of the circumstances, including the nature of the conduct and evidence of the absence or presence of good faith.[102]

Intent to deceive can be inferred from evidence that the applicant could not have made its patentability argument had the information been disclosed.[103] The materiality of an undisclosed reference may lead to an inference of intent. Intent to deceive also can be inferred when a party or its counsel fails to correct a representation made to the Examiner, even after learning that it was incorrect. Intent can also be inferred from evidence that the patentee submitted the material information to other entities, such as the FDA.[104] Conversely, shielding material information

---

[102] AIPLA Model Patent Jury Instruction 11.2; *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268(Fed. Cir. 2001); *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315 (Fed. Cir. 2000); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997); *LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066 (Fed. Cir. 1992); *eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 480 F.3d 1129 (Fed. Cir. 2007).

[103] *LaBounty Mfg., Inc. v. United States ITC*, 958 F.2d 1066, 1076 (Fed. Cir. 1992); *Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1275 (Fed. Cir. 2001).

[104] *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005); *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989).

from counsel or other individuals who owe the duty of good faith and candor is also indicative of intent to deceive.[105] Burying material information also supports intent to deceive.[106]

---

105 *Novo Nordisk Pharms., Inc. v. Bio-Technology Gen. Corp.*, 424 F.3d 1347, 1361-62 (Fed. Cir. 2005); *Synthon IP, Inc. v. Pfizer Inc.*, 472 F.Supp.2d 760, 779-80 (E.D. Va. 2007); *FMC Corp. v. Hennessy Industries, Inc.*, 836 F.2d 521, 526 n. 6 (Fed. Cir. 1987).

106 *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995) ("[B]urying' a particular material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith."); *eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 417 F. Supp. 2d 580, 598 (D. Del. 2006) (the "blizzard of paper is therefore more consistent with an intent to hide than to disclose.").

7.4 BALANCING OF MATERIALITY AND INTENT

The more material the withheld, misrepresented or buried information is, the less intent must be shown to reach a conclusion of inequitable conduct. For example, omitting a highly material piece of information requires less proof of intent, thereby allowing you to infer intent. You must be the judge of this balance.

If you find that Roche has proven by clear and convincing evidence that there was a material withholding or a material misrepresentation of information and that Amgen or its attorneys acted with intent to deceive the examiner, then you must balance these two factors to determine whether or not, in your view, there was inequitable conduct.[107]

[107] Delaware Model Jury Instruction 5.4; *Halliburton Co. v. Schlumberger Technology Corp.*, 925 F.2d 1435, 1439 (Fed. Cir.), *reh'g denied*, 1991 U.S. App. Lexis 4501 (Fed. Cir. 1991).

8 DELIBERATION AND VERDICT

8.1 INTRODUCTION

That concludes the part of my instructions explaining the rules for considering some of the testimony and evidence. Now let me finish up by explaining some things about your deliberations in the jury room, and your possible verdicts.

Once you start deliberating, do not talk to the court security officer, or to me, or to anyone else except each other about the case. If you have any questions or messages, you must write them out and give them to the court security officer, who will give them to me. I may have to talk to the lawyers about what you have asked, then we will bring you back in here and I will answer as best I can. Then we will send you back out.

Do not ever write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. That should stay secret until you are finished.[108]

You should not feel obligated to complete your deliberations today. If you have not reached a unanimous verdict by ten minutes to 5:00, we will call you back into the courtroom before you are dismissed for the day, and you will continue deliberations tomorrow.

---

[108] Delaware Model Jury Instruction 7.1

8.2 UNANIMOUS VERDICT

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

It is your duty, as jurors, to consult with one another and to deliberate with a view towards reaching an agreement, if you can do so without violence to your individual judgment. Each of you must decide the case for yourself, but do so only after an impartial consideration of the evidence with your fellow jurors. In the course of your deliberations, do not hesitate to reexamine your own views and change your opinion, if convinced it is erroneous. But do not surrender your honest conviction 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. Your sole interest is to seek the truth from the evidence in the case.

A form of verdict 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. Then tell the court security officer that you have reached a verdict, but do not give him the verdict slip. You will then return to the courtroom and your foreperson will give your verdict.

It is proper to add the caution that nothing said in these instructions and nothing in the form of verdict is meant to suggest or convey in any way or manner any intimation as to what verdict I think you should find. What the verdict shall be is the sole and exclusive duty and responsibility of the jury.[109]

[109] Delaware Model Jury Instruction 7.2.

8.3 DUTY TO DELIBERATE

Now that all the evidence is in and the arguments are completed, you are free to talk about the case in the jury room. In fact, it is your duty to talk with each other about the evidence, and to make every reasonable effort you can to reach unanimous agreement. Talk with each other, listen carefully and respectfully to each other'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 ever change your mind just because other jurors see things differently, or just to get the case over with. In the end, your vote must be exactly that – your own vote. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience.

No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. So you should all feel free to speak your minds.

Listen carefully to what the other jurors have to say, and then decide for yourself.[110]

[110] Delaware Model Jury Instruction 7.3.

8.4 THE COURT HAS NO OPINION

Let me finish up by repeating something that I said to you earlier. Nothing that I have said or done during this trial was meant to influence your decision in any way. You must decide the case for yourselves based on the evidence presented.[111]

[111] Delaware Model Jury Instruction 7.4.