UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LAROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 05-12237 WGY

PRE-TRIAL AND POST-TRIAL JURY INSTRUCTIONS

PROPOSED BY AMGEN INC.

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I. PRE-TRIAL JURY INSTRUCTIONS INTRODUCTION

Ladies and gentlemen, at this time in this courtroom there are thirteen judges. You twelve men and women are the judges of the facts. You are the only judges of the facts. That is not my function. I am the judge of the law. You are going to determine the facts in this case based solely and entirely on the evidence as you see it and hear it here in this courtroom and on nothing else whatsoever. No bias. No prejudice. No sympathy for anyone. No desire that anyone be punished or have revenge. No consideration of which company is better or which company makes a better product. No consideration of whether your decision will impact consumer choice or the availability of products in the market place. Your decision of the facts must be guided by the law as I explain it to you.

You can take notes during this case. Ms. Smith is passing out to you now notebooks and pens. Put your names on them. We will lock them up after every court session. You just carry them out with you, or leave them on the table in the jury room. Ms. Smith will collect them, lock them up, and we will give them back to you the next day.

So you have the right to take notes. Now, while you are allowed to take notes, no one says you have to take notes. It's not a test. If you are one of those people who by background and life experience you get your best judgment about people by watching them very closely, no one says you have to take notes. But this case is going to take awhile and maybe you would want to keep the names of witnesses or particular things, dates or data that you think is of significance, feel free to take notes.

Your notes are private to you. No one will ever see them. When the trial is over, Ms. Smith will destroy the notes. You should not pass your notes among the jurors. And the reason for that is they are not evidence of anything. They are your notes to refresh your recollection.

The lawyers have also put together notebooks of exhibits as to which there is no

objection and I will pass those out to you now. These exhibits are ones we will be talking about during the first days. There may be additional notebooks with exhibits as we move forward with the case.

You can ask questions. It's a formal proceeding, so if you have a question write your question out, rip it out of your notebook, pass it down to the foreperson. Ms. Smith and I will be watching. We'll come collect it. The question will get to me and I'll read it. Now, I may not ask it. The reason I may not ask it is because it is a question that I would not let the lawyers ask, or I think it is a question that does not legally make a difference, or the rules of evidence won't let the witness answer or for some other legal reason. If I decide to ask the question, I may not ask it exactly as you've written it but rather will ask it or a series of questions to elicit the information in a neutral manner. All questions that you pass to me will, whether they are asked or not, will be put on Ms. Smith's bench so that the attorneys can review them

The acoustics are quite good in this courtroom. We give the witnesses microphones, but if you do not hear the witness's testimony raise your hand. I'll have it repeated for you.

Now, I'm the judge of the law. You were carefully chosen to be the judges of the fact. But you were not chosen to make up your own law. It is my job to teach you the law. I will tell you who has to prove what and what the standard of proof is by which they must prove it. And it's your job to follow the law as I have explained it to you. You cannot make up your own law. You can't decide that one of the parties has to prove something else in addition to what I tell you or that some other factor, like the ones I mentioned before such as prejudice or which company or product is better or the impact on consumer choice, which is not part of the law, should be considered.

The attorneys are also teachers. They are teachers through evidence. They only get limited chances to talk to you directly and even then I will always caution you and say, well now,

remember, these lawyers were not there. They do not know what happened. They are teachers. They got into this after there was a dispute. Their job is to marshal, to present the evidence to you. They, themselves, are not sources of evidence.

At times during a lawyer's questioning of a witness, the other lawyer may object. It's perfectly appropriate for a lawyer to object to another lawyer's question. I will then say sustained, which means that the lawyer cannot ask that question, the lawyer must ask another question; or I will say overruled, which means no, that question is all right, and the witness may answer it.

After I rule on an objection, one side or the other may want to address the matter further with me. They may want to make a little argument on it. And I'm receptive to that so they will say May I approach? May I come to the side bar. What that means is the lawyers will come up and we will huddle over here. Now if we go over there, we are talking about things like the rules of evidence. We could go back and forth in front of you but it is distracting from the evidence so I do not do it that way. I will then decide the matter and we will proceed with the questioning.

II. THIS CASE

Amgen is the plaintiff in this patent case, and that means Amgen filed the case against the defendants F. Hoffmann-LaRoche LTD, Roche Diagnostics GMBH, and Hoffmann LaRoche, Inc. who I will collectively refer to as "Roche." It is a civil case. There is no criminal conduct charged here or involved. This is a civil dispute between these two companies who stand equal before the law.

As I said, the suit is brought by Amgen. And it's brought with respect to five patents held by Amgen that cover a medical drug that it markets and sells.

What is a patent? Well, I have the five patents that are at issue in this case right here. [Note: Amgen will make available the ribbon copies of the five patents-at-issue for the Court's use in court on September 4, 2007.] We've had patents as long as we've had a country. Patents are mentioned in the Constitution. And our patent law is designed to accomplish two related ends. On the one hand it's designed to encourage useful inventions that will help everyone; and on the other hand, it's designed to spread the knowledge of those inventions to everyone. Not just to keep them to the inventor himself.

III. THE PATENT SYSTEM, GENERALLY

What happens with a patent, is that the inventor or the company that employs the inventor, submits a patent application to the United States Patent and Trademark Office, which is a part of the Executive Branch of the government. The government is authorized by the United States Constitution to enact patent laws and issue patents to protect inventions. Inventions that are protected by patents may be products, compositions, or methods for doing something, or for using or making a product or composition.

The owner of a patent has the right, for the life of the patent, to prevent others from making, using, offering for sale, selling or importing the invention covered by the patent.

A patent is granted for a set period of time, which, in this case, is up to17 years from the date each patent issued. Once a patent expires, anyone is free to use the invention covered by the patent.

During the term of the patent, however, if another person makes, uses, offers to sell, sells or imports something that is covered by the patent without the patent owner's consent, that person is said to infringe the patent. The patent owner enforces a patent against persons believed to be infringers in a lawsuit in federal court, such as in this case.

To be entitled to patent protection an invention must be new, useful and nonobvious. A patent cannot legally take away from people their right to use that which was known, or that which was obvious from what was known, before the invention was made. Thus, a patent will not be valid if it deprives people of the right to use old or known products or processes, or of their right to use products or processes that were obvious at the time the invention was made. That which was already known at the time of the invention is called the "prior art." You will hear about the prior art relating to the patents-in-suit during the trial, and I will give you more instructions about what constitutes prior art at the end of the case.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Jury Instruction 2.2

IV. HOW A PATENT IS OBTAINED

The U.S. Patent and Trademark Office is the agency of our government that examines patent applications and issues patents. When an applicant for a patent files a patent application with the Patent and Trademark Office, the application is assigned to a Patent Examiner. The Patent Examiner examines the application to determine whether or not the inventions described in the patent application meets the requirements of the patent laws.

The Patent Examiner advises the applicant of his or her findings in a paper called an "office action." The Examiner may "reject" the claims describing the inventions if he or she believes they do not meet the requirements for patentable inventions. The applicant may respond to the rejection with arguments to support the claims by making changes or amendments to the claims, or by submitting new claims. If the Examiner concludes that the legal requirements for a patent have all been satisfied, he or she "allows" the claims and the application issues as a patent.

This process, from the filing of the patent application to the issuance of the patent, is called "patent prosecution." The record of papers relating to the patent prosecution is referred to as the prosecution history or file history. The prosecution history becomes available to the public when the patent issues.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Jury Instruction 2.5

V. THE PARTS OF A PATENT

A patent includes two basic parts, a written description of the invention and the patent claims. The written description, which may include drawings, is often referred to as the "specification" of the patent.

You have been provided with copies of the patents at issue in this case. Please refer to the '933 patent, which is in your juror notebook at Tab ___ as an example as I identify its different sections.

The cover page of the '933 patent provides identifying information, including the date the patent issued and patent number along the top right, as well as in the left-hand column the inventor's name, the filing date, the assignee, history of the applications that were filed and led to issuance of the patent, and a list of the prior art publications considered by the examiner who reviewed Dr. Lin's patent applications in the Patent Office. This list of prior art considered extends for several more pages to page 10.

The "Related U.S. Application Data" explains that this patent issued from a series of related patent applications filed by the inventor, Dr. Lin, the first of which was filed on Dec. 13, 1983. Each claimed invention may have a different effective filing date, depending on which of Dr. Lin's patent applications first disclosed that particular claimed invention. The last application in the series that led to this final issued '933 patent was filed on Jun. 7, 1995. The "Date of Patent" on the top indicates the date on which the '933patent issued.

The specification of the '933 patent begins with an abstract, found on the cover page in the lower right. The abstract is a brief statement about the general subject matter of the invention.

After the list of prior art, next are the drawings, which appear as Figures 1 to 21 on the next 27 pages. The drawings depict various aspects, features or examples of the inventions.

They are described in words later in the patent specification. The written description of the inventions appears next. In this portion of the patent, each page is divided into two columns, which are numbered at the top of the page. The lines in each column are also numbered. The written description of the '933 patent begins at column 1, line 1, and continues to column 38, line 16. It includes a description of the application filing history of the patent there in column 1, a "background" section that starts just below that and continues over to column 10, and a section entitled "brief summary" that begins in column 10 and extends over to column 38, which contains a detailed description of the inventions, including some specific examples.

The specification ends with one or more numbered paragraphs. These are called the claims. The claims may be divided into a number of parts or steps, referred to as "claim limitations" or claim elements. In the '933 patent, the claims begin at column 38, line 17 and continue to the end of the patent, at column 40, line 9. As you can see, there are 14 claims in this '933 patent. Each of those claims addresses a different invention. Not all of those claims are being asserted by Amgen against Roche in this case. We'll talk more about that later.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 2.3

VI. THE SIGNIFICANCE OF PATENT CLAIMS

The claims of a patent are the main focus of a patent case because it is the claims that define the patent owner's rights under the law. That is, the claims define what the patent owner may exclude others from doing during the term of the patent.

The claims of a patent serve two purposes. First, they set out the boundaries of the inventions covered by the patent. Second, they provide notice to the public of those boundaries. Thus, when a product or process is accused of infringing a patent, it is the patent claims that must be compared to the accused product or process to determine whether or not there is infringement. It is the claims of the patent that are infringed when patent infringement occurs. The claims are at issue as well when the validity of a patent is challenged. In reaching your determinations with respect to infringement and invalidity, you must consider each claim separately.

Before trial, I decided the meaning of certain, not all, but certain terms that are used in the five patents that we are concerned with here. I am now going to give to you a glossary that contains the terms that I have defined prior to trial. You must use these meanings when you decide the issues of infringement and validity.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Jury Instructions 2.4

VII. AMGEN'S CONTENTIONS

Here, Amgen contends that Roche will infringe certain claims of the five patents that Amgen owns which describe and claim inventions relating to erythropoietin, or "EPO" for short and to methods of making EPO. Dr. Lin's inventions with respect to EPO have resulted in the development of a treatment for anemia and related blood disorders. Under the protection of these five patents, which I discussed a few minutes ago, Amgen markets and sells a product called EPOGEN®.

The five specific patents at issue here are (1) U.S. Patent No. 5,441,868 (the "'868 Patent"); (2) U.S. Patent No. 5,547,933 (the "'933 Patent"); (3) U.S. Patent No. 5,618,698 (the "'698 Patent"); (4) U.S. Patent No. 5,955,422 (the "'422 Patent"); and (5) U.S. Patent No. 5,756,349 (the "'349 Patent"). And the specific claims of these patents that Amgen asserts Roche will infringe are as follows:

- Claims 1 and 2 of the '868 Patent
- Claims 6, 7, 8 and 9 of the '698 Patent
- Claim 7 of the '349 Patent
- Claims 3, 7, 8, 9, 11, 12 and 14 of the '933 Patent
- Claim 1 of the '422 Patent

Amgen contends that these claims will be infringed if Roche is permitted to market its accused product in the United States. I have already determined as a matter of law that Roche will infringe Claim 1 of the '422 patent, so you do not have to consider or deliberate on that issue. But you should not let that affect your determination as to whether the other claims are infringed by Roche's product or processes. Other than for Claim 1 of the '422 patent, Roche contends that all the other claims are not infringed. Roche contends that all the claims are invalid and unenforceable.

Amgen has to prove by a preponderance of the evidence that Roche in fact has infringed or will infringe a particular claim or claims. And a preponderance of the evidence simply means more likely to be true than not true. If based upon all the evidence you believe it's more likely to be true than not true that Roche has infringed a specific claim of one of the five patents, then you must find infringement as to that claim.

What do we mean by infringement? In order to infringe Roche has to have taken steps to produce or sell a product that has every one of the elements in a particular claim. Each claim of each patent that is in issue here is comprised of elements. So when you are looking at infringement, you must determine whether Roche's product has every one of the elements in the claim that is being asserted as infringed or whether Roche's method of making or administering its product has every one of the steps included in the asserted claims. So if Roche's product or process has all of the elements of the claim or performs all of the steps of a claim, even if there are additional elements or additional steps, it is said to infringe. If Roche's product does not have all the elements of the claim or it does not perform all of the steps of the claim than it is said not to infringe. This is called literal infringement.

For this analysis, you do not compare Amgen's product to Roche's product, that is not the relevant analysis. The relevant analysis is for you to compare separately each claim that Amgen asserts is infringed to Roche's product or method of making or using its product to see if Roche infringes that specific claim. When you get the jury verdict form you will see that it goes claim by claim and asks separately for each claim whether Roche infringes.

Amgen also asserts that even if Roche does not literally infringe there is infringement by the doctrine of equivalents. Now, what that means is that Roche's product is so close that although it does not literally have one of the elements in the claim, there is something in the Roche product or process that accomplishes substantially the same function, in substantially the

same way, with substantially the same result as that element. So this means that Amgen must prove that it is more probable than not that, for each claim element not literally found in Roche's product or method of making or using its product, that the product or method contains an equivalent structure or step.

In order to be equivalent, the differences between that missing claim element and Roche's structure or step must be insubstantial. I will explain in more detail in my final instructions the various ways by which you may determine whether or not these differences, if they exist, are insubstantial.

VIII. ROCHE'S CONTENTIONS

Roche denies that it infringes. Roche also asserts even if it does infringe, it does not matter because the patents are invalid.

Because the US Patent and Trademark Office already examined all these patents and granted them, you are to presume the Patent Office did its job correctly. Thus, the patents are presumed to be valid because the United States Patent Office issued the patents-in-suit, and the law presumes that each invention recited in each claim in each patent was new, useful and constituted an advance which was not, at the time of the invention, obvious to one of ordinary skill in the art.

However, Roche asserts the patents are invalid for several reasons.

Roche must prove that each asserted claim in the patents is invalid by clear and convincing evidence. Clear and convincing evidence means evidence which produces in your minds an abiding conviction that the truth of what Roche contends is highly probable.

First, Roche asserts that the patents are invalid because they were obvious. The standard by which Roche must prove that a claim is obvious is the higher standard of clear and convincing evidence because, as I have indicated, the Patent Office issued the patents so the claims are presumed valid.

What is obviousness? The test of whether something is obvious is whether the subject matter of the specific patent claim when viewed in light of the prior art would have been obvious to a person having ordinary skill in the art at the time the invention was made. In this case, Amgen contends the inventions were made prior to November 30, 1984. The prior art that you use in your comparison consists of what was publicly known before Dr. Lin made the invention. It includes patents, printed publications, commercial products in the United States, and certain other publicly available information in the United States. You compare each asserted claim

separately to the prior art and then decide whether it would have been obvious, to a person having ordinary skill in the art that is the subject of the patent. When I say the art, I mean the specific area of knowledge which is the subject of the patent.

Now in figuring out whether something's obvious, you do not use hindsight, you don't look at what is known by these people of ordinary skill today, who would have, for example, the benefit of the teachings of the patent, you look at what was known at the time the patent was applied for, what was known to a person reasonably skilled in the art at the time the patent was applied for. Prior art has to be public, it cannot just be privately known to someone, it has to be out there where people can know it.

Second, Roche asserts that some of the patent claims are invalid for obviousness-type double patenting. What does that mean? It means that the inventions defined by these patent claims must be patentably distinct from the inventions defined by the claims in other, earlier-issued patents owned by Amgen.[1]

Third, Roche asserts that some or all of the patents were anticipated. What does that mean? That means that somewhere in the literature, somewhere in the publicly known data there was what we call a reference. It simply means a document. And to anticipate one of the asserted claims, that document had to have taught every particular element in the claim. If that document was out there publicly or someone else invented it or someone else knew it, then the claim was

[1] As noted in the Joint Pretrial Memorandum (D.I. 807), it is Amgen's position that ODP is a matter of law purely for the Court to decide. *See In re Metoprolol Succinate Patent Litig.*, 2007 U.S. App. LEXIS 17463, at *10-11 (Fed. Cir. July 23, 2007). Amgen maintains this position, and offers these provisional jury instructions regarding ODP in the alternative, should the Court decide to submit ODP issues to the jury. Amgen reserves the right to contest the submission of ODP issues to the jury.

ODP is not addressed in the model patent jury instructions from the Federal Circuit Bar Association, the American Intellectual Property Law Association (AIPLA), or the Northern District of California.

anticipated. Again because the patents are presumed valid, Roche bears the burden of showing anticipation of each claim by clear and convincing evidence.

Fourth, Roche asserts that some or all of the asserted claims were not enabled. What does that mean? It simply means that teachings in the patent combined with what the person of ordinary skill knew at the time, were not enough to let that person of skill practice the invention. Recited in the claim without undue experimentation. Because the exchange involved in the Patent Office granting a patent is that the inventor gets this exclusivity over a period of time in return for teaching the world the technology so that the world can practice that technology when the patent expires. Again, because the patent claims are presumed valid, it is Roche's burden to prove that a claim was not enabled by clear and convincing evidence.

Fifth, Roche asserts that the patents are invalid because the written description of the patents is inadequate. What does that mean? It means the description of the invention must be sufficiently clear and informative so that a person skilled in the art would recognize, at the time of the application, that the inventor in fact possessed a means to make and use the claimed invention. The patent laws do not require any particular form of written description, nor do they require that the exact words found in the claims be found in the specification. Because the patent claims are presumed valid, it is Roche's burden to prove that a claim was not adequately described in the patents by clear and convincing evidence.

Lastly, Roche asserts that some or all of the asserted claims are invalid because they are indefinite. What does that mean? The claims of a patent must be written in a way that this person of ordinary skill reading them would have known what was covered by the claims, and what is not. Because the patent claims are presumed valid, it is Roche's burden to prove that a claim is indefinite by clear and convincing evidence.

With respect to enforcing the patents, Roche also asserts that Amgen may not enforce these five patents against Roche, because Dr. Lin engaged in inequitable conduct before the Patent and Trademark Office when Dr. Lin was seeking to get the patents issued by the Patent Office. Roche must prove inequitable conduct by the higher clear and convincing evidence standard. Thus Roche must prove that it is highly probable that Dr. Lin, or his attorney or representative, withheld or misrepresented material information, and did so with an intent to mislead or deceive the Patent and Trademark Office. I will provide you with more details about inequitable conduct at the end of the case.[2]

[2] As noted in the Joint Pretrial Memorandum, D.I. 807, it is Amgen's position that inequitable conduct is an equitable issue that should be decided by the Court without an advisory jury. Amgen maintains this position, and offers these provisional jury instructions regarding the law of inequitable conduct in the alternative, should the Court decide to submit inequitable conduct issues to an advisory jury over Amgen's objection. Amgen reserves the right to contest the submission of inequitable conduct issues to the jury.

IX. CONCLUDING REMARKS

These are the preliminary instructions I will provide to you regarding the law. There is one other matter I want to explain and that is the fact that I have decided that this case will be presented to you in three phases. The first phase will focus Roche's contentions that the patents are invalid. The second phase will focus on Amgen's contentions that the patents are infringed. The last phase will focus on Roche's contentions that the patents are not enforceable because Dr. Lin or Amgen committed inequitable conduct. Because I have decided to have the evidence presented to you in these three phases, the lawyers will provide a 15-minute opening statement about each phase at the start of that phase. So the first opening statements you will hear will be about invalidity. Now because it is, as I have explained, Roche's burden to prove invalidity, Roche's counsel will go first.

X. POST-TRIAL FINAL INSTRUCTIONS INTRODUCTION

Now the way the lawyers and I have worked this out, the way we think this makes this most intelligible for you, is to have me go first and explain to you in detail the law which you must follow in this case.

When I'm done explaining the law we'll take a break. Then the lawyers will get a chance to give their closing arguments to talk about the evidence and urge you to certain conclusions within the legal framework as I describe it. When that's done I'll just give you some explanation about how you may deliberate together, how juries deliberate together, and then the case is yours.

So we start this morning with my explanation as to the law which must govern in this particular case.

You must listen carefully now because this is a form of law teaching. This is like a law class here. And it's a little stilted because you can't raise your hand now and say, well, you didn't explain that very well, explain that a little better. But what you can do if you don't understand any aspect of the law, write out your question, write it out, there will be a court security officer outside the door here, come out the door, give the question to the court security officer, we'll set things all up in here, we'll have you back in the courtroom and I will explain it better. Don't hesitate to do that. If justice is to be done here you people must understand the law in the case, and I must be good enough to teach it to you. So if you have any questions about the law be sure to ask them, don't just go ahead without understanding what the law is.

I start my charges by a brief explanation of what our separate roles are, and then from there we'll go into what the evidence has been, at least the tools you have to do the job, and then from there we'll go directly into what the law is that governs this case.

SOURCES & AUTHORITIES:

Jury Instructions in *Read Corp. v. Powerscreen of America, Inc*., Civ. Action No. 96-11025-WGY ("Read Instructions"), p 3.

A. ROLE OF THE JURY

First your role. You are the judges of the facts. The only judges of the facts. Though I will necessarily have to make mention of evidence and make mention of particular witnesses, that's only to remind you of testimony or evidence that may, it's entirely up to you, bear on certain aspects of the case. You're the judges of the evidence. I have nothing to say about the evidence.

Now, you're going to judge the evidence as I said at the beginning of the case fairly and impartially without any bias or prejudice, without any sympathy for anyone, without any desire that anyone be punished or have revenge. Carefully and coolly sifting through this evidence to see that justice may be done.

Your verdict must be unanimous. We're going to ask you certain questions that can be answered yes or no. So you must be unanimous as to a yes, you must be unanimous as to a no. And unanimous means that you all come genuinely to agree. And you'll deliberate. Not that ten of you think this and the other couple go along with it. It must be a genuinely unanimous verdict.

And your verdict must be concentrated entirely on the evidence. You can, and I know how carefully you will listen to the lawyers to better to understand the evidence. You may look at the demonstrative aids to better to understand the evidence. But the evidence is what governs and you, and you alone, decide what you believe about the evidence.

Now, I'm the judge of the law. I've said that a number of times. I simply mean to point out to you that in this courtroom I'm the one who has the responsibility of teaching you the law. We make a careful record of what I've said. And that's the fair way. You cannot quarrel with the law as I explain it to you. I'm going to tell you who has to prove what in this case. I'm going to tell you the burden of proof that that side bears. But you can't add to the parties' burden. You

can't say gee, I, I really want them to show us this or that. But likewise you can't subtract from their burden. When I say they've got to prove something, then they have to prove that. You can't say, well, forget about that because this or that, something else is proved. I'll tell you what has to be proved and what the burden, what the standard of proof is. Listen to my whole charge start to finish. Don't seize on one part of it and say, "Aha, the case turns on this or that." Listen to the whole charge and consider all aspects of the charge together.

Likewise, don't think that because I charge you as to all aspects of the case that I think anything is proved or not proved. I have nothing to say about that. I simply am trying to build for you a complete mental framework so that you will understand the law which you have to follow. That's my role.

Now, I emphasize that you must confine your analysis to the evidence. So let's take a moment and go over the evidence in this case, not witness by witness but rather type by type, so that you know what tools you have.

SOURCES & AUTHORITIES:

Read Instructions, pp. 4-6.

B. EVIDENCE

The first thing I think of is the testimony of the witnesses. You have the power to believe everything of the witnesses. You have the power to believe everything that any witness said to you here from the witness stand. To believe it all. Equally, you have the power to disbelieve and disregard everything a witness said as though that witness never testified. Between those two extremes you have the power to believe some things a witness says but to disbelieve other things the witness says. You are not prevented from reaching a verdict because one witness has testified to one version of an event and another witness has testified to another version of the same event and both witnesses were under oath. You can believe one or believe the other. You can decide where the truth lies.

How do you do it? You use your common sense as you are reasonable men and women. You may use everything. You know about the witness. How did the witness impress you testifying on the witness stand? How did the witness respond to questions both on direct and on cross-examination? What was the opportunity of the witness to observe, to comprehend, to understand, to recall those matters about which the witness testified? Does the witness stand to gain or lose anything depending upon how the case comes out? Is the witness allied with, employed by one side or the other in the case? Do those things affect the witness' testimony? Is the testimony of the witness backed up – lawyers say corroborated – by other evidence in the case? The exhibits or depositions or any other evidence in the case? Or, does the other evidence in the case undercut, take away from, make less believable the testimony of the witness who is before you?

In short, you can sum up a witness' testimony and as reasonable men and women you can decide what you believe.

SOURCES & AUTHORITIES:

Read Instructions, pp. 4-6.

1. EXPERT WITNESSES

Some witnesses have been allowed to give their opinion about certain things. The law provides that when a witness has background, experience, and training that the judges and juries don't have, we'll let that witness render his or her opinion to the jury to aid the jury in doing their function.

Like any other witness, your powers with respect to opinions given by these witnesses are no different. That is, if I've allowed you to hear an opinion you may believe it; but equally you may disregard it. You may decide that's just not believable, that's not credible. Or you could believe part of what a witness says and disbelieve other parts of an opinion given by a witness. It's left to your good judgment.

I suggest to you that in evaluating opinion given by these witnesses you want to look at what undergirds them or underlies them. What was the witness relying on? How did the witness come to that opinion? Both by their experience, generally having nothing to do with this case, but also what do they know about things having to do with this case upon which their opinion rests. You're the judge of that. So with respect to opinions you may believe them, but you may disbelieve them or believe them in part.

SOURCES & AUTHORITIES:

Read Instructions, pp. 7-8.

2. TESTIMONY BY DEPOSITION

Now, not all the witnesses in this case testified live, that is, were here in court. Some witnesses, because of the geographical distance here, or for whatever other legal reasons, testified by way of videotaped deposition or lawyers reading portions of a deposition. The fact that a witness testifies by way of deposition doesn't make that witness any more believable or less believable than a witness testifying in court. That testimony as a matter of law starts even. And like any other testimony in the case, you may believe it, disbelieve it, believe parts of it.

Now, with respect to witnesses who testified by way of deposition, you listened very carefully to their testimony, and you should compare that testimony with the testimony of other witnesses, including testimony in other depositions. It's evidence in the case. You may believe it, disbelieve it, or believe part of it.

SOURCES & AUTHORITIES:

Read Instructions, pp. 9-10.

3. EXHIBITS

Now, in this case also there are a large number of exhibits. And shortly after we send you out, once the arguments are over, when we send you out to begin your deliberations, those exhibits will be brought into the jury room.

Well, they're evidence. Now, I'm talking about the exhibits that are evidence, not the charts that are not evidence, though some charts are evidence.

Exhibits are like the testimony of witnesses and your powers are exactly the same. That is, you may read, look at, view an exhibit, and if it persuades you of some aspect of the case that's perfectly appropriate because it's evidence.

But equally, if you don't find an exhibit believable, either because you think it's a fake, I'm not suggesting anything is a fake, but if you don't think it's genuine, or if you come to believe that even though this may be genuine, it's either inaccurate or it doesn't help you, disregard it. That's your power. You're the judges of the facts. And as with any other evidence in the case you could take part of an exhibit and say, well, this is persuasive, but another part is not persuasive.

SOURCES & AUTHORITIES:

Read Instructions, pp. 9-10.

4. STIPULATIONS

Lastly, you have some stipulations in this case. I've read them. The lawyers read them. And they're designed to shorten the time and make things clear to you. Stipulations are agreements among the lawyers, as they represent their clients. That's evidence. But that is special. That evidence is not disputed. So you don't have the right just to disregard it. You take that as given. The lawyers have agreed to that so we'll start out with that taken as given. It's evidence.

SOURCES & AUTHORITIES:

Read Instructions, p. 10.

C. DELIBERATIONS

Now, that's the body of evidence that you have in this case. A few words about what you do with it, how you analyze it.

You use your common sense. You don't check your common sense at the door to the jury room. Rather I charge you to apply your common sense to the evidence in this case to the end that justice may be done.

At the same time, you don't go in there and guess or speculate or maybe or perhaps or even probably. But you can use your common sense as you are reasonable men and women and you can draw what are called reasonable inferences. Now, a reasonable inference is a logical deduction. It's common sense. And I'm going to give you an example that has nothing to do with this case better to illustrate what a reasonable inference is and also to illustrate how far you can take it.

Let's say we have a witness and she testifies that she's walking along a road and she looks out and there's a field of tall grass . . . and she sees through the grass the grass is all knocked down in an irregular course through the field. And suppose you believe that testimony. From that alone you could infer something went through the field. I mean, it just doesn't happen that grass falls down along a path unless something knocks it down. It isn't all fallen down in a windstorm, it's fallen down in a course through the field. So it's a reasonable inference that something went through the field. We don't have a witness who saw the something, but there's a reasonable inference something went through that field.

Now, that's a reasonable inference. But unless you had other evidence from some other source in the case you wouldn't know what went through the field. A child. An adult. A big animal. A small animal. You just wouldn't know. That would be guessing.

Now, there might be other evidence and you can draw inferences from it. But the reasonable inference, if you believe the witness I gave you as an example, is something went through the field. But you can't guess about it unless there's other evidence. That's reasonable inferences.

Okay. We've talked about our roles. We've talked about the tools that you have to resolve this case. I want to say just a very few words about what's not evidence in the case, not to emphasize it but just point out to you what's not evidence in the case.

You're not going to judge this case in any way, shape or form based upon how you react to the lawyers as human beings. They've done their job, and they will later on this morning keep on doing it for their respective clients, and so far they've done a fine job. I mean that. But it plays no role in what you do. You've got to focus on the evidence. The lawyers are not sources of the evidence. And your reaction to them plays no role.

Equally important. If you somehow think that I think something about this case based upon the manner in which I have presided over it, I most earnestly instruct you to disregard it, I don't. And I tell you candidly I have no idea how this case will come out, nor is it my business. My business is to teach you the law.

This, however, I tell you and this I believe passionately. I believe in the jury system. I believe that you will do justice in this case. But I, clear as I am about constantly saying, oh, yes, I'm the judge of the law, I have nothing to say about the facts in this case. I believe that you will justly and impartially decide the facts in this case. Now let's get to it.

SOURCES & AUTHORITIES:

Read Instructions, pp. 13-14.

XI. BURDEN OF PROOF

In any legal action, facts must be proved by a required standard of evidence, known as the "burden of proof." In a patent case such as this, there are two different burdens of proof that are used, which I mentioned at the beginning of the trial.

The first burden of proof standard ("preponderance of the evidence") requires that, in order for a party to prevail, you must be persuaded that what the party seeks to prove is more probably true than not true.

The second burden of proof standard ("clear and convincing evidence") is a higher one. Clear and convincing evidence is evidence which produces in your mind an abiding conviction that the truth of the factual contentions is highly probable.

You may have heard of a burden of proof that is used in criminal cases called "beyond a reasonable doubt." That requirement is the highest burden of proof. It does not apply to a patent case such as this one, and you should, therefore, put it out of your mind.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 1.1; *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1360 (Fed. Cir. 2007) (citations omitted).

XII. THE CLAIMS OF THE PATENTS-IN-SUIT

As I told you at the beginning of the trial, the claims of a patent are the numbered sentences at the end of the patent. The claims describe the inventions made by the inventor and describe what the patent owner owns and what the patent owner may prevent others from doing. Claims may describe products, such as machines or chemical compounds, or processes for making or using a product.

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

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 7.

A. CONSTRUCTION OF THE CLAIMS

I will instruct you now about the meaning of some of the claim language.

In deciding whether or not an accused process or product infringes a patent, the first step is to understand the meaning of the words used in the patent claims.

It is my job as Judge to determine what the patent claims mean and to instruct you about that meaning. You must accept the meanings I give you and use them when you decide whether or not the patent is infringed, and whether or not it is invalid.

At the start of the trial, I instructed you about the meaning of the words of the claims and the different types of claims that are at issue in this case. I will now review those instructions with you again.

It may be helpful to refer to the copy of the '933 patent that you have been given as I discuss the claims at issue here. The claims are at the end of the '933 patent, starting in column 38. I will be giving you a list of the claims of the '933 patent, the '868 patent, the '698 patent, the '349 patent and the '422 patent at issue as part of the verdict form when I conclude my instructions.

[NOTE:]

If the claim constructions are included in the pre-trial instructions, Instructions XII. A-E may be included as well.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 7.1; *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384-391 (1996); *Bell Atlantic Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001); *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001); *SciMed Life Systems, Inc. v. Advanced Cardiovascular Sys.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001); *AFG Indus., Inc. v. Cardinal IG Co.*, 239 F.3d 1239, 1244-45 (Fed. Cir. 2001); *Hill-Rom Co. v. Kinetic Concepts, Inc.*, 209 F.3d 1337, 1340-41 (Fed. Cir. 2000); *Pitney Bowes, Inc. v. Hewlett-Packard* Co., 182 F.3d 1298, 1304-06 (Fed. Cir. 1999); *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988-90 (Fed. Cir. 1999); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1455-56 (Fed. Cir. 1998); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1581-84 (Fed. Cir. 1996); *Markman v. Westview*

Instruments, Inc., 52 F.3d 967, 977 (Fed. Cir. 1995) *(en Banc); Rival Co. v. Sunbeam Corp.*, 987 F. Supp. 1167, 1171 (W.D. Miss. 1997) *affd without* op., 185 F.3d 885 (Fed. Cir. 1999); *Minuteman Int'l, Inc. v. Critical-Vac Filtration Corp.*, No. 95C 7255, 1997 WL 187326, at *2 (N .D. Ill. April 11, 1997).

B. INDEPENDENT AND DEPENDENT CLAIMS

Patent claims may exist in two forms, referred to as independent claims and dependent claims. An independent claim does not refer to any other claim of the patent. Thus it is not necessary to look at any other claim to determine what an independent claim covers. Claim 3 of the '933 patent, for example, is an independent claim.

A dependent claim refers to at least one other claim in the patent A dependent claim includes each of the limitations of the other claim or claims to which it refers, as well as the additional limitations recited in the dependent claim itself. Therefore, to determine what a dependent claim covers, it is necessary to look at both the dependent claim and the other claim or claims to which it refers.

For example, claims 7, 8 and 9 of the '933 patent are dependent claims because they each refer to previous claims in the patent. To determine what dependent claim 7 covers, for example, the words of that claim and the words of either claims 3, 4 5, or 6 must be read together. Here, however, Amgen is only asserting claim 7 as it depends from claim 3, so you need not consider claim 7 as it depends from claim 4, 5, or 6.

NOTE:

Consider providing the jurors with a table setting out the relationship of the asserted claims to each other.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 7.2; 35 U.S.C. § 112 ¶ 4 (1984); *Globetrotter Software, Inc. v. Elan Computer Group, Inc*., 236 F.3d 1363, 1369-70 (Fed. Cir. 2001); *Dow Chem. Co. v. United States*, 226 F.3d 1334, 1341-42 (Fed. Cir. 2000); *Sibia Neurosciences, Inc. v. Cadus Pharm. Corp*., 225 F.3d 1349, 1359 (Fed. Cir. 2000); *Wolverine World Wide, Inc. v. Nike, Inc*., 38 F.3d 1192, 1199 (Fed. Cir. 1994); *Carroll Touch, Inc. v. Electro Mech. Sys., Inc*., 15 F.3d 1573, 1576 (Fed. Cir. 1993); *Marsh-McBirney, Inc. v. Montedoro-Whitney Corp*., 882 F.2d 498, 504 (Fed. Cir . 1989); *Wahpeton Canvas Co., Inc. v. Frontier, Inc*., 870 F.2d 1546, 1552-23 (Fed. Cir. 1989).

C. PROCESS AND SOURCE LIMITATIONS IN PRODUCT CLAIMS

Sometimes a product may best be described by the process by which it is made, or by the source from which it is derived, instead of by describing its structure or chemical characteristics. Claims which describe a product by describing the process by which it is made are called "product-by-process" claims.

Claims 3, 7-9, 11, 12 and 14 of the '933 patent are product-by-process claims or depend from product-by-process claims. Claim 1 of the '422 patent is not, however, a product-by-process claim; it is a product claim with a source limitation. The "purified from mammalian cells grown in culture" limitation of '422 Claim 1 "only speaks to the source of the EPO and does not limit the process by which the EPO is expressed." *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 13131, 1329 (Fed. Cir. 2003).

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instructions 7.3; *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372-73 (Fed. Cir. 2000); *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557-58 (Fed. Cir. 1995); *Mentor Corp. v. Colopast, Inc.*, 998 F.2d 992, 997 (Fed. Cir. 1993); *All. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 837 (Fed. Cir. 1992), reh'g en Banc denied, 974 F.2d 1279 (Fed. Cir. 1992); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991).

D. "COMPRISING" CLAIMS

The beginning portion, or preamble, of the claims of the patents use the words "comprising," "comprising the steps of" or "comprises." "Comprising" means "including" or "containing." A claim that uses the word "comprising" or "comprises" is not limited to products or processes having only the elements or steps that are recited in the claim, but also covers products or processes that have additional elements or steps.

Let's take our example of the claim that covers a table. If the claim recites a table "comprising" a tabletop, legs and glue, the claim will cover any table that contains these structures, even if the table also contains other structures, such as a leaf or wheels on the legs. All of the claims at issue use the "comprising" language.

SOURCE & AUTHORITIES

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 7.4; *Vehicular Techs. Corp. v. Titan Wheel Intl, Inc., 212* F.3d 1377, 1382-83 (Fed. Cir. 2000); *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.,* 200 F.3d 795, 811-12 (Fed. Cir. 1999); *Georgia-Pacific Corp. v. United States Gypsum Co.,* 195 F.3d 1322, 1327-29 (Fed. Cir. 1999); *Elkay Mfg. Co. v. Ebco Mfg.* Co., 192 F.3d 973, 977 (Fed. Cir . 1999); *Spectrum Intl, Inc. v . Sterilite Corp.,* 164 F.3d 1372,1379-80 (Fed . Cir. 1998); *Phillips Petroleum Co. v. Huntsman Polymers Corp.,* 157 F.3d 866, 874 (Fed. Cir. 1998); *Stiftung v. Renishaw PLC,* 945 F .2d 1173, 1177-79 (Fed. Cir. 1991).

E. LIMITATIONS OF THE CLAIMS AT ISSUE

I have now instructed you as to the types of claims at issue in this case. I have already provided you with a glossary defining the meaning of the words used in the patent claims at issue. You must use the definitions I provided to you in your consideration of infringement and invalidity issues.

[Construction of the claims to be supplied in juror notebooks.]

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 7.8

XIII. INFRINGEMENT

A. PATENT INFRINGEMENT GENERALLY – DIRECT INFRINGEMENT

A patent owner has the right to stop others from using the inventions covered by its patent claims during the life of the patent. If any person makes, uses, sells or offers to sell or imports what is covered by the patent claims without the patent owner's permission, that person is said to infringe the patent. This type of infringement is called "direct infringement." In addition to enforcing a patent against a direct infringer, a patent owner also has the right to enforce the patent against those who are known as "indirect infringers."

In reaching your decision on infringement, keep in mind that only the claims of a patent can be infringed. You must compare the asserted patent claims, as I have defined them, to Roche's peg-EPO product and process for making peg-EPO, and determine whether or not there will be infringement. You should not compare Roche's peg-EPO product and process with any specific example set out in the Lin patents, or with Amgen's commercial EPO product or process. The fact that there may be differences between Roche's peg-EPO product and Amgen's commercial products, Epogen® or Aranesp®, is irrelevant. The only correct comparison is with the language of the claim itself, as I have explained its meaning to you.

You must consider each claim individually and must reach your decision as to each assertion of infringement based on my instructions about the meaning and scope of the claims, the legal requirements for infringement, and the evidence presented to you by the parties. I will first discuss direct infringement.

Whether or not Roche knew that what it was doing was an infringement does not matter. A person may be found to be a direct infringer of a patent even if he or she believes in good faith that what he or she is doing is not an infringement of any patent, and even if he or she does not even know of the patent.

In this case, Amgen asserts that Roche's peg-EPO product and process will directly infringe the asserted claims. It is your job to determine whether or not Amgen has proved by the more probable than not standard that Roche will directly infringe any of the asserted claims.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 8.1

B. INFRINGEMENT - EVERY CLAIM LIMITATION MUST BE PRESENT, EITHER LITERALLY OR UNDER THE DOCTRINE OF EQUIVALENTS

In order to infringe a patent claim, a product or process must include every limitation of the claim. If Roche's peg-EPO product and the process Roche uses to make the EPO in that product omit a recited claim limitation, then you must find that Roche will not infringe that claim. You must consider each of the patent claims separately.

A claim limitation may be present in an accused product or process in one of two ways, either literally or under what is known as the doctrine of equivalents. A claim limitation is literally present if it exists in the accused product or process just as it is described in the claim language, either as I have explained that language to you or, if I did not explain it, as you understand it.

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

A person of ordinary skill is a person with average education and training in the field.

Equivalency is determined by what was known at the time of the activities accused of infringement, and not by what was known at the time the patent application was filed or when the patent issued. Thus, the inventor need not have foreseen, and the patent need not describe, all potential equivalents to the invention covered by the claims. Also, slight changes in technique or improvements made possible by technology developed after the patent application is filed may still be equivalent for doctrine of equivalents purposes.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 8.3; *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 37 (1997); *Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 609 (1950)*; *Allen Engineering Corp. v. Bartell Indus., Inc.*, 2002 WL 1765989 (Fed. Cir. 2002); *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1334 (Fed. Cir. 2001); *Biovail Corp. Int'l v. Andrx Pharms., Inc.*, 239 F.3d 1297, 1302-03 (Fed. Cir. 2001); *Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1107 (Fed. Cir. 2000); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1287 (Fed. Cir. 2000); *Bayer AG v. Elan Pharm., Research Corp.*, 212 F.3d 1241, 1247-50 (Fed. Cir. 2000); *Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1301-02 (Fed. Cir. 1999); *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987) (en banc).

C. INFRINGEMENT OF OPEN ENDED OR "COMPRISING" CLAIMS

The preamble to the asserted claims uses the phrases "comprising" or "comprises." The words "comprising" or "comprises" means "including the following but not excluding others."

If you find that Roche's peg-EPO product and process for making peg-EPO include all of the elements or steps in the asserted claims, the fact that Roche's product and process might include additional components and process steps will not mean that Roche's product and process do not literally infringe a claim that uses "comprising" or "comprises" language.

SOURCES & AUTHORITIES:

AIPLA's Model Patent Jury Instructions 3.7; *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1484, 221 USPQ 649, 655 (Fed. Cir.), *cert. denied*, 469 U.S. 924 (1984); *AB Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703, 218 USPQ 965, 967-68 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1042 (1984); *Mannesmann Demag Corp. v. Engineered Metal Prods. Co.*, 793 F.2d 1279, 1283, 230 USPQ 45, 47 (Fed. Cir. 1986); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1271, 229 USPQ 805, 812 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987); *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 314 F.3d 1313, 1351-52 (Fed. Cir. 2003).

D. INFRINGEMENT OF DEPENDENT CLAIMS

My instructions on infringement so far have related to independent claims. As I told you, Amgen has also asserted dependent claims. A dependent claim includes each of the limitations of the independent claim to which it refers, plus additional elements.

If you find that an independent claim will be infringed, you must separately determine whether a claim which depends from it will also be infringed.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 8.10; *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1383 (Fed. Cir. 2000); *Finnigan Corp. v. United States Int'l Trade Comm 'n*, 180 F.3d 1354, 1364 (Fed. Cir. 1999); *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 685-86 (Fed. Cir. 1990); *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552-53 n.9 (Fed. Cir. 1989).

E. INFRINGEMENT OF PROCESS CLAIMS UNDER 35 U.S.C. 271(G)

Amgen contends that Roche will infringe the asserted process claims ('868 claims 1 and 2, '698 claims 6-9, and '349 claim 7) by practicing these patented processes for making EPO in Germany, and then importing the EPO product produced by those processes into the United States. To determine infringement of the asserted process claims, you must first determine whether Roche's process for making EPO in Germany satisfies all of the limitations of the asserted process claims.

If you find that Roche's process for making EPO satisfies all of the limitations of an asserted process claim, you must then determine whether the EPO is materially changed by subsequent processes prior to the importation into the United States as a part of Roche's peg-EPO product. If the EPO contained in Roche's peg-EPO product is materially changed by its attachment to polyethylene glycol, then Roche will not infringe the asserted process claim. A change is not a material change unless it is a significant change in a compound's structure or properties, which changes the basic utility, or use for, the compound.

You must also determine whether the EPO contained in peg-EPO is a trivial and non-essential component of peg-EPO. If you find that it is, then Roche will not infringe the asserted process claims.

Therefore, in order to find that Roche will infringe the asserted process claims, you must find that (1) Roche's process for making peg-EPO in Germany satisfies all of the limitations of the asserted process claims, (2) the EPO product of the process claims is not materially changed by subsequent processing steps, including the attachment of peg and (3) the EPO in peg-EPO is not a trivial and non-essential component of peg-EPO.

SOURCES & AUTHORITIES:

35 U.S.C. 271(g); *Oki America, Inc. v. Advanced Micro Devices, Inc*. No. C-04-3171, 2006 WL 2711555 (N.D. Ca., Sept. 21, 2006); *Eli Lilly & Co. v. American Cyanamid*, 82 F.3d 1568, 1571,

1573 (Fed. Cir. 1996).

F. INFRINGEMENT AND IMPROVEMENTS TO PATENTED INVENTION

Roche contends that its peg-EPO product and process accused of infringement represents an improvement to the inventions described in the Lin patent claims. Proof of this fact does not necessarily mean that the Roche's accused peg-EPO product and process do not infringe Dr. Lin's patent claims. Furthermore, peg-EPO may infringe the Lin patent claims whether or not Roche has a patent on peg-EPO. Improvements may be separately patentable, yet still infringe another's patent.

The tests for infringement remain as I have instructed you. As long as you find that Roche's peg-EPO product and process include all of the limitations of at least one of the asserted patent claims, either literally or under the doctrine of equivalents, then you must find that the patent claim(s) will be infringed by Roche's product and process, despite what Roche contends to be improvements.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 8.11; *Nat'l Presto Indus., Inc. v. W. Bend Co.*, 76 F.3d 1185, 1191-92 (Fed. Cir. 1996); *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1570 (Fed. Cir. 1996); *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1582 (Fed. Cir. 1996); *Stiftung v. Renishaw, PLC*, 945 F.2d 1173, 1179 (Fed. Cir. 1991); *Marsh-McBirney, Inc. v. Montedoro-Whitney Corp.*, 882 F.2d 498, 504 (Fed. Cir. 1989); *Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1580-81 (Fed. Cir. 1984).

G. DETERMINATION OF INFRINGEMENT

Taking each of the asserted claims separately, if you find that Amgen has proven that it is more probably true than not true that each and every limitation of the claim is present in Roche's peg-EPO product and process, either literally or under the doctrine of equivalents, then you must find that Roche's product or process will infringe that claim.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 8.7

H. INDUCING INFRINGEMENT

As I have told you, in addition to enforcing a patent against a direct infringer, a patent owner may also enforce the patent against indirect infringers. The act of encouraging or inducing others to infringe a patent is called "inducing infringement".

There can be no indirect infringement unless someone is or will directly infringe the patent. Thus, in order to prove that Roche is inducing another person to infringe, Amgen must prove that it is more probable than not that the other person has or will directly infringe at least one claim of the patent.

In this case, Amgen accuses Roche of inducing infringement of claims 11 and 14 of the '933 patent. Amgen must prove that it is more probable than not that Roche will induce infringement of these claims.

A person induces patent infringement if he or she purposefully causes, urges or encourages another to infringe a patent. Inducing infringement cannot occur unintentionally. This is different than direct infringement, which, as I've just told you, can occur unintentionally. In order to prove inducement, the patent owner must prove that it is more probable than not that the accused inducer knew of the patent and encouraged or instructed another person to use a product or perform a process in a manner that infringes the patent. The patent owner must also prove that it is more probable than not that the other person is or will infringe the patent. A person can be an inducer even if he or she thought that what he or she was encouraging or instructing the other person to do was not an infringement.

Amgen asserts that Roche has or will induce infringement of '933 claims 11 and/or 14. Amgen must prove four things by the more probable than not standard:

First, Roche has or will encourage or instruct another person how to perform a process in a manner than you, the jury, find infringes the '933 patent claims 11 and/or 14.

Second, Roche knows of the '933 patent.

Third, Roche knows or should know that his or her encouragement or instructions has or will induce actual infringement.

Fourth, the other person has or will infringe the '933 patent claims 11 and/or 14.

If, and only if, you are persuaded of each of these four things may you find that Roche has or will induce patent infringement.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 8.12, 8.12.1; 35 U.S.C. § 271(b) (1984);*Aro Mfg. Co. v. Convertible Top Replacement Co*., 365 U.S. 336, 340-41 (1961); *Arthur A. Collins, Inc. v. N. Telcom Ltd.*, 216 F.3d 1042, 1049 (Fed. Cir. 2000); *Porter v. Farmers Supply Serv., Inc.*, 790 F.2d 882, 884-86 (Fed. Cir. 1986); *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F.3d 1293 (Fed. Cir. 2006); *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1261 (Fed. Cir. 1999); *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1311-12 (Fed. Cir. 1998); *Insituform Techs., Inc. v. Cat Contracting, Inc.*, 161 F.3d 688, 695 (Fed. Cir. 1998); *Carborundum Co. v. Molten Metal Equip. Innovations, Inc.*, 72 F.3d 872, 876 n.4 (Fed. Cir. 1995); *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774-76 (Fed. Cir. 1993); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553-54 (Fed. Cir. 1990); *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468-69 (Fed. Cir. 1990).

XIV. VALIDITY

A. PRESUMPTION OF VALIDITY

Under the law, each of Dr. Lin's patent claims is presumed to be valid, and Roche, the party attacking the validity of the patent claims, has the burden of proving invalidity by clear and convincing evidence. Moreover, if the United States Patent Office considered a particular prior art reference asserted by Roche as a basis for invalidity, then Roche has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job. This is a higher burden of proof than Amgen bears for proving infringement. The presumption of validity is strong and relates to each patent as a whole, no matter what grounds Roche seeks to invalidate the patents. This means that, because the United States Patent Office issued the patents-in-suit, the law presumes that each invention claimed in each patent was new, useful and constituted an advance which was not, at the time of the invention, obvious to one of ordinary skill in the art. Because the Patent Office issued multiple patents to Amgen for its inventions, the presumption of validity means that the law presumes that those patents are not obvious over one another. It also means that the patent and each claim is presumed to comply with the patent laws' written description, enablement, and definiteness requirements.

When considering if Roche has met its burden of proving invalidity by clear and convincing evidence, you must consider each asserted claim of each of Dr. Lin's patents separately. You must presume that each claim of each patent (whether in independent, dependent, or multiply dependent form) is valid independently of what you find as to the validity of other claims of each patent. You must presume that dependent or multiply dependent claims are valid even if they depend upon a claim you find to be invalid.

In assessing Roche's invalidity defenses, you must take into consideration this

presumption. To determine validity, you must decide whether all the evidence introduced by both sides established that Roche has carried its burden so as to have persuaded you by clear and convincing evidence that the patents-in-suit and each asserted claim in those patents can no longer be accepted as valid.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.1; 35 U.S.C. §§ 282; *See Morton Int'l v. Cardinal Chem. Co.*, 5 F.3d 1464, 1471-2 (Fed. Cir. 1993); *Mendenhall v. Cedar Rapids Inc*, 5 F.3d 1557, 1563-64 (Fed. Cir. 1993); *Avia Group Int'l. Inc. v. L.A. Gear Cal.*, 853 F.2d 1557, 1567 (Fed. Cir. 1988); *DMI, Inc. v. Deere & Co.*, 802 F.2d 421, 427 (Fed. Cir. 1986); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126F.Supp.2d 69, 105 (D. Mass 2001).

B. PATENT VALIDITY – GENERALLY

For Roche to prove than any of the asserted claims are invalid, Roche must prove that the invention claimed in the patent does not meet certain requirements under the patent laws. These requirements require that the invention recited in the claim be new, useful, and non-obvious. The terms "new," "useful" and "nonobvious" have special meanings under the patent laws. I will explain these terms to you as we discuss Roche's grounds for asserting invalidity of the patents-in-suit.

In addition, a patent itself must meet three additional requirements to be valid. First, a patent must provide a complete written description of the claimed invention. Second, a patent must enable one skilled in the art to make and use the claimed invention. Third, the claims of the patent must be sufficiently definite. I will discuss each of these in more detail momentarily.

In this case, Roche has challenged the validity of the patents-in-suit on a number of these grounds. To successfully challenge the validity of Amgen's patents, Roche must prove, by clear and convincing evidence, that each claim of the patents-in-suit is invalid, on a claim-by-claim basis. Clear and convincing evidence is a more exacting standard than proof by a preponderance of the evidence, which only requires that the party's allegation be more likely true than not true. If the United States Patent Office considered a particular prior art reference asserted by Roche as a basis for invalidity, then Roche has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job. Each claim of each patent is presumed valid regardless of the status of any other claim in the patent.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.1; 35 U.S.C. §§ 101, 102, 103 and 112; *See Morton Int'l v. Cardinal Chem. Co.*, 5 F.3d 1464, 1471-2 (Fed. Cir. 1993); *Mendenhall v. Cedar Rapids Inc*, 5 F.3d 1557, 1563-64 (Fed. Cir. 1993); *Avia Group Int'l. Inc. v. L.A. Gear Cal.*, 853 F.2d 1557, 1567 (Fed. Cir. 1988); *DMI, Inc. v. Deere & Co.*, 802 F.2d 421, 427 (Fed. Cir. 1986); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126F.Supp.2d 69, 105 (D. Mass 2001).

C. PRIOR ART: DEFINITION

Under the patent laws, a person is entitled to a patent only if the invention claimed in the patent is new and unobvious in light of what came before. That which came before is referred to as the "prior art". In order to be prior art, it must have been available, without restriction, to that segment of the public most likely to make use of the prior art's contents. Private or secret knowledge, such as knowledge confidentially disclosed within a small group, is not part of the prior art because it is not part of the general knowledge in the field.

Roche is relying on various items of prior art to show that Amgen's patents are invalid. Roche must prove by clear and convincing evidence that the items it asserts are prior art fall within one or more of the different categories of prior art recognized by the patent laws. These categories include:

First, anything that was publicly known or used in the United States by someone other than the inventor before the inventor made the invention.

Second, anything that was in public use or on sale in the United States more than one year before the application for the patent was filed.

Third, anything that was patented or described in a printed publication anywhere in the world before the inventor made the invention, or more than one year before the application for the patent was filed.

Fourth, anything that was invented by another person in this country before the inventor made the invention, if the other person did not abandon, suppress or conceal his or her prior invention.

Fifth, anything that was described in a patent that issued from a patent application filed in the United States or certain foreign countries before the inventor made the invention.

It is Roche's burden to show by clear and convincing evidence that prior to the date of

invention, the asserted reference was in the prior art as defined by any one of the definitions I just mentioned.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.6.1; 35 U.S.C. 102.

D. CONCEPTION AND REDUCTION TO PRACTICE

Many of the different categories of prior art refer to the date on which the inventor made the invention. This is called the "date of invention." In this case, Amgen contends that the claimed inventions were made prior to November 30, 1984, the last date on which a continuation-in-part application disclosing Lin's inventions was filed with the Patent Office.

There are two parts to the making of an invention. When the inventor first has a complete idea of the invention, it is called the "conception" of the invention. A conception of an invention is complete when the inventor has formed the idea of how to make and use every aspect of the claimed invention, and all that is required is that the invention be made without the need for any further inventive effort. The actual making of the invention is referred to as "reduction to practice." An invention is said to be "reduced to practice" when it is made and shown to work for its intended purpose.

It is possible to have a simultaneous conception and reduction to practice. Sometimes, it is impossible to have full conception of an idea until it is actually reduced to practice. This situation is known as the doctrine of simultaneous conception and reduction to practice and is especially likely to occur in the unpredictable arts such as biology. This doctrine may apply to product claims or to process and product-by-process claims.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.6.1; *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001); *Singh v. Brake*, 222 F.3d 1362, 1366-70 (Fed. Cir. 2000); *Genentech Inc. v. Chiron Corp.*, 220 F.3d 1345, 1351 (Fed. Cir. 2000); *Bruning v. Hirose*, 161 F.3d 681, 684-85 (Fed. Cir. 1998); *Cooper v. Goldfarb*, 154 F.3d 1321, 1326-31 (Fed. Cir. 1998); *Hyatt v. Boone*, 146 F.3d 1348, 1352-55 (Fed. Cir. 1998); *Estee Lauder Inc. v. L'Oreal*, S.A., 129 F.3d 588, 592-93 (Fed. Cir. 1997); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577-79 (Fed. Cir. 1996); *Burroughs Wellcome Co. v. Barr Labs.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994); *Griffith v. Kanamaru*, 816 F.2d 624, 626 (Fed. Cir. 1987); *Bey v. Kollonitsch*, 806 F.2d 1024, 1026 (Fed. Cir. 1986); *Morgan v. Hirsch*, 728 F.2d 1449, 1452 (Fed. Cir. 1984); *Amgen, Inc. v. Chugai Pharma. Co.*, 927 F.2d 1200, 1205-06 (Fed. Cir. 1991).

E. PRIOR ART—PRIOR INVENTION

An invention made by another person before the inventor on the patent made the invention is prior art to the patent claim, unless that other person abandoned, suppressed or concealed his or her invention.

As a general rule, the first person to reduce an invention to practice is said to be the first inventor. An invention is reduced to practice either when a patent application is filed or when the invention is made and shown to work for its intended purpose. Thus, if another person reduces to practice an invention before the inventor on the patent, then the reduction to practice by the other person will be prior art to the patent claims.

Let's consider an example. Mr. Smith has a patent on a table. He reduced his table to practice on April 1. Ms. Jones invents the same table. She built her table on March 1, one month before Mr. Smith reduced his table to practice. Ms. Jones' invention of the table is prior art to Mr. Smith's patent claims because Ms. Jones reduced her table to practice one month before Mr. Smith's reduction to practice.

The final requirement for a prior invention to be prior art is that the prior inventor did not abandon, suppress or conceal his or her invention. Generally, 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. The filing of a patent application that discloses the invention is evidence that the invention was not abandoned, suppressed or concealed.

AUTHORITIES

Dow Chem. Co. v. Astro-Valcour, Inc., 267 F.3d 1334,1341-43 (Fed. Cir. 2001); *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031 (Fed. Cir. 2001); *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001); *Singh v. Brake*, 222 F.3d 1362, 1366-70 (Fed. Cir. 2000); *Genentech Inc. v. Chiron Corp.*, 220 F.3d 1345, 1351 (Fed. Cir. 2000); *Bruning v. Hirose*, 161 F.3d 681, 684-85 (Fed. Cir. 1998); *Cooper v. Goldfarb*, 154 F.3d 1321, 1326-31 (Fed. Cir. 1998); *Hyatt v. Boone*, 146 F.3d 1348, 1352-55 (Fed. Cir. 1998); *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 593 (Fed. Cir. 1997); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577-79 (Fed. Cir. 1996); *Checkpoint Sys, v. United States Int'l Trade Comm'n*, 54 F.3d 756, 761-63

(Fed. Cir. 1995); I*nnovative Scuba Concepts, Inc. v. Feder Indus., Inc*., 26 F.3d 1112, 1115-16 (Fed. Cir. 1994); *Griffith v. Kanamaru*, 816 F.2d 624, 626 (Fed. Cir. 1987); *Bey v. Kollonitsch*, 806 F.2d 1024, 1026 (Fed. Cir. 1986); *Dunlop Holdings Ltd. v. Ram Golf Corp*., 524 F.2d 33, 34 (7th Cir. 1975); *Palmer v. Dudzik*, 481 F.2d 1377, 1385-87 (C.C.P.A. 1973); *Gould v. Schawlow*, 363 F.2d 908 (C.C.P.A. 1966).

F. PRIOR ART: PRINTED PUBLICATION

Printed publications from anywhere in the world are prior art if the printed publications were published, either before the inventor made the claimed invention or more than one year before the priority application for the patent was filed. A document is a printed publication if it was reasonably accessible to that portion of the public most likely to use it. It is not necessary that the publication be available to every member of the public. Thus, publications may include not only such things as books, periodicals or newspapers, but also publications that are not as widely available to the public, such as trade catalogues, journal articles or scholarly papers that are distributed or available to those skilled in the field of the invention. However, unpublished or concealed writings are not printed publications and, therefore, are not part of the prior art. The date that a printed publication becomes prior art is the date that it becomes available to the public. Published patent applications are printed publications as of their publication dates. If a printed publication was published more than one year before the priority application was filed, then the publication would be prior art, regardless of the date of invention for the patent claims.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.6.7; 35 U.S.C. §§102(a)-(b); *Mahurkar v. C.R. Bard*, Inc., 79 F.3d 1572, 1576 (Fed. Cir. 1996); *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 936-37 (Fed. Cir. 1990); *In re Cronyn*, 890 F.2d 115, 1159-61 (Fed. Cir. 1989); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1568-69 (Fed. Cir. 1988); *In re Hall*, 781, F.2d 897-899 (Fed. Cir. 1986); *Mass. Inst. of Tech. v. AB Fortia*, 774 F.2d 1104, 1108-09 (Fed. Cir. 1985); *In re Wyer*, 655 F.3d 221, 225 (C.C.P.A. 1981).

G. PRIOR ART: PRIOR KNOWLEDGE OR USE BY ANOTHER IN THE UNITED STATES

Knowledge or use in the United States of a patented invention can be prior art to the patent claims. The knowledge or use will be prior art if it meets the following requirements. First, the knowledge or use must be by someone other than the inventor. Second, the knowledge or use must be before the inventor's date of invention. Third, the knowledge or use must be in the United States. Prior knowledge or use outside the United States cannot be relied upon to invalidate a patent claim. Fourth, the knowledge or use must have been public. Private or secret knowledge or use by someone other than the inventor is not prior art.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.6.4; 35 U.S.C. §102(a); *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998); *Ecolochem, Inc., v. S. Cal. Edison Co.*, 227 F.3d 1361, 1369 (Fed. Cir. 2000).

H. ANTICIPATION – GENERALLY

A person or party cannot obtain a patent on an invention if someone else has already made the same invention. In other words, in order to qualify as patentable, an invention must be new. If an invention is not new, we say that it was "anticipated" by the prior art. An invention that is anticipated by prior art is not entitled to patent protection. Roche asserts that claims 3, 7, 8, 9 and 12 of the '933 patent and claim 1 of the '422 patent are invalid because each of the claimed inventions contained within them were anticipated by prior art, and thus were not new. To overcome the presumption of validity of an issued patent and establish invalidity on the basis of anticipation, Roche is required to demonstrate invalidity by clear and convincing evidence, on a claim by claim basis. Roche must show that each and every limitation of the claim is present in a single piece of prior art, whether that prior art is a publication, a prior patent, a prior invention, a prior public use or sale, or some other piece of prior art. The corollary of the rule is that the absence from the reference of any claimed element negates anticipation. Almost is not enough, there must be true identity of invention. Moreover, you may not find that the prior art anticipates a patent claim by combining two or more items of prior art. Every element must be found in a single reference.

Because the United States Patent Office issued the patents-in-suit, the law presumes that the inventions claimed in the patents are new, and therefore not anticipated by any piece of prior art. This is particularly true when the prior art relied upon to prove anticipation was previously considered by the United States Patent Office during the prosecution of the patent application. In that case, Roche must overcome the deference owed to the Patent Office, who is presumed to have correctly issued the patents over that prior art.

A printed publication or patent will not be an anticipation unless it contains a description of the invention covered by the patent claim that is sufficiently detailed to teach a skilled person

how to make and use the invention without undue experimentation. That means that a person skilled in the art of the invention reading the printed publication or patent would be able to make and use the invention using only an amount of experimentation that is appropriate for the complexity of the field of the invention and for the level of expertise and knowledge of persons skilled in that field.

In deciding whether or not a single item of prior art anticipates a patent claim, you should consider that which is expressly stated or present in the item of prior art, and also that which is inherently present. Something is inherently present in an item of prior art if it is always present in the prior art or always results from the practice of the prior art, and if a skilled person would understand that to be the case. You may also consider any expert testimony and other publications that shed light on the knowledge such a person would have had.

Unless you find that a claim of the patents-in-suit is invalid because it was anticipated by an item of prior art offered by Roche by clear and convincing evidence, you then must find the claim to be valid.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.8; 35 U.S.C. §102; *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1367-70 (Fed. Cir. 2000); *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999); *Abbot Labs. v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1318 (Fed. Cir. 1999); *Finnegan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1364 (Fed. Cir. 1999); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349 (Fed. Cir. 1998); *W.L. Gore & Assocs., Inc., v. Garlock, Inc.*, 721 F.2d 1540, 1548 (Fed. Cir. 1983); *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983); *Pall Corp. v. Micron Separations, Inc.*, 792 F. Supp. 1298, 1314 (D. Mass. 1992), *aff'd in part, rev'd in part*, 66 F.3d 1211 (Fed. Cir. 1995); *Amgen v. HMR/TKT*, 126 F. Supp. 2d at 105-06, *aff'd in pertinent part*, 314 F.3d 1313 (Fed. Cir. 2003). *American Hoist*

I. ANTICIPATION – EFFECT OF PROCESS OR SOURCE LIMITATIONS

Source or process limitations can serve to define the structure of a claimed product where such limitations distinguish a claimed product over prior art. Product claims may include process steps to wholly or partially define the claimed product. To the extent that these source or process limitations distinguish the product over the prior art, they must be given the same consideration as traditional product characteristics.

SOURCES & AUTHORITIES:

Amgen Inc. v. F. Hoffmann-La Roche, Civ. Action No. 05-12237, Doc. No. 613 July 3, 2007 Memorandum and Order at 18; *In re Luck*, 476 F.2d 650, 653 (C.C.P.A. 1973); *Amgen v. Hoechst Marion Roussel*, 314 F.3d 1313, 1329 (Fed. Cir. 2003); *Amgen Inc. v. Hoechst Marion Roussel, Inc*., 457 F.3d 1293, 1304 (Fed. Cir. 2006).

J. ANTICIPATION – PURIFIED COMPOUNDS

A material occurring in nature in less-pure form does not anticipate claims to the pure material.

SOURCES & AUTHORITIES:

In re Bergstrom, 166 U.S.P.Q. 256, 262 (C.C.P.A. 1970); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1381 (Fed. Cir. 2003); Manual of Patent Examining Proc. § 2144.04.

K. OBVIOUSNESS

Generally, as I have already discussed with you, an inventor is not entitled to a patent if his or her invention would have been obvious to a person of ordinary skill in the field or "art" of the invention at the time the invention was made. Unlike anticipation, obviousness may be shown by considering more than one item of prior art. The question to be addressed, when weighing the issue of obviousness, is whether, at the time an invention was made, that claimed invention would have been obvious to a person of ordinary skill in the field of the invention. If the answer to that question is "yes," then the patent claim is invalid. For each claim that Roche challenges based on invalidity, Roche has the burden of proving, by clear and convincing evidence, that the asserted claim of the patents-in-suit was invalid for obviousness at the time the invention was made. In this case, Amgen contends that date is prior to November 30, 1984.

To prove that a claimed invention was obvious, Roche must establish by clear and convincing evidence, on a claim-by-claim basis, that a person of ordinary skill in the art, at the time the claimed invention was made, would have had reason to attempt to make the claimed composition, or carry out the claimed process, and would in fact have had a reasonable expectation of successfully making and using the claimed invention. Whether a person of ordinary skill in the art would have had a reasonable expectation of actually making and using the claimed invention requires an objective assessment of:

1) the scope and content of the prior art;
2) the differences, if any, between the claimed invention and the prior art;
3) the level of ordinary skill in the art at the time of the inventions; and
4) other indications of non-obviousness, such as:
    a. whether there was a long-felt need for the invention;
    b. whether others tried but failed to make the claimed invention;

c. whether the patentee deviated from the accepted wisdom indicated by the prior art;

d. whether unexpected results were achieved by the invention;

e. contemporaneous expressions of surprise or acclaim by those skilled in the art following the invention;

f. praise of the invention by the infringer or others in the field;

g. commercial success of products covered by the patent claims or made by a process covered by the patent claims;

h. the taking of licenses under the patent by others; and

i. copying of the invention by others in the field.

The presence of any of these objective indicators may suggest that the invention was not obvious. No single factor, however, is alone dispositive, and you must consider the obviousness or non-obviousness of the invention as a whole.

Obviousness is determined from the perspective of a person of ordinary skill in the art of the invention at the time the inventions were made. The issue is not whether the claimed inventions would have been obvious to you as jurors, to me as a judge, or to a genius in the field of the invention. Rather, the question is whether or not the inventions would have been obvious to a person of ordinary skill in the art of the invention at the time of the inventions.

Virtually all inventions consist of combinations of particular elements. Sometimes these combinations comprise elements already known in the art, one or more new elements, or a mixture of both old and new elements. There is nothing unusual or incorrect about a patent claim directed to a particular combination of elements even if some, or all, of those elements were known to people in the art at the time of the inventions.

In deciding obviousness, you must avoid using hindsight; that is, you should not consider what is known today, or what was learned from the teachings of the patent-in-suit. You should not use the patent-in-suit as a road map for selecting and combining items of prior art. You must

instead put yourself in the place of a person of ordinary skill in the art at the time the inventions were made, without access to or use of the inventions and teaching disclosed in the patent.

You must also keep in mind that the test for obviousness is not whether it would have been "obvious to try" to make the invention, but rather whether the invention would have been obvious to a person of ordinary skill in the art at the time the invention was made, including whether that person would have had a reasonable expectation of successfully practicing the claimed invention at the time the invention was made. The "obvious to try" standard applies only where there was strong market pressure to solve a problem for which there were a finite number of previously identified solutions that would predictably solve the problem. That was not the case here.

Obviousness cannot be founded upon what is unknown. That which was inherent in the prior art and was not known, is not available for combination with other prior art to support obviousness of an invention. Inherency is not a substitute for some teaching or suggestion supporting obviousness.

It is against this backdrop that you must decide whether or not Roche has proven, by clear and convincing evidence, that an invention covered by an asserted claim would have been obvious at the time of the invention.

I will now describe in more detail the specific determinations you must make in deciding whether or not a claimed invention would have been obvious.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.9; 35 U.S.C. §103; *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1367-70 (Fed. Cir. 2000); *LNP Eng'g Plastices, Inc. v. Miller Waster Mills, Inc.*, 275 F.3d 1347, 1359 (2001); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662-68 (Fed. Cir. 2000); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1124-31 (Fed. Cir. 2000); *Stratoflex, Inc, v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983); *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 857; *United States v. Adams*, 383 U.S. 39, 52 (Ct. Cl. 1966); *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 697 (Fed. Cir. 1983), *cert.*

denied, 464 U.S. 1043 (1984); *WL Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563 (Fed. Cir. 1983); *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000); *In re Dembiczak*, 175 F.3d 994, 998-1000 (Fed. Cir. 1999); *In re Rouffet*, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998); *In re Deuel*, 51 F.3d 1552, 1557-60 (Fed. Cir. 1995); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1574-75 (Fed. Cir. 1986*); KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007); *Pharmastem Therapeutics, Inc. v. Viacell, Inc*., 491 F.3d 1342 (Fed. Cir. 2007); *Takeda Chemical Indus. v. Alphapharm Pty*., 2007 U.S. App. LEXIS 15349 (Fed. Cir. 2007); *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993); *In re Spormann*, 363 F.2d 444, 448 (C.C.P.A. 1966).

L. OBVIOUSNESS: SCOPE AND CONTENT OF THE PRIOR ART

In arriving at your decision on the issue of whether a claimed invention was obvious to one of ordinary skill in the art, you must first determine the scope and content of the prior art. This means that you must determine what prior art was reasonably pertinent to the particular problem that Dr. Lin faced. Prior art was reasonably pertinent if it is in the same field as the claimed invention or was from another field that a person of ordinary skill would look to in trying to solve the problem Dr. Lin was trying to solve. In making this determination, you will need to keep in mind the effective filing dates of the asserted claims. The prior art is only pertinent if it was patented or described in a printed publication anywhere in the world before Dr. Lin made the inventions, or more than one year before the effective filing date of the patent. Once you have determined the pertinent prior art, you should determine what a person of ordinary skill in the art would have understood was disclosed in that prior art.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.9.1; 35 U.S.C. §103; *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007); *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662-68 (Fed. Cir. 2000); *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356-57 (Fed. Cir. 2000); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1124-31 (Fed. Cir. 2000); *Stratoflex, Inc, v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983); *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888 (Fed. Cir.), *cert. denied*, 469 U.S. 857; *United States v. Adams*, 383 U.S. 39, 52 (Ct. Cl. 1966); *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 697 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984); *WL Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563 (Fed. Cir. 1983); *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000); *In re Dembiczak*, 175 F.3d 994, 998-1000 (Fed. Cir. 1999); *In re Rouffet*, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998); *In re Deuel*, 51 F.3d 1552, 1557-60 (Fed. Cir. 1995); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1574-75 (Fed. Cir. 1986); *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881-83 (Fed. Cir. 1998); *Wang Lab. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716-17 (Fed. Cir. 1991).

M. OBVIOUSNESS: DIFFERENCES BETWEEN THE INVENTIONS OF THE CLAIMS AND THE PRIOR ART

Next, you should determine the differences between the prior art and the claimed inventions. Although it is proper for you to note any differences between the claimed inventions and the prior art, in making this analysis you should not look at the individual differences in isolation. You must consider the claimed inventions as a whole and determine whether or not they would have been obvious in light of all the prior art. Each claim must be considered in its entirety and separately from the other claims.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.9.2; 35 U.S.C. §103; *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007); *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Yamanouchi Pharm. Co. v. Danbury Pharmacal Inc.*, 231 F.3d 1339, 1343-45 (Fed. Cir. 2000); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1367-70 (Fed. Cir. 2000); *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000); *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 (Fed. Cir. 2000); *In re Dembiczak*, 175 F.3d 994, 998-1000 (Fed. Cir. 1999); *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881-83 (Fed. Cir. 1998); *Wang Lab. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716-17 (Fed. Cir. 1991).

N. OBVIOUSNESS: LEVEL OF ORDINARY SKILL

Obviousness is determined from the perspective of a person of ordinary skill in the art at the time the inventions were made. This person is presumed to know all of the prior art, not just what the inventor may have known. When faced with a problem, this ordinarily skilled person is able to apply his or her experience and ability to the problem, and also to look to any available prior art to help solve the problem. It is your job to determine the level of ordinary skill in the art at the time the claimed inventions were made, i.e., prior to November 30, 1984. Factors to be considered in determining the level of ordinary skill in the art include:

1) the level of education and experience of persons actively working in the field at the time of the inventions;

2) the types of problems encountered in the art at the time of the inventions;

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.

Amgen contends that the level of ordinary skill in the pertinent art was a scientist working in the field of molecular biology in 1984, having a doctoral degree (a Ph.D. or an M.D.) or equivalent education and at least 1-2 years of laboratory research experience, including experience in expressing exogenous genes in cells and assaying the expression thereof.

Roche contends that the level of ordinary skill in the art was a person with a Ph.D. or M.D. and two or three years of research experience in _____.

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

When you decide the issue of obviousness, you must decide whether or not the inventions would have been obvious to one having this ordinary level of skill in the art.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.9.3; 35 U.S.C. §103; *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007); *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662-68 (Fed. Cir. 2000); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1124-31 (Fed. Cir. 2000); *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356-57 (Fed. Cir. 2000); *Stratoflex, Inc, v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983); *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888 (Fed. Cir.), *cert. denied*, 469 U.S. 857 (1984); *United States v. Adams*, 383 U.S. 39, 52 (Ct. Cl. 1966); *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 697 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984); *WL Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed.Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563 (Fed. Cir. 1983); *In re Dembiczak*, 175 F.3d 994, 998-1000 (Fed. Cir. 1999); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716-17 (Fed. Cir. 1991); *In re Dance*, 160 F.3d 1339, 1343 (Fed. Cir. 1998); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 256 (D. Mass. 2004).

O. OBVIOUSNESS: MOTIVATION TO COMBINE

Once the prior art is assembled and considered, you should determine whether the prior art, considered as a whole, suggested the claimed invention. As I mentioned earlier, virtually all patents claim inventions that consist of combinations of new elements with previously known elements. In order to prove obviousness, Roche must prove by clear and convincing evidence that one of ordinary skill in the art at the time the inventions were made would have been prompted to combine the elements in the way Dr. Lin did. A need or problem known in the field of the art at the time of the invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

You may also consider whether the prior art provided some teaching, suggestion, or motivation to combine old and new elements in the way Dr. Lin did, and whether that combination of the prior art would have been reasonably likely to achieve the goal of the inventions.

In making this determination, you must avoid using hindsight; that is, you should not consider what is known today. You also must not consider what was learned from the teachings of the patent. You should not use the patent as a road map for selecting and combining elements from the prior art with new elements. You must put yourself in the place of a person of ordinary skill in the art at the time the inventions were made, without the benefit of Dr. Lin's disclosures. If the results of the combinations were unexpected and/or surprising at the time of Dr. Lin's inventions, this may be strong support that the inventions would not have been obvious to a person of ordinary skill in the art.

To find obviousness, you must find not only that the prior art would have taught one of ordinary skill to try the combination of elements that Dr. Lin did, but also that prior art would sufficiently direct such a person how to obtain the desired result. If the prior art merely disclosed

that it would have been obvious to explore a new technology or general approach that seemed to be a promising field of experimentation, this would not constitute a suggestion of the claimed invention. Similarly, if the prior art merely disclosed numerous possible combinations but gave no direction as to which of those of many choices was likely to be successful, this did not constitute a suggestion of the invention. Finally, you should also consider whether the prior art "taught away" from the inventions covered by the patent claims, that is, whether someone reading the prior art at the time the inventions were made would have been discouraged from following the path taken by Dr. Lin.

SOURCES & AUTHORITIES:

KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1734 (2007); *Pharmastem Therapeutics, Inc. v. Viacell Inc*., 491 F.3d 1342 (Fed. Cir. 2007); T*akeda Chemical Indus. v. Alphapharm Pty*., 2007 U.S. App. LEXIS 15349 (Fed. Cir. 2007); *Graham v. John Deere Co.,* 383 U.S. 1 (1966); *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276 (Fed. Cir. 2004); *Pro-Mold and Tool Co. v. Great Lakes Plastics*, Inc., 75 F.3d 1568, 1573 (Fed. Cir. 1996); *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1997)); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361 (Fed. Cir. 2000); *Mandel Bros., Inc. v. Wallace*, 335 U.S. 291, 295 (1948); *Merck & Co. v. Biocraft Lab., Inc.*, 874 F.2d 804, 807-09 (Fed. Cir. 1989); *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988); *In re Yates*, 663 F.2d 1054 (C.C.P.A. 1981); *In re Clinton*, 527 F.2d 1226, 1228 (C.C.P.A. 1976).

P. OBVIOUSNESS: OBJECTIVE INDICATIONS CONCERNING OBVIOUSNESS

In making your decision as to the obviousness or non-obviousness of each asserted claim, you must consider the following objective evidence that may tend to show the non-obviousness of the claims at issue:

1) whether there was a long-felt need for the invention;

2) whether others tried but failed to make the claimed invention;

3) whether the patentee deviated from the accepted wisdom indicated by the prior art;

4) whether unexpected results were achieved by the invention;

5) contemporaneous expressions of surprise or acclaim by those skilled in the art following the invention;

6) praise of the invention by the infringer or others in the field;

7) commercial success of products covered by the patent claims or made by a process covered by the patent claims;

8) the taking of licenses under the patent by others; and

9) copying of the invention by others in the field.

The presence of any of these objective indicators may suggest that the invention was not obvious, however, no factor is alone dispositive, and you must consider the obviousness or non-obviousness of the invention as a whole. I will now address each of these factors in turn.

1. LONG-FELT NEED

One of the factors you should consider is whether or not Amgen has shown a long felt need in the art which was satisfied by the inventions of the patents-in-suit, that would tend to indicate that the inventions would not have been obvious.

2. FAILURE OF OTHERS

One of the factors you should consider is whether Amgen has shown that others had tried, but failed to solve the problem solved by the inventions of the patents-in-suit, that would tend to

indicated that the inventions would not have been obvious. To prove this Amgen must show that it was the merits of the inventions that allowed the inventor of the patents-in-suit to succeed.

3. SKEPTICISM

One of the factors that you should consider is whether Amgen has shown that those skilled in the art were skeptical of the patented inventions. Proceeding contrary to the accepted wisdom of the art is strong evidence of nonobviousness. To prove this, Amgen must show that there was skepticism about the merits of the patented inventions, or about whether the patented inventions would solve the problem. If you were to find that those skilled in the art were skeptical of the patented inventions, this would tend to indicate that the inventions were not obvious.

4. UNEXPECTED RESULTS

One of the factors you should consider is whether Amgen has shown that the results achieved by the inventions were unexpected. Unexpected results may be strong evidence that the inventions would not have been obvious to a person of ordinary skill in the art. Results which would have been a surprise, or an insight that was contrary to the understanding and expectations of a person of ordinary skill in the art at the time of the invention, tend to indicate that the inventions would not have been obvious.

5. EXPRESSIONS OF SURPRISE

One of the factors you should consider is whether Amgen has shown that the making of the inventions claimed in the patents-in-suit invoked expressions of surprise by experts and those skilled in the art. If you were to find that the patented inventions were the subject of expressions of surprise, this would tend to indicate that the inventions would not have been obvious.

6. AWARDS/RECOGNITION BY OTHERS

One of the factors you should consider is whether Amgen has shown that the inventions claimed in the patents-in-suit received awards and/or recognition by others. The fact that experts

perceived the inventions as exceptional technological achievements is good evidence of nonobviousness. If you were to find that the patented inventions were the subject of awards and/or recognition by others, this would tend to indicate that the inventions would not have been obvious.

7. COMMERCIAL SUCCESS

One of the factors you should consider is whether Amgen has shown any commercial success of the products covered by the patents-in-suit due to the merits of the inventions. Examples of commercial success include widespread or quick adoption of the product. To prove this, Amgen would have to provide evidence to satisfy you that there is a causal connection between the commercial success of the products and the claimed inventions, that would tend to indicate that the inventions would not have been obvious.

8. ACCEPTANCES OF LICENSES

One of the factors you should consider is whether Amgen has shown that others have accepted licenses under the patents-in-suit because of the merits of the claimed inventions, which tend to indicate that the claimed inventions were not obvious. If others accepted licenses due to factors such as the cost of litigation or the low cost of the license, then it has not been established that the acceptance of licenses was due to the merits of the inventions themselves. If you were to find that others took licenses as a result of the merits of the claimed inventions, however, this would tend to indicate that the inventions were not obvious.

9. COPYING

One of the factors you should consider is whether Amgen has shown copying by others of the inventions claimed in the patents-in-suit. If you were to find that others copied the invention because of its merits this would tend to indicate that the inventions were not obvious.

Regarding these factors, there must be a connection between the evidence showing any of these factors and the claimed inventions if this evidence is to be given weight by you in arriving at your conclusion on the obviousness issue. For example, if commercial success is due to advertising, promotion, salesmanship or the like, or is due to features of the product other than those claimed in the asserted patents, then any commercial success may have no relation to the issue of obviousness. A nexus is required between the merits of the claimed inventions and the evidence offered, if that evidence is to be given substantial weight *en route* to a conclusion on the obviousness issue.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.9.4; *Graham v. John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662-68 (Fed. Cir. 2000); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc*., 229 F.3d 1120, 11124-31 (Fed. Cir. 2000); *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356-57 (Fed. Cir. 2000); *Stratoflex, Inc, v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Perkin-Elmer Corp. v. Computervision Corp.,* 732 F.2d 888 (Fed. Cir. 1984), *cert. denied,* 469 U.S. 857 (1984); *United States v. Adams*, 383 U.S. 39, 52 (Ct. Cl. 1966); *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 697 (Fed. Cir. 1983), *cert. denied,* 464 U.S. 1043 (1984); *WL Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed.Cir. 1983), *cert. denied,* 469 U.S. 851 (1984); *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563 (Fed. Cir. 1983); *In re Dembiczak*, 175 F.3d 994, 998-1000 (Fed. Cir. 1999); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716-17 (Fed. Cir. 1991); *In re Dance*, 160 F.3d 1339, 1343 (Fed. Cir. 1998); *Specialty Composites v. Cabot Corp.*, 845, F.2d 981 (Fed. Cir. 1988); *In re Soni*, 54 F.3d 746 (Fed. Cir. 1995); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132 (Fed. Cir. 1985); *Takeda Chem. Indus. v. Alphapharm Pty., Ltd*., 2007 U.S. App. LEXIS 15349, *10 (Fed. Cir. 2007); 35 U.S.C. §103; *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007); *Poly-America, L.P. v. GSE Lining Technology, Inc*., 2003 WL 21946842 (N.D. Tex. 2003); *ATP Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998).

Q. OBVIOUSNESS: SUMMARY

Roche contends that the inventions claimed in the patents-in-suit would have been obvious to a person of ordinary skill in the art of the invention at the time the inventions were made in light of the prior art cited. If you find that Roche has not proven obviousness by clear and convincing evidence, then you must find that the claims of the patents-in-suit are not invalid on this basis.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.9.5; 35 U.S.C. §103; *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007); *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1367-70 (Fed. Cir. 2000); *LNP Eng'g Plastics, Inc. v. Miller Waster Mills, Inc.*, 275 F.3d 1347, 1359 (2001); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662-68 (Fed. Cir. 2000); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1124-31 (Fed. Cir. 2000); *Stratoflex, Inc, v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983); *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 857; *United States v. Adams*, 383 U.S. 39, 52 (Ct. Cl. 1966); *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 697 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984); *WL Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563 (Fed. Cir. 1983); *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000); *In re Dembiczak*, 175 F.3d 994, 998-1000 (Fed. Cir. 1999); *In re Rouffet*, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998); *In re Deuel*, 51 F.3d 1552, 1557-60 (Fed. Cir. 1995); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1574-75 (Fed. Cir. 1986).

R. [PROVISIONAL INSTRUCTION] Obviousness-Type Double Patenting[3]

The legal doctrine of obviousness-type double patenting prevents an inventor from claiming, in two different patents, two inventions that are not "patentably distinct" from each other. The question to be addressed, when determining whether two claimed inventions are "patentably distinct," is whether, at the time the later-claimed invention was made, that invention would have been obvious to a skilled person who knew of the earlier-claimed invention and the prior art. If the answer to that question is "yes," then the two inventions are not patentably distinct, and the later-issued claim is invalid.

In this case, Roche has alleged that claims in Dr. Lin's '868 and '698 patents are invalid for obviousness-type double patenting over claims in Dr. Lin's earlier-issued '008 patent. Therefore, your job is to determine whether the inventions claimed in the '868 and '698 patents are patentably distinct from the inventions claimed in the '008 patent. Roche's obviousness-type double patenting defense does not apply to the '349, '422 and '933 patents and those patents cannot be considered in your analysis of obviousness-type double patenting. While the obviousness-type double patenting analysis parallels the general obviousness analysis that I explained to you a moment ago, there is a significant difference in the law between obviousness-type double patenting and obviousness, and it is important to understand the distinction.

When assessing obviousness-type double patenting, you must focus on the two patent ***claims*** at issue. Remember that the "claims" of a patent are the numbered paragraphs at the end of the patent document. Your role is to determine whether the two claims at issue define

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[3] As noted in the Joint Pretrial Memorandum (D.I. 807), it is Amgen's position that ODP is a matter of law purely for the Court to decide. *See In re Metoprolol Succinate Patent Litig.*, 2007 U.S. App. LEXIS 17463, at *10-11 (Fed. Cir. July 23, 2007). Amgen maintains this position, and offers these provisional jury instructions regarding ODP in the alternative, should the Court decide to submit ODP issues to the jury. Amgen reserves the right to contest the submission of ODP issues to the jury.

ODP is not addressed in the model patent jury instructions from the Federal Circuit Bar Association, the American Intellectual Property Law Association (AIPLA), or the Northern District of California.

inventions that are patentably distinct from each other. In making this determination, you cannot consider the other information set forth in the patents. The reason you must not consider the other information in the patents, such as the inventor's detailed written description or other claims, is that Dr. Lin's patents are not part of the relevant prior art.

You must evaluate obviousness-type double patenting separately for each asserted claim in Dr. Lin's '868 and '698 patents. This means that you must determine, on a claim-by-claim basis, if an invention claimed in the later-issued '868 or '698 patent is patentably distinct from the invention of a single claim of the earlier-issued '008 patent. You cannot combine multiple claims from the '008 patent when considering whether a claim in that '868 or '698 patent is patentably distinct.

The patentably distinct analysis requires you to determine whether the differences between the later-issued claim and the earlier-issued claim would have been obvious to a person of ordinary skill in the art just before the time of the second invention — in this case, no later than November 30, 1984. You must view each claimed invention "as a whole." You should not look at individual differences in isolation. Also, you must avoid using hindsight; that is, you should not consider what is known today, or what was learned from the teachings of the patent-in-suit. Rather, you must consider what was known before November 30, 1984.

As with obviousness, the determination of whether a later-claimed invention is "patentably distinct" from an earlier-claimed invention is made from the perspective of a person of ordinary skill in the art. The issue is not whether the later-claimed invention would have been patentably distinct to you as jurors, to me as a judge, or the inventor himself.

You must also consider whether the person of ordinary skill would have had a reasonable expectation of success in obtaining the inventions claimed in the '868 and '698 patents or, alternatively, whether the level of predictability in the art was such that the person of ordinary skill would not have reasonably expected success.

Additionally, you should consider the objective indicators of non-obviousness that I described to you previously in explaining the test for obviousness. These included indicators such as a long felt need for the invention and failed attempts by others to make the invention.

As with ordinary obviousness, the invalidity of one claim because of obviousness-type double patenting does not affect the presumption of validity with respect to other claims in the same patent. Therefore, if you determine that one of the claims in Dr. Lin's '868 or '698 patents is invalid for obviousness-type double patenting, you are not automatically required to conclude that other claims in the '868 and '698 patents are invalid for obviousness-type double patenting. Similarly, because Roche's obviousness-type double patenting defense does not apply to Dr. Lin's '933, '422 and '349 patents, any decision you make regarding obviousness-type double patenting for claims of the '868 and '698 patents does not affect the validity of the '933, '422 and '349 patents.

Finally, it is Roche's burden to prove obviousness-type double patenting by clear and convincing evidence. Roche's burden is particularly heavy here because the United States Patent Office previously considered allegations of obviousness-type double patenting and determined that the process claims were not obvious over claims of the '008 patent.

Relying on the principles that I have just explained, you must determine if Roche has proven, by clear and convincing evidence, that any of the asserted claims in the '868 or '698 patents are invalid for obviousness-type double patenting. For each claim, if Roche has failed to prove obviousness-type double patenting, then you must find that claim valid.

SOURCES & AUTHORITIES:

In re Metoprolol Succinate Patent Litig., 2007 U.S. App. LEXIS 17463 (Fed. Cir. July 23, 2007); *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272 (Fed. Cir. 1992); *Gerber Garment Tech., Inc., v. Lectra Sys., Inc.*, 916 F.2d 683 (Fed. Cir. 1990); *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985); *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936 (Fed. Cir. 1992); *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *In re Baird*, 348 F.2d 974 (C.C.P.A. 1965); *In re Gladrow*, 406 F.2d 1376 (C.C.P.A. 1969); *In re Emert*, 124 F.3d 1458 (Fed. Cir. 1997); *Applied Material, Inc. v. Adv. Semiconductor Materials Am., Inc.*, 98 F.3d 1563 (Fed. Cir. 1996); *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569 (Fed. Cir. 1991); *Studiengesellschaft Kohle mbH v. N.*

Petrochemical Co., 784 F.2d 351 (Fed. Cir. 1986); *In re Research Corp. Techs., Inc. Patent Litig.*, 1999 U.S. Dist. LEXIS 22589, at *18-21 (D.N.J. 1999), *aff'd*, 10 Fed. Appx. 85 (Fed. Cir. 2001).

S. WRITTEN DESCRIPTION

The patent laws require that a patent application contain an adequate written description of each invention claimed in a patent. The adequacy of the written description must be analyzed claim by claim. In order to satisfy the written description requirement, the description must be sufficiently clear and informative so that a person of ordinary skill in the art would recognize, at the time of the application, that the applicant in fact possessed a means to make and use the claimed invention. A patent specification does not need to describe the accused product. The fact that an accused product contains features beyond those claimed in the patent does not establish inadequate description if the specification adequately describes the inventions as claimed in the patent. The patent laws do not require any particular form of written description, nor do they require that the exact words found in the claim be found in the specification.

To prove a claim invalid for lack of adequate written description, Roche must prove by clear and convincing evidence that the patent specification does not reasonably convey to a person of ordinary skill in the art that Dr. Lin in fact possessed a means to make and use the invention recited in a claim at the time the application was filed. Each claim must be assessed separately, on a claim-by-claim basis.

If you find that Roche has not proven by clear and convincing evidence that the patents-in-suit do not contain an adequate written description of the invention recited in a claim, then you must find that that claim is valid.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.2; *Enzo Biochem, Inc. v. Gen-Prove, Inc.*, 285 F.3d 1013, 1018 (Fed. Cir. 2002); *Turbocare Div. Of Demag Delaval Turbomachinery Corp. v. General Elect. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001); *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000); *Lampi Corp. v. Am. Power Prods., Inc.*, 228 F.3d 1365, 1377-78 (Fed. Cir. 2000); *Union Oil Co, of Cal. V. Atl. Richfield Co.*, 208 F.3d 989, 996-1001 (Fed. Cir. 2000); *Sun Tiger Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1334 (Fed. Cir. 1999); *Tronzo v. Biomet Inc.*, 156 F.3d 1154, 1158-60 (Fed. Cir. 1999); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478-80 (Fed. Cir. 1998); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

T. ENABLEMENT

A claim is said to be "enabled" when the specification of a patent provides enough detail to teach or enable persons skilled in the art of the invention to make and use the claimed invention without undue experimentation. This is referred to as the enablement requirement. If the patent does not enable a person skilled in the art to make and use the claimed invention without undue experimentation, then the claim is invalid. A patent does not need to enable the accused product, only the claimed invention. As with assertions of patent invalidity on other grounds, Roche bears the burden of establishing that the enablement requirement is not met for a claim by clear and convincing evidence.

To determine whether a patent enables a claim, you must look to the time the application for the patents at issue was filed. To be enabling, the patent disclosure must have allowed a person of ordinary skill in the art to practice the invention without undue experimentation. Because descriptions in patents are addressed to those skilled in the art to which the invention pertains, a patent need not expressly disclose information that is commonly understood by persons skilled in the art. Thus, a patent need not expressly state information that skilled persons would be likely to know or could obtain. The fact that some experimentation may be required for a skilled person to practice the claimed invention does not mean that a patent does not meet the enablement requirement. Moreover, a specification need not describe every conceivable embodiment of the invention. A specification need only enable those elements recited in the claims and is enabling so long as undue experimentation is not needed to make or use the invention recited in the claim.

A permissible amount of experimentation is that amount that is appropriate for the complexity of the field of the invention and for the level of expertise and knowledge of persons skilled in that field. It is a conclusion that is reached by weighing many factual considerations including: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (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 or unpredictability of the art; and (8) the breadth of the claims.

In this case, Roche contends that certain claims of the patents-in-suit are invalid for lack of enablement. If, after weighing the relevant factual considerations, you find that Roche has not proven by clear and convincing evidence that the written description of the patents-in-suit do not enable a person skilled in the art to make and use the invention recited in the asserted claims of those patents without undue experimentation, then you must find such claims to be valid.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.3; AIPLA Model Jury Instructions; *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc*., 326 F.3d 1226, 1234 (Fed. Cir. 2003); *Hybritech Inc. v. Monoclonal Antibodies, Inc*., 802 F.2d 1367, 1384 (Fed. Cir. 1986); *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 392 F. Supp. 2d 676, 681-82 (Fed. Cir. 2005); *Ralston Purina Co. v. Far-Mor Co*., 772 F.2d 1570, 1573-74 (Fed. Cir. 1985); *SRI, Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985); *White Consolidated Indus., Inc. v. Vega Servo Control, Inc*., 713 F.2d 788, 791 (Fed. Cir. 1983); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co*., 730 F.2d 1452, 1463 (Fed. Cir. 1984); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); *Warner-Lambert Co., v. Teva Pharms*., USA, Inc., 418 F.3d 1326, 1337 (Fed. Cir. 2005).

U. DEFINITENESS

The patent laws include certain requirements for the way patent claims must be written. Those laws require that patent claims be sufficiently clear that a person of ordinary skill in the field of the invention who read the claims at the time of the invention would be able to determine what will infringe the claims. If a patent claim does not meet this requirement, then the claim is said to be indefinite, and invalid on this basis. Whether or not a particular claim is definite must be analyzed on a claim by claim basis. The amount of detail required for a claim to be definite depends on the particular invention, the prior art and the description of the invention in the patent. Simply because claim language may be imprecise does not automatically mean that the claim is indefinite if the claim language is as precise as the subject matter reasonably permits as of the date of the invention.

You must determine on a claim-by-claim basis whether, as of the date of the invention, one of ordinary skill in the field reading the patent and the patent claims would have understood what combination of elements or steps would infringe the claim. Even if one needs to experiment so as to determine the limits of the claims of the patent, that would not necessarily be a basis for holding the claims invalid.

If you find that Roche has not proven by clear and convincing evidence that a claim in a patent-in-suit is indefinite, you must find that that particular claim is valid.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.5; *LUP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1357 (Fed. Cir. 2001); *S3 Inc. v. nVIDA Corp.*, 259 F.3d 1364, 1367 (Fed. Cir. 2001); *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376 (Fed. Cir. 2001); *Union Pac. Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001); *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1378-80 (Fed. Cir. 2000); *Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1378-82 (Fed. Cir. 1999); *Personalized Media Communications, L.L.C. v. Int'l Trade Comm'n*, 161 F.3d 696, 700 n.5, 705 (Fed. Cir. 1998); *In re Dossel*, 115 F.3d 942 (Fed. Cir. 1995); *Eiselstein v. Frank*, 52 F.3d 1035, 1040-41 (Fed. Cir. 1995); *In re Donaldson Co.*, 16 F.3d 1189 (Fed. Cir. 1994); *N. Am. Vaccine, Inc., v. Am. Cynamid Co.*, 7 F.3d 1571, 1579-80 (Fed. Cir. 1993); *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*,

842 F.2d 1275, 1280 (Fed. Cir. 1988); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1056 (Fed. Cir. 1988); *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984).

XV. [Provisional Instruction] INEQUITABLE CONDUCT[4]

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, also relies on information provided by the applicant with respect to the technical field of the invention and the prior art.

Applicants for patents have a duty of honesty and good faith in their dealings with the Patent and Trademark Office. Persons who have this duty include the inventor named on the patent application, persons who represent the inventor before the Patent and Trademark Office, and other persons involved in a substantial way with the application.

This duty of honesty and good faith exists from the time the application is filed and continues for the entire time that an application is pending before the Patent and Trademark Office. It requires that the applicant, the applicant's representatives, and others involved in a substantial way with the application fully disclose to the Patent and Trademark Office all information of which they are aware, that they are further aware is material to examination of the

[4] As noted in the Joint Pretrial Memorandum, D.I. No. 807, it is Amgen's position that inequitable conduct is an equitable issue that should be decided by the Court without an advisory jury. Amgen maintains this position, and offers these provisional jury instructions regarding the law of inequitable conduct in the alternative, should the Court decide to submit inequitable conduct issues to an advisory jury over Amgen's objection. Amgen reserves the right to contest the submission of inequitable conduct issues to the jury.

application, including material prior art. I will explain to you in a moment how you may determine whether or not information is material.

Failure to fulfill this duty of honesty and good faith with intent to deceive the Patent and Trademark Office is called inequitable conduct. When inequitable conduct occurs during the course of obtaining a patent, the patent is unenforceable. This means that the patent owner may not prevent others from using the invention covered by the claims of the patent.

Roche asserts that Amgen engaged in inequitable conduct by allegedly withholding from or misrepresenting to the United States Patent and Trademark Office information that was material to the examination of the patents-in-suit with intent to deceive the PTO. Roche must prove inequitable conduct by clear and convincing evidence. Roche must prove that the inventor, the inventor's representative, or someone involved in a substantial way with the application withheld or misrepresented information known to this person or persons to be material to the examination of the patents-in-suit, and that this person or persons acted with an intent to deceive or mislead the Patent Examiner.

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

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 11; 37 C.F.R. § 1.56 (2001), *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1318 (Fed. Cir . 2000; *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256-57 (Fed. Cir. 1997); *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 938-39 (Fed. Cir. 1990); *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) *(en banc); KangaROOS U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1576-77 (Fed. Cir. 1985).

A. MATERIALITY

In considering the issue of materiality, you must first determine whether or not information was withheld from or misrepresented to the Patent and Trademark Office. If you find that the inventor, the inventor's representative, or others involved in a substantial way with the application withheld or misrepresented information when applying for the patent, you must then determine whether or not that information was material.

Information is material if there is a substantial likelihood that a reasonable Patent Examiner would consider it important in deciding whether or not to allow the application to issue as a patent.

In other words, information is material if it establishes, either alone or in combination with other information, that a claim of the patent application more likely than not does not meet one of the requirements for a patent, such as the requirements that a patented invention be new, useful and non-obvious. Information is also material if it refutes or is inconsistent with arguments made to persuade the Examiner that the invention is entitled to patent protection. Information that is cumulative of, that is, that adds little to, other information the Examiner already had, is not material. Information is cumulative if it teaches no more than what a reasonable Examiner would consider to be taught by the prior art already before the PTO.

Legal arguments characterizing references submitted by the patent applicant cannot rise to the level of inequitable conduct. Legal arguments are not "material information" for purposes of an inequitable conduct charge. To satisfy the duty of disclosure, the applicant need not explain to the examiner the relevance of a particular piece of prior art, or otherwise take steps to ensure that the examiner actually considers those references that have been submitted.

If you find that material, non-cumulative information was not disclosed by a person having a duty of disclosure, you must next consider whether that person intended to mislead or deceive the Patent and Trademark Office.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 11.1; 37 C.F.R. § 1.56 (2000); *Li Second Family Ltd. P'ship v. Toshiba Corp*., 231 F.3d 1373, 1379-80 (Fed. Cir. 2000); *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc*., 225 F.3d 1315,1321-22 (Fed . Cir. 2000); *Life Tech., Inc. v. Clontech Labs., Inc*., 224 F.3d 1320, 1324-26 (Fed. Cir. 2000); *Union Oil Co. of Cal. v. Atl. Richfield Co*., 208 F.3d 989 (Fed. Cir. 2000); *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co*., 204 F.3d 1368, 1374 (Fed. Cir. 2000); *Elk Corp. of Dallas v. GAF Bldg. Materials Corp*., 168 F.3d 28, 31 (Fed. Cir. 1999); *Baxter Intl, Inc. v. McGaw, Inc*., 149 F.3d 1321 (Fed. Cir. 1998); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc*., 120 F.3d 1253, 1257-59 (Fed. Cir. 1997); *Regents of the Univ. of California v. Eli Lilly & Co*., 119 F.3d 1559, 1574-75 (Fed. Cir. 1997); *Litton Sys., Inc. v. Honeywell, Inc*., 87 F.3d 1559, 1570-71 (Fed. Cir. 1996); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178-79 (Fed. Cir. 1995); *Environ Prods., Inc. v. Total Containment, Inc*., 951 F. Supp. 57, 61 (E.D. Pa. 1996); *Fiskars v. Hunt*, 221 F.3d 1318, 1326-1327 (Fed. Cir. 2000); *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006).

B. INTENT

Roche must prove intent to deceive the PTO by clear and convincing evidence. Evidence relevant to the question of intent to deceive or mislead the Patent and Trademark Office includes any direct evidence of intent, as well as evidence from which intent may be inferred. You may infer intent from conduct. That means you may conclude that a person intended the foreseeable results of his or her actions. You should decide whether or not to infer an intent to deceive or mislead based on the totality of the circumstances, including the nature of the conduct and evidence of the absence or presence of good faith.

Intent to deceive cannot be inferred solely from the fact that information was not disclosed to the PTO; there must be a factual basis for a finding of deceptive intent. Where the only evidence of intent is a lack of a good faith explanation for the nondisclosure, this cannot constitute clear and convincing evidence of an intent to deceive.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 11.2; *Li Second Family Ltd. P'ship v. Toshiba Corp.*, 231 F.3d 1373, 1379-80 (Fed. Cir. 2000); *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321-22 (Fed. Cir. 2000); *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1374 (Fed. Cir. 2000); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120* F.3d 1253, 1257-59 (Fed. Cir. 1997); *Refac Int'l Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576 (Fed. Cir. 1996); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180-81 (Fed. Cir. 1995); *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) *(en banc); Allied Colloids Inc. v. Am. Cyanamid Co*., 64 F.3d 1570, 1578 (Fed. Cir. 1995); *Purdue Pharma L.P. v. Endo Pharms., Inc*., 438 F.3d 1123, 1134 (Fed. Cir. 2006); *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co*., 439 F.3d 1335, 1341 (Fed. Cir. 2006); *eSpeed v. BrokerTec USA*, 417 F. Supp. 2d 580 (D. Del. 2006) *aff'd* on other grounds, 480 F.3d 1129 (Fed. Cir. 2007); *Golden Valley v. Weaver Popcorn*, 837 F. Supp. 1444, 1477 (N.D. Ind. 1992), *aff'd without opinion,* 11 F.3d 1072 (Fed. Cir. 1993).

C. BALANCING OF MATERIALITY AND INTENT

If you find that Roche has proved by clear and convincing evidence that material information was withheld or misrepresented and that there was an intent to deceive or mislead the Patent Examiner, you must then balance the degree of materiality and the degree of intent to determine whether or not the evidence is sufficient to establish clearly and convincingly that there was inequitable conduct.

The higher the materiality of the withheld or misrepresented information is, the lower the intent needed to establish inequitable conduct, and vice versa. Materiality ranges from an objective "but-for" test (where there was a misrepresentation that was so material that the patent should not have issued) at the highest level of materiality to the "reasonable examiner" test (as I previously explained to you) at the lowest threshold.

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 11.3; *Li Second Family Ltd. P'ship v. Toshiba Corp.*, 231 F.3d 1373, 1378 (Fed. Cir. 2000); *Barer Intl, Inc. v. McGaw, Inc*., 149 F.3d 1321, 1327 (Fed. Cir. 1998); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc*., 120 F.3d 1253, 1256 (Fed. Cir. 1997); *Molins PLC v. Textron, Inc*., 48 F.3d 1172, 1178 (Fed. Cir. 1995); *FMC Corp. v. Manitowoc Co*., 835 F.2d 1411, 1416 (Fed. Cir. 1987); *Am. Hoist & Derrick Co v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363-64 (Fed. Cir. 1984); *Digital Control, Inc. v. Charles Machine Works*, 437 F.3d 1309, 1315-16 (Fed. Cir. 2006).

Respectfully Submitted,

Date: August 31, 2007

AMGEN INC.,
By its attorneys,

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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 and paper copies will be sent to those indicated as non-registered participants on August 31, 2007.

/s/ Michael R. Gottfried
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