UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GMBH, a German Company, and HOFFMANN LA ROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 1:05-CV-12237 WGY

AMGEN INC.'S [PROPOSED] REVISED FINAL JURY INSTRUCTIONS

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I – IX PRELIMINARY INSTRUCTIONS

Not relevant for final instructions.

X. INTRODUCTION[1]

I am going to 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 certain conclusions within the legal framework as I describe it.

So we start this morning with my explanation as to the law which governs this particular case. You must listen carefully now because you are required to apply and follow my instructions on the law. You can ask questions, but please keep your questions until you go back into your deliberation room and talk among yourselves so that collectively you form a question. When deliberating, if you don't understand any aspect of the law, write out your question and there will be a court security officer outside the door here. Give the question to the court security officer, and if I believe I can clarify the question, we'll have you back in the courtroom and I will explain it better. Do not hesitate to do that. If justice is to be done here you must understand and apply the law in the case, and it is my job to teach and explain the applicable law to you.

I start my charges by a brief explanation of what our separate roles are, the nature of the evidence that has been presented, the tools you have to work with, and 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 Corp.* Instructions"), p. 3.

[1] Proposed Instructions I - IX relate to pre-trial instructions and have not been included in these post-trial instructions. The numbering system of Amgen's original instructions has been retained. [Dkt. #918] Where Amgen has made a material change to the instruction, it is designated as "modified."

A. ROLE OF THE JURY [MODIFIED]

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

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 sift 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, and you must be unanimous as to a no. Unanimous means that you all come genuinely to agree. And you'll deliberate. Not that seven 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 listen to the lawyers to better understand the evidence. You may look at the demonstrative aids to better understand the evidence. But the evidence is what governs and you, and you alone, decide what you believe about the evidence.

Now, I am the judge of the law. I simply mean to point out to you that in this courtroom I am 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 am going to tell you who has to prove what in this case. I am going to tell you the burden of proof that each side bears. But you can't add to the parties' burden. 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, what the burden of proof is, and what the standard of proof is to meet that burden. 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.

Finally, as I told you during this trial, my role is also to decide what remedy will be available, if any. You should not speculate about any remedy in this case, or what effect any remedy might have in this case. You should not consider issues of whether patients will or will not have access to MIRCERA, or whether patients should or should not have a choice between Amgen's products and Roche's product (such considerations should not enter your deliberations on any issue in this case). I alone will make that determination. 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.

Source & Authorities

Read Corp. Instructions, pp. 4-6.

B. EVIDENCE

The first category of evidence for you to consider is the testimony of the witnesses. You have the power to believe everything that any witness said to you here from the witness stand. 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. You believe one or believe the other. You can decide where the truth lies.

How do you do it? You use your common sense as reasonable men and women. You may use everything you know about the witness. What was the opportunity of the witness to observe, to comprehend, to understand, to recall those matters about which the witness testified? Is the testimony of the witness backed up, or corroborated, by other evidence in the case? Is it backed up by exhibits or depositions or any other evidence in the case? Or, does the other evidence in the case undercut, or take away from the testimony of the witness who was before you? 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?

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

Source & Authorities

Read Corp. 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 any opinion given by any expert witness you want to look at what underlies their opinion. 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, you may disbelieve them or you may believe them in part.

Sources & Authorities

Read Corp. Instructions pp. 7-8.

2. Testimony by Deposition

Now, not all the witnesses in this case testified live here in court. Some witnesses, because of geographical distance from here, or for whatever other reason, testified by way of videotaped deposition or lawyers reading portions of a deposition. The fact that a witness testifies by way of deposition does not make that witness any more believable or less believable than a witness testifying in court. Like any other testimony in the case, you may believe it, disbelieve it, or 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 Corp. Instructions, pp. 9-10.

3. Exhibits

In this case 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.

Exhibits are like the testimony of witnesses and your powers are exactly the same. That is, you may read, look at or view an exhibit. 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 is not genuine, or if you believe that even though this may be genuine, it is either inaccurate or it doesn't help you, disregard it. That's your power. You are the judges of the facts. And as with any other evidence in the case you can take part of an exhibit and say, well, this is persuasive, but another part is not persuasive.

Sources & Authorities

Read Corp. Instructions pp. 9-10.

4. Stipulations

Withdrawn.

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. You can use your common sense as reasonable men and women and 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 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. She sees that the grass is knocked down in an irregular course through the field. And suppose you believe that testimony. From that alone you could infer that 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 that something go through the field, but there's a reasonable inference something went through that field.

Now that is 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. 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 what went through the field unless there's other evidence. Guessing about what went through the field would be speculation – not a reasonable inference.

Okay, we've talked about our roles and the tools that you have to resolve the case. I want to say a few words about what's not evidence in the case, not to emphasize it but just to 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, or how you judge them as speakers or presenters of witnesses. They've done their job, and they will later on this morning keep doing it for their respective clients. 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.

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 I am the judge of the law, I have nothing to say about the facts of 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 Corp. Instructions pp. 13-14.

XI. BURDENS OF PROOF [MODIFIED]

In this case, as with all other cases, facts must be proved by a required standard of evidence, known as the "burden of proof." It's not a question of how much evidence there is on one side or the other, it's a question of what you believe the evidence proves and whether evidence that convinces you unanimously that the party that has the burden of proof on an issue has met that burden. In a patent infringement 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, called the "clear and convincing evidence" standard, applies to Roche's claim that the patents are invalid. Clear and convincing evidence is evidence which produces in your mind an abiding conviction that the truth of the factual contentions is highly probable. As I have said repeatedly, this standard applies to the defendant Roche's invalidity defenses. As I instructed you at the start of the case, Roche has to make things clear to you. If it is not clear to you, then you cannot declare the patents invalid. Roche also has got to present convincing evidence that the claims are invalid. Convincing evidence leaves you with the abiding conviction that the truth of the factual contentions is highly probable.

The second burden of proof standard, called "fair preponderance of the evidence" standard, applies to Amgen's claims that Roche infringes Amgen's patent claims. A "fair preponderance of the evidence" means that you must be persuaded that it is more likely to be true than something else. In other words, if evidence regarding infringement by Amgen was placed on a scale, you must find that the scale tips in favor of Amgen by just the slightest bit in order for Amgen to meet its burden on its infringement case.

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 applies to criminal cases, and not to civil cases like this patent infringement case. Therefore, put "beyond a reasonable doubt" out of your mind.

Sources & Authorities

Read Corp. Instructions pp.15-16; Fed. Cir. Bar Assoc. Model Patent Jury Instruction 1.1; *Pfizer, Inc. v. Apotex, Inc.* 480 F.3d 1348, 1360 (Fed. Cir. 2007).

XII. 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 machine 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 fastens the legs to the tabletop. The tabletop, legs and glue are each a separate element of the claim.

Source & 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 as well as the glossary in your juror notebook with the construction of the claims. The claims are at the end of the '933 patent, starting in column 38. The claims of the '933 patent, the '868 patent, the '698 patent, the '349 patent and the '422 patent that are at issue in this case are shown on the verdict form.

[Read constructions from juror notebook glossary]

Sources & Authorities

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 7.1; *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384-91 (1996).

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 elements of the other claim or claims to which it refers, as well as the additional elements 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 either claims 3, 4, 5, or 6 must be read together along with the words of claim 7. Here, Amgen is only asserting claim 7 as it depends from claim 3. So you must read the words of claim 7 together with the words of claim 3. You need not consider claim 7 as it depends from claims 4, 5, or 6.

Sources & Authorities

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 7.2; 35 USC § 112 ¶ 4 (1984); *Globetrotter Software, Inc. v. Elan Computer Group, Inc.*, 236 F.3d 1363, 1369-70 (Fed. Cir. 2001).

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. Claims which describe a product by reference to the source from which the product is obtained are called "source" claims. Claim 1 of the '422 patent is a product claim with a source element. (The "purified from mammalian cells grown in culture" element of '422 Claim 1 "only speaks to the source of the EPO and does not limit the process by which the EPO is expressed.")

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); *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1329 (Fed. Cir. 2003).

D. "COMPRISING" CLAIMS

The beginning words, or preamble, of a patent claim may 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 beyond those stated in the claim.

Let's take the example of a claim to a table. If the claim recites a table "comprising" a tabletop, four legs and glue, the claim will cover structures that contain other structures, such as a fifth leg or wheels on the legs.

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); *Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1327-29 (Fed. Cir. 1999).

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. The construction of certain claim terms is supplied in your juror notebooks.

Sources & Authorities

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

XIII. INFRINGEMENT [MODIFIED]

A. INFRINGEMENT GENERALLY [MODIFIED]

This is the test for infringement: does the alleged infringing product contain every element of the patent claim? If only one element of the claim is missing from the accused product or process, there is no infringement, even if all the other elements of the claim are present.

If the accused product contains other things beyond the elements of the claim, or if the accused process includes other steps beyond those stated in the claim, it still infringes so long as the accused product or process has every element or step of the claim. If the accused product or process is improved, made better or more sophisticated, it still infringes so long as it has every element or step of the claim. Miss an element and there is no infringement. But add to the elements or make the elements better, and there is still infringement so long as Roche's MIRCERA has every element of an Amgen patent claim.

To prove infringement, it is Amgen's burden to prove by a fair preponderance of the existence that MIRCERA or the process by which MIRCERA is made includes every element of an Amgen product or process claim.

Amgen's burden is not clear and convincing proof. Rather, it is by a fair preponderance of the evidence. On all the evidence you believe does the evidence tend to prove that it is more likely than not that Roche's MIRCERA product infringes every element of the claim? That's infringement.

When you get to the dependent claims, you must consider both the referenced claim and the dependent claim together. If you find that that referenced claim is infringed, you still must separately determine whether the claim which depends from it will also be infringed. You have to go back to the referenced claim, and consider every element of the referenced claim plus the dependent claim.

Sources & Authorities

Ethos Techs., Inc., v. RealNetworks, Inc., No. 02-11324 (4/12/06 Trial Tr. at 2694:21-2697:16; 2710:2-11); *Read Corp.* Instruction, p. 26; Fed. Cir. Bar. Assoc Model Patent Jury Instruction 8.10.

1. Proposed Instruction for Infringement of '933 Claims 3, 7-9, 11 and 12

'933 claims 3, 7-9, 11 and 12 are product-by-process claims or depend from product-by-process claims. A product-by-process claim describes a product by reference to the process by which the product is made, not by reference to the particular structure or function of the claimed product. In order for MIRCERA to infringe a product-by-process claim, you must find that Amgen has proved by a fair preponderance of the evidence that MIRCERA contains the claimed product made by the same process described in the claim. The fact that MIRCERA may contain additional elements, including elements not made by the process recited in the claims, does not mean that MIRCERA does not infringe the claim. Like a product claim, a product-by-process claim is still infringed by a product that meets every element of claim, even if the accused product also contains elements beyond those stated in the claim.

Sources & Authorities:

Fed. Cir. Bar Assoc. Model Patent Jury Instructions 8.9; *Atl. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 837 (Fed. Cir. 1992); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991); *Northern Telecom Ltd. v. Samsun Elec. Co.*, 215 F.3d 1281 (Fed. Cir. 2000); *Suntiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1336-37 (Fed. Cir. 1999); *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703 (Fed. Cir. 1983); *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482-83 (Fed. Cir. 1984); *Stiftung v. Renishaw PLC*, 945 F .2d 1173, 1177-79 (Fed. Cir. 1991)

2. Proposed Instruction for Infringement of '868 Claims 1-2, '698 Claims 6-9, and '349 Claim 7

'868 claims 1 and 2, '698 claims 6-9, and '349 claim 7 are process claims. Amgen contends that Roche will infringe the asserted process claims 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 elements of the asserted

process claims. The fact that MIRCERA may contain elements beyond those contained in the product of Amgen's claimed process, or that Roche uses steps beyond those recited in a patented process claim to produce MIRCERA, does not mean that Roche's process does not satisfy all of the elements of an asserted process claim. An accused process that uses every step of the claimed process infringes the claim regardless of whether other steps are used as well, or the imported product contains additional elements or features beyond those produced by the claimed process.

If you find that Roche's process for making EPO satisfies every element of an asserted process claim, you must then determine whether the EPO product of the claimed process is materially changed by Roche prior to its importation of MIRCERA into the United States. If you find, for example, that the EPO product contained in MIRCERA is materially changed by the attachment of polyethylene glycol, then Roche will not infringe the asserted process claim. A material change is a significant change to the structure and properties of the EPO product, which changes the basic utility of the EPO product. The attachment of additional structure to the EPO product of the claimed process is not a material change to the product of the process unless it changes the structure and properties of the EPO product in a way that alters the basic utility of the EPO product. Even a significant change to the structure and properties of the EPO product will not be a "material change" if it would not be possible or commercially viable to make MIRCERA but for the use of Amgen's patented process.

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

Therefore, in order to find that Roche will infringe an asserted process claim, you must find that (1) Roche's process for making MIRCERA in Germany includes every element of an asserted process claim, (2) the EPO product of the claimed process is not materially changed by Roche, and (3) the EPO product in MIRCERA is not a trivial and non-essential component of MIRCERA.

Sources & Authorities

35 U.S.C. 271(g); *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703 (Fed. Cir. 1983); *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482-83 (Fed. Cir. 1984); *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, 1575 (Fed. Cir. 1996).

3. Proposed Instruction for Infringement of '933 Claims 11 and 14

The act of encouraging or inducing others to infringe a patent is called "inducing infringement." In this case, Amgen asserts that Roche will induce others to infringe the methods of treatment claimed in claims 11 and 14 of the '933 patent as soon as it receives regulatory approval to sell MIRCERA in the United States.

There can be no inducement of infringement unless someone will directly infringe the patent. Thus, in order to prove that Roche will induce another person to infringe '933 claims 11 and 14, Amgen must prove by a fair preponderance of the evidence that another person will directly infringe claims 11 or 14 and that Roche will induce that infringement.

A person induces patent infringement if he or she purposefully causes, urges or encourages another to perform an act that infringes a patent claim and knows or should have known that his or her actions would induce actual infringement. Inducing infringement cannot occur unintentionally.

Amgen asserts that Roche will induce infringement of '933 claims 11 and 14. Amgen must prove by a fair preponderance of the evidence that:

Roche has or will encourage or instruct another person to use the method described in '933 claim 11 or 14.

Roche knows of the '933 patent.

Roche knows or should know that its encouragement or instructions will induce others to use MIRCERA in a manner that will infringe '933 claim 11 or 14.

The other person will use MIRCERA to perform the method described in '933 claim 11 or 14.

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); *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F.3d 1293 (Fed. Cir. 2006) (en banc); *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); *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); *Joy Tchs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774-76 (Fed. Cir. 1993); *DSU Medical Corp. v. JMS Co.* , 471 F.3d 1293, 1306 (Fed. Cir. 2006).

B. DOCTRINE OF EQUIVALENTS[2] [MODIFIED]

The law says this: A copier who changes the invention a bit may still be guilty of infringement. And that's known as infringement by the doctrine of equivalents. If you build what's really the equivalent of the patented invention, the law will hold that to be an infringement.

What must you do? You must look at the claim again. We always start with the claim. And then ask yourselves this. If there is a particular element in the claim that is literally missing in Roche's MIRCERA, there may still be infringement under the doctrine of equivalents. Ask yourself with respect to each claim element, considered separately, whether Roche's MIRCERA product contains the claimed element or an equivalent thereto that performs substantially the same function, in substantially the same way, to achieve substantially the same result, as the claimed element.

If Amgen persuades you by a fair preponderance of the evidence that MIRCERA does, then MIRCERA infringes by the doctrine of equivalents.

Sources & Authorities

Read Corp. Instructions, pp. 28-29; *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950).

[2] This instruction expands on the previous subsection B regarding the necessity for every claim element must be present, either literally or under the doctrine of equivalents.

C. INFRINGEMENT OF OPEN-ENDED OR "COMPRISING" CLAIMS

This instruction has been incorporated into subsection A.

D. INFRINGEMENT OF DEPENDENT CLAIMS

This instruction has been incorporated into subsection A.

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

This instruction has been incorporated into subsection A

F. INFRINGEMENT AND IMPROVEMENTS TO PATENTED INVENTION

Roche contends that MIRCERA and the process by which it is produced constitute improvements to the inventions claimed in the Lin patents.

Proof of this fact does not necessarily mean that MIRCERA or the process by which it is produced does not infringe Amgen's asserted patent claims. If MIRCERA contains every element of an asserted product or product-by-process claim, it infringes that claim regardless of whether it contains additional elements beyond those stated in the claim, or improves upon the invention described in the claim. Similarly, if the process by which Roche produces MIRCERA includes steps beyond those stated in the claim, it still nonetheless infringes the claim if it uses every step stated in the claim.

Roche may infringe Amgen's patents, whether or not Roche has a patent on MIRCERA. 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 MIRCERA or the process by which it is produced include every element 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, despite what Roche contends to be improvements.

Sources & Authorities

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 8.11; *Temco Elec. Motor Co. v. Apco Mfg. Co.*, 275 U.S. 319 (1928); *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); *Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1580-81 (Fed. Cir. 1984).

G. DETERMINATION OF INFRINGEMENT

This instruction has been incorporated into subsection A.

H. INDUCEMENT

This instruction has been incorporated into subsection A.

XIV. VALIDITY

Each patent claim is presumed to be valid. Roche has the burden to prove to you by clear and convincing evidence that each of the asserted patent claims is invalid. In addition to the presumption of validity, when no prior art other than that which was considered by the United States Patent Office examiner is relied on by a challenger, the challenger has the added burden of overcoming the deference that is due to United States Patent Office examiners, who are presumed to have properly performed their job and to have some expertise in doing so.

A. PRESUMPTION OF VALIDITY

Under the law, each of Amgen'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. 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 each of those patents was 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.

If you find that the United States Patent Office considered the prior art references 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.

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 any other claim 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 to persuade you by clear and convincing evidence that each asserted claim in each patent-in-suit 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 American Hoist & Derrick Co. v. Sowa & Sons, 725 Fed. Cir. 2d 1350, 1359 (Fed. Cir. 1984); 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.*, 126 F.Supp.2d 69, 105 (D. Mass 2001).

B. PATENT VALIDITY - GENERALLY

For Roche to prove that an asserted claim is invalid, Roche must prove that the invention as 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 "non-obvious" 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 claim must meet three additional requirements to be valid. First, the patent specification must provide a complete written description of the claimed invention. Second, the patent specification 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 requirement in more detail as they specifically relate to this case.

In this case, Roche has challenged the validity of the patents-in-suit on some but not all of these grounds. To successfully challenge the validity of an asserted patent claim, Roche must prove, by clear and convincing evidence, that the claim is invalid, and it must do so on a claim-by-claim basis.

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.*, 126 F.Supp.2d 69, 105 (D. Mass 2001).

C. PRIOR ART: DEFINITION [MODIFIED]

Under the patent laws, a person is entitled to a patent only if the invention claimed in the patent is new and not obvious in light of what came before the date the invention was made.

That which came before the date of invention is referred to as the "prior art". In order to be prior art, it must have been publicly available, without restriction, to the segment of the public that was 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, whether the invention at issue in this case 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.

Let me pause for a moment. I've been talking about prior art. Art that is dated after Amgen's invention date is not prior art and cannot be used to prove prior art. You should not

consider such art when determining the issues of anticipation and obviousness. You should further keep in mind that the '008 patent cannot be prior art as a matter of law. And work by Amgen employees on the inventions is also not prior art. As to the other references or work that that you have heard about during this case, it is up to you to determine whether they are prior art. That's factual. Just because they've called these things out as prior art, and I made mention of them, that's just to focus you. It's up to you to decide whether they're prior art. That's factual, not for me to decide.

It is Roche's burden to show by clear and convincing evidence that prior to the date of Dr. Lin's inventions, 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; 35 U.S.C.§ 103(c).

D. CONCEPTION AND REDUCTION TO PRACTICE [MODIFIED]

The date on which the inventor made the invention is called the "date of invention." In this case, the claims of the patents define several different inventions, each of which may have different dates of invention. The date of an invention is the first date it was conceived if it is followed by a diligent reduction to practice. Here, Amgen contends that the dates of the DNA sequence of human EPO was conceived and reduced to practice no later than October 1983 and that all of Dr. Lin's other inventions were conceived and reduced to practice before September 1984.

Consequently, you must separately consider as to each claimed invention, the date of that invention, and thus the date before which a reference may qualify as prior art.

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 claimed purpose.

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 [MODIFIED]

An invention made by another person before the inventor made the invention claimed in the patent may be prior art to the claimed invention, 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. This showing of invention by another person must be corroborated by independent evidence.

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.

Sources & 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 Dr. Lin filed his original priority patent application for the issued patent. 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 [MODFIIED]

Roche contends that claims 3, 7-9, 11, 12 & 14 of the '933 Patent are invalid under the doctrine of anticipation. 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. A party challenging the validity of a patent must prove anticipation by clear and convincing evidence.

A claim is anticipated only if each and every element as set forth in the claim is disclosed, either expressly or inherently, in a single prior art reference.

To establish that an element of a claim is inherent in the prior-art reference, even if not explicitly set forth, the evidence must make it clear that the missing descriptive matter is necessarily present in the thing described in the prior art, and that it would be recognized to have been present in the prior art by persons of ordinary skill in that art at the time of Amgen's invention. A mere possibility or probability that the missing element is present in a prior art embodiment is not sufficient to prove that it was inherently present. In order for you to conclude that something not expressly described in a prior art reference was present in that prior art reference at the time of the invention, it must be necessarily present. That it, it must necessarily and naturally result from the operation of the prior art reference as taught by the reference.

To establish that a prior art reference anticipates a claimed invention, the prior art reference must also enable one of ordinary skill in the art to make and use an embodiment of the claimed invention without undue experimentation. What does "enabled" mean? It means that the prior art reference must provide sufficient guidance for one of ordinary skill in the art at the time of the invention to make and use an embodiment of the claimed invention without access to or use of the patent.

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 1361, 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 69, 105-06, *aff'd in pertinent part*, 314 F.3d 1313 (Fed. Cir. 2003); *American Hoist & Derrick Co.*, 730 F.2d 1452, 1463 (Fed. Cir. 1984); *Ethos Techs., Inc., v. RealNetworks, Inc.*, No. 02-11324 (4/12/06 Trial Tr. at 2694:21-2697:16); *Amgen Inc. v. F. Hoffmann-La Roche*, Civ. Action No. 05-12237, Doc. No. 613 July 3, 2007 Memorandum and Order at 18; *In 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); Manual of Patent Examining Proc. § 2144.04; Fed. Cir. Bar Assoc. Model Patent Jury Instruction 10.6.1; 35 U.S.C. § 102.

I. ANTICIPATION – EFFECT OF PROCESS OR SOURCE LIMITATIONS [MODIFIED]

A product may be claimed by reference to the source or process from which it is obtained without regard to the structure of the product if the source or process elements help to distinguish the claimed product over prior art. Product claims may include process steps to wholly or partially define the claimed product. A product claim that contains source elements or product-by-process elements must be given the same consideration as claims having traditional product characteristics.

To establish that the source element of '422 claim 1 does not distinguish the claimed invention over the prior art, Roche must first prove by clear and convincing evidence that the claimed product is not novel. That is, Roche must prove that a product identical to the claimed product previously existed in the prior art. So, for example, Roche must prove by clear and convincing evidence that Dr. Goldwasser's EPO product purified from urine is identical in structure and function to "human EPO purified from mammalian cells grown in culture," as recited in 422 claim 1.

Similarly, to establish that the process elements of claims 3, 7-9, 11, 12 and 14 of the '933 patent do not distinguish the claimed inventions over the prior art, Roche must first prove by clear and convincing evidence that Dr. Goldwasser's EPO product purified from urine is identical in structure and function to the products claimed in each of those claims.

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); *Sandt Technology v. Resco*, 264 F.3d 1344, 1350 (Fed. Cir. 2001); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996); *Sinskey v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 494, 498-99 (Fed. Cir. 1992); *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1445 (Fed. Cir. 1984); *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1567 (Fed. Cir. 1983).

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 [MODIFIED]

As I have said, a patent claim is presumed valid. If you find that the differences between a claim and the prior art are such that the claimed invention as a whole would have been objectively obvious to a person having ordinary skill in the art at the time the invention was made, the claim is invalid for obviousness. You must determine whether each asserted claim would have been obvious or not on a claim-by-claim basis. For each claim, Roche must prove by clear and convincing evidence that the inventions as claimed would have been obvious as of the date of invention.

In reaching your decision you should consider:

1) the scope and content of the prior art;
2) the differences between the claimed invention and the prior art;
3) the level of ordinary skill in the art; and
4) the evidence, if any, of non-obviousness.

Important evidence of non-obviousness includes:

1) evidence of the commercial success of products covered by the patent claims or made by a process covered by the patent claims,
2) evidence of a long-felt but unmet need for the invention,
3) evidence that others tried but failed to accomplish the result achieved by the invention;
4) whether unexpected results were achieved by the invention;
5) contemporaneous expression of surprise or acclaim by those skilled in the art following the invention;
6) praise of the invention by people in the field;
7) the taking of licenses under the patent by others; and
8) copying of the invention by others in the field.

What constitutes "prior art" for the purposes of determining obviousness is a factual matter for you, the jury, to decide. Just because someone, even me, refers to something as "prior art" does not mean that it is in fact prior art. It is up to you to decide what is and is not prior art.

You are not to consider whether the claimed inventions would have been obvious to you as jurors, to me as a judge, to a genius in the field of the inventions, or to any one of the witnesses as individuals. Rather, you must consider whether each claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time it was made. In making that determination, you must decide whether a person of ordinary skill in the art at the time of the invention would in fact have had a reasonable expectation of successfully making and using the claimed invention. You must consider obviousness from the objective perspective of the knowledge and skill then available to a person of ordinary skill in the art.

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 patents. What may seem obvious in hindsight may not appear so at the time of the invention to those skilled in the art at the time. You cannot use the patents as road maps for selecting and combining items of prior art. You must instead objectively put yourself in the place of a person of ordinary skill in the field at the time the inventions were made and consider what was known and not known to that person before the inventions were made.

You are not to consider the subjective beliefs of the inventor, Dr. Lin, with respect to what he thought to be obvious at the time he conceived of the inventions. Nor may the work of other Amgen scientists in carrying out certain elements of the claimed inventions be considered for the purpose of determining whether the claims were obvious. You are not to consider how the inventions were made, that is, whether they were the result of extensive research or of extraordinary insights.

A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was separately known in the prior art. Most inventions rely upon and utilize building blocks known in the art. New and non-obvious discoveries often involve

combinations of what, in some sense, is already known. You cannot find obviousness simply by indiscriminately combining prior art references. For an invention to be obvious, a person of ordinary skill in the art must have had some reason at the time to combine prior art references in a way that would result in the claimed invention.

An invention is not invalid for obviousness simply because one skilled in the act would have been motivated to try numerous possible alternatives until one possibly arrived at a successful result. An invention is not obvious if the solution to a problem entails many different parameters, and the prior art gave no indication of which parameters were critical or no direction as to which of many possible choices would likely prove to be successful. Likewise, an invention is not obvious where all that was suggested was to explore a new technology or general approach that seemed to be a promising field of experimentation.

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 successful practice of the claimed invention would have been obvious to a person of ordinary skill in the art at the time the invention was made. The "obvious to try" standard applies only if 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.

Sources & Authorities

Adapted from Instructions in *Ethos Technol., Inc. v. Realnetworks, Inc.*, Civil Action No. 02-11324-WGY, pp. 2697-2698; 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); *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734 (2007); *In re Deuel*, 51 F.3d 1552, 1557-60 (Fed. Cir. 1995); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 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*) In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988) *quoted* in *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); *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356-57 (Fed. Cir. 2000); *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).

L. OBVIOUSNESS: SCOPE AND CONTENT OF THE PRIOR ART

This instruction is incorporated into other instructions or is withdrawn.

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

This instruction is incorporated into other instructions or is withdrawn.

N. OBVIOUSNESS: LEVEL OF ORDINARY SKILL

This instruction is incorporated into other instructions or is withdrawn.

O. OBVIOUSNESS: MOTIVATION TO COMBINE

This instruction is incorporated into other instructions or is withdrawn.

P. OBVIOUSNESS: OBJECTIVE INDICATIONS CONCERNING OBVIOUSNESS

This instruction is incorporated into other instructions or is withdrawn.

Q. OBVIOUSNESS: SUMMARY

This instruction is incorporated into other instructions or is withdrawn.

R. OBVIOUSNESS-TYPE DOUBLE PATENTING

This issue is not to be decided by the jury and this instruction is withdrawn.

S. WRITTEN DESCRIPTION [MODIFIED]

Roche contends that some, but not all, of the claims in Amgen's patents lack adequate written description. To prevail, Roche must prove to you by clear and convincing evidence that each of these claims is invalid for failing to meet the written description requirement.

The patent laws require that a patent specification as a whole contain an adequate written description of each invention claimed in the patent to ensure that the inventor was in possession of the claimed invention at the time the patent application was filed. The adequacy of the written description of each claim must be analyzed claim by claim from the perspective of one skilled in the art. In order to satisfy the written description requirement, the description must be sufficiently clear that a person of ordinary skill in the art would recognize that the applicant in fact possessed a means to make and use the claimed invention at the time of the application. 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, so long as the patent specification as a whole adequately conveys to one skilled in the art that the inventor in fact possessed the claimed invention at the time the application was filed.

The written description requirement does not insist that the exact words found in the claims be found in any portion of the specification, whether in its words, structures, figures, diagrams, formulas, or other portions. You must consider not only what the specification states or illustrates explicitly, but also what it describes inherently. You should conclude that the specification inherently describes a claim element if the person of ordinary skill in the art would have recognized, at the time the patent application was filed, that the description disclosed the element, even if it is not stated in so many words.

A patent specification must describe the invention that is claimed, not the accused product. An accused product may contain features in addition to those claimed in the patent without causing the description in the patent specification to be inadequate.

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); *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1423 (Fed. Cir. 1987).

T. ENABLEMENT

Roche contends that claim 7 of the '349 patent is invalid for lack of enablement. To prevail, Roche must persuade you by clear and convincing evidence that the written description of the ‘349 patent did not enable a person skilled in the art as of 1984 to make and use the invention claimed in claim 7 without undue experimentation.

A claim is said to be “enabled” when the specification of a patent provides sufficient information to teach or enable persons skilled in the art of the invention to make and use the claimed invention without undue experimentation. 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. As with assertions of patent invalidity on other grounds, Roche bears the burden of proving by clear and convincing evidence that the enablement requirement was not met.

To determine whether a patent specification is enabling, you must consider the time the application for patent was filed and decide whether the patent specification as a whole allowed a person of ordinary skill in the art at that time to practice the invention without undue experimentation. Because the patent specification is 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. In addition, 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 covered by the claims and is enabling so long as undue experimentation is not needed to make or use the invention as claimed.

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.

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 [MODIFIED]

Roche contends that claims of the '422, '933, '349, and '868 patents are invalid for failing to satisfy the definiteness requirement. To prevail, Roche must persuade you by clear and convincing evidence that these claims are indefinite because a person of ordinary skill in the art would not understand what is, and what is not, covered by the claims.

The patent laws include certain requirements for the way patent claims must be written. Claims must be sufficiently clear that a person of ordinary skill in the field of the invention reading the claim is able to determine what products or activities would infringe the claim, and what products or activities would not infringe the claim. If a patent claim does not meet this requirement, then the claim is indefinite and invalid. The detail required for a claim to be definite depends on the particular invention, the state of the art at the time of the invention and the description of the invention in the patent specification. Simply because claim language may not appear to be precise today does not automatically mean that the claim is indefinite. The claim language need only be as precise as the subject matter permitted at the time of the invention.

You must determine whether one of ordinary skill in the field reading the patent as of the date of the invention would understand what is claimed when the claim is read in light of the patent specification as a whole. 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.

Sources & Authorities

Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F.Supp.2d 69, 137-138 (D. Mass. 2001); 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).

XV. INEQUITABLE CONDUCT [MODIFIED]

In order to obtain a patent, an applicant must first persuade the Patent Office, and more precisely its examiner, that the applicant invented a patentable invention. During the course of this period of negotiation between the applicant and the Patent Office, the applicant can provide information to the Patent Office in an attempt to demonstrate that the patent should issue. As one might expect, for the Patent Office to determine intelligently whether a patent should issue, an applicant must disclose all of the information known to the applicant to be material to the patentability of the inventions claimed in the application. If the applicant ultimately obtains the patent, but does so by either withholding material information from, or by misrepresenting material facts to, the Patent Office while possessing the intent to deceive the Patent Office, the patents are rendered unenforceable.

To prove the defense of inequitable conduct, Roche must show that Dr. Lin or his representatives were aware of certain information that was material to the patentability of the claimed inventions but withheld that information from the patent examiner, or submitted false information that was material to the patentability of the claimed inventions, and that they did so with the intent to deceive or mislead the examiner into allowing the patent. Both materiality and intent to deceive are independent elements, each of which must be proven by clear and convincing evidence. Information is material if there is a substantial likelihood that a reasonable examiner would consider the information important in deciding whether to allow the application to issue as a patent. A reference, however, need not be disclosed to the examiner if it is merely cumulative of, or no more material than, other references already before the examiner. A reference that is actually submitted to the examiner cannot form a basis for inequitable conduct, regardless of whether it is submitted alone or along with a large volume of other references. In assessing intent, you should consider any "evidence indicative of good faith." Finally, and importantly, the intent to deceive cannot be inferred "solely from the fact that information was not disclosed. There must be a factual basis for a finding of deceptive intent."

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

Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F.Supp.2d 69, 137-138 (D. Mass. 2001); 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).

A. MATERIALITY

In considering the issue of materiality, you must first determine whether or not information known to the applicant or his representatives was withheld from or misrepresented to the PTO. If you first find that Dr. Lin, Mr. Borun, 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 is not material if it is cumulative of, that is, adds little to, other information already available to the examiner. Information is cumulative if it teaches no more than that which is taught by the other information or prior art already before the Patent Office.

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).

B. INTENT

If you find that material information known to the applicant or his representatives was withheld from or misrepresented to the patent examiner, then you must determine whether it was done with intent to deceive the Patent Office. Roche must prove intent to deceive the Patent Office by clear and convincing evidence. Evidence relevant to the question of intent to deceive or mislead the Patent 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 Patent Office; 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); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F. Supp. 2d 508, 546 (D. N.J. 1999).

C. BALANCING OF MATERIALITY AND INTENT

If you find that Roche has proved by clear and convincing evidence that material information was withheld from or misrepresented to the Patent Office 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).

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Respectfully Submitted,

AMGEN INC.,
By its attorneys,

Of Counsel:

Stuart L. Watt
Wendy A. Whiteford
Monique L. Cordray
Darrell G. Dotson
Kimberlin L. Morley
Erica S. Olson
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

/s/ Michael R. Gottfried
D. Dennis Allegretti (BBO#545511)
Michael R. Gottfried (BBO# 542156)
Patricia R. Rich (BBO# 640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4200
Facsimile: (857) 488-4201

Lloyd R. Day, Jr. (*pro hac vice*)
DAY CASEBEER, MADRID &
BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

William G. Gaede, III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

Kevin M. Flowers (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago, IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

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.

/s/ Michael R. Gottfried
Michael R. Gottfried