UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

ROCHE'S PRELIMINARY OBJECTIONS TO AMGEN'S [PROPOSED] REVISED FINAL JURY INSTRUCTIONS

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ROCHE'S PRELIMINARY OBJECTIONS TO AMGEN'S PROPOSED POST-TRIAL JURY INSTRUCTIONS

Defendants F. Hoffman-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively, "Roche"), object as follows to Amgen's proposed post-trial jury instructions (as set forth in D.N. 918). Roche has proposed its own jury instructions for the Court's consideration (D.N. 917 and D.N. 1030) and requests that the Court give these instructions instead. Because Amgen filed its revised instructions only late last night, Roche has not yet had the opportunity to review and object to the revised instructions (which Amgen has substantially modified from its previous version) as thoroughly as it would like and thus reserves the right to modify and supplement these objections before the final jury charge or the final charge conference at the close of all the evidence.

ROCHE'S GENERAL OBJECTIONS

1. Roche objects to Amgen's proposed post-trial jury instructions because they are worded in a manner that favors Amgen's position, rather than in a neutral manner, and are thus argumentative and prejudicial.

2. Roche objects to Amgen's proposed post-trial jury instructions to the extent that they are repetitive, misleading, confusing, or vague. *See Grajales-Romero v. American Airlines, Inc.,* 194 F.3d 288, 299 (1st Cir. 1999) (jury instruction must "show no tendency to confuse or mislead the jury with respect to the applicable principles of law"); *Sweeney v. Westvaco Co*., 926 F.2d 29, 35 (1st Cir. 1991) ("Parties have no right to an instruction that would confuse the jury").

3. Roche objects to Amgen's proposed post-trial jury instructions to the extent that they fail to state the correct burdens, presumptions, or standards or otherwise to state the law correctly. *Id*; *see also, e.g*., *Hathaway v. Coughlin*, 99 F.3d 550, 552-53 (2d Cir. 1996); ("A jury

charge is erroneous if it misleads the jury as to the correct legal standard, or if it does not adequately inform the jury of the law").

4. Roche objects to Amgen's proposed post-trial instructions to the extent that they are not supported by the evidence admitted at trial. *See, e.g., Prentiss & Carlisle Co. v. Koehring-Waterous Div. of Timberjack, Inc.*, 972 F.2d 6, 10 (1st Cir. 1992) (affirming district court's refusal to give requested instruction, stating that "[a] jury instruction should not be given if there is not sufficient evidence to support it").

5. Roche incorporates each of its general objections into the specific objections below.

Note: For the Court's convenience, each of Amgen's proposed instructions is reprinted below (single spaced, block indented), immediately followed by Roche's objection to that instruction. The instructions are numbered and labeled as in Amgen's original proposal.

OBJECTIONS TO AMGEN'S INTRODUCTORY INSTRUCTIONS
(Section X of Amgen's Instructions)

X. POST-TRIAL FINAL INSTRUCTIONS INTRODUCTION

> 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 urge you to certain conclusions within the legal framework as I describe it.
>
> 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 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.

In addition to the General Objections, and without waiving any, Roche specifically objects to the phrase "If justice is to be done here" because that phrase suggests that there is an injustice that needs to be rectified and it is slanted towards a plaintiff's perspective in the courtroom. As such, the instruction unfairly prejudices Roche.

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.

Roche repeats its General Objections and does not specifically object to this instruction other than to note that it omits concepts concerning the deliberation process that the jury should hear. Roche requests that the Court instead give Roche's proposed instructions 8.1-8.4 [D.N. 917 at pp. 84-87] concerning deliberation and verdict.

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? It is 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 question 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.

In addition to the General Objections, and without waiving any, Roche specifically objects to this instruction because it fails to instruct the jury that the number of witnesses who testified is irrelevant and that the jury's decision should be based on the credibility of each witness and the amount of weight each witness's testimony deserves. Roche requests that the Court give Roche's proposed instruction No. 1.7 [D.N. 917 at p. 7]. The jury should also be instructed as to the effect of mistakes in testimony. See Roche's proposed instruction No. 1.6 [D.N. 917 at p. 6].

Roche further objects to this section because it fails to instruct the jury on the difference between direct and circumstantial evidence. The jury should be instructed that it should consider both direct and circumstantial evidence and that it should not make a distinction between the weight given to either one. Amgen's failure to instruct the jury in this manner is prejudicial to Roche and will mislead the jury. Roche requests that the Court give Roche's proposed instruction No. 1.4 [D.N. 917 at p. 4].

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, but you may disbelieve them or believe them in part.

Other than its General Objections, which Roche maintains, Roche does not specifically object to this instruction.

2. TESTIMONY BY DEPOSITION

> Now, not all the witnesses in this case testified live here in court. Some witnesses, because of the geographical distance from here, or for whatever other reasons, 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, 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.

Other than its General Objections, which Roche maintains, Roche does not specifically object to this instruction.

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's 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.

In addition to the General Objections, and without waiving any, Roche objects to the last paragraph of this instruction to the extent it is repetitive and unnecessary. Roche requests that the Court instead give Roche's proposed instruction No. 1.9 [D.N. 917 at p. 9].

4. STIPULATIONS

Withdrawn.

Although Amgen has now withdrawn this proposed instruction (which had provided that stipulations could not be disregarded or contradicted), Roche requests that the Court instruct the jury that any admission that Amgen made in response to Rule 36 requests is evidence and cannot be disregarded or contradicted. *See* Trial Transcript, Vol. 10, at 1377-79 (reading into evidence admission by Amgen in response to a Rule 36 request).

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 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'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. 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. 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

> 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, 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 in this case. I believe that you will justly and impartially decide the facts in this case. Now let's get to it.

Other than the General Objections, which Roche maintains, Roche does not specifically object to this instruction.

OBJECTIONS TO AMGEN'S INSTRUCTION ON BURDEN OF PROOF
(Section XI of Amgen's Instructions)

XI. BURDEN 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.

In addition to the General Objections, and without waiving any, Roche specifically objects to Amgen's definition of "clear and convincing evidence." In the 2007 AIPLA Model Instructions, at page 9, this burden is defined as evidence that shows that it is "highly probably" that the claims are invalid or that the fact has been established. Roche also objects to the framing of the preponderance of the evidence standard and, in particular, the words "fair" (which prejudicially suggests some fairness rationale should be applied) and "by just the slightest bit,"

which prejudicially suggests that the burden of proof is easier than the law actually requires. The instructions should also make clear that the jury must find for Roche if it finds either that Amgen has not sustained its burden or that Roche has sustained its burden on invalidity. Roche requests that the Court give Roche's proposed instruction on this issue, which accurately explains each party's burden of proof. *See* Roche's proposed instruction No. 3 [DN 917 at p. 17].

Roche also objects to the instruction regarding preponderance of the evidence in that it fails to include the instruction that, in the event that the jury believes the evidence is split evenly, then the party with the burden has failed to prove its case. *See Yamaha Int'l Corp. v. Hoshino Gakki Co*., 840 F.2d 1572, 1580, n. 11 (Fed Cir. 1988); *see also Director, Office of Workers' Compensation Programs v. Greenwich Collieries*, 512 U.S. 267, 281 (1994).

OBJECTIONS TO AMGEN'S INSTRUCTIONS ON THE CLAIMS OF THE PATENTS-IN-SUIT
(Section XII of Amgen's Instructions)

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to the term "describe.". A claim does not describe but rather "defines" an invention. *Markman v. Westview Instruments, Inc*., 517 U.S. 370, 373 (1996). This distinction is important and is not merely semantic. Amgen's term improperly suggest that a patent claim functions as a teaching tool (which is the role of the patent's specification) rather than as a boundary marker. As such, Amgen's term improperly suggest that a claim can be broadened at the whim of the jury when, in many cases, a claim should be read narrowly. *Athletic Alternatives, Inc. v. Prince Mfg., Inc*., 73 F.3d 1573, 1581 (Fed. Cir. 1996) ("Where there is an equal choice between a broader and a narrower meaning of a claim, . . . we consider the notice function of the claim to be best served by adopting the narrower meaning").

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. 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]

Other than its General Objections, which Roche maintains, Roche does not specifically object to this instruction. Roche, however, requests that the Court give Roche's proposed post-trial instruction on this issue. *See* Roche's Proposed Jury Instructions No 5.1 [DN 917 at p. 44].

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 claim 4, 5, or 6.

In addition to the General Objections, and without waiving any, Roche specifically objects to this instruction because it fails to state the requirement of 35 U.S.C. § 112 that the jury must not imply the limitations of a narrower dependent claim into a broader independent claim if that broader claim does not include the same limitations. *See Fromson v. Advance Offset Plate, Inc.,* 720 F.2d 1565, 1570 (Fed. Cir. 1983). Roche requests that the Court give Roche's proposed post-trial instruction on this issue. *See* Roche's proposed instruction No 5.2 [DN 917 at p. 45].

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 not, however, a product-by-process claim; it 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.")

In addition to the General Objections, and without waiving any, Roche specifically objects to Amgen's instruction because, as written, it does not make clear the difference between product-by-process claims of the '933 patent versus the product claim reciting a source limitation of the '422 patent. The instruction should make clear that a product-by-process claim simply claims a product and "that a claimed product shown to be present in the prior art cannot be rendered patentable solely by the addition of source or process limitations." *Amgen Inc. v. Hoechst Marion Roussel,* 314 F.3d 13131, 1354 fn. 20 (Fed. Cir. 2003). The instruction should further make clear that '422 claim 1 is simply a product claim that recites a source limitation and "source limitations cannot impart novelty to old compositions." *Id.* at 1356. Because Amgen

chose to draft its claims in these formats, Amgen bears the burden of proving that source or process limitations impart a structural distinction over the prior art.

Roche further objects to the proposed instruction because it does not make clear that any purported distinction of the claimed product over the prior art must be based on technology for generating the experimental data that was available as of the earliest effective filing date of the patents-in-suit, i.e., before November 30, 1984.

Roche further objects to the sentence describing Claim 1 of the '422 patent as a product claim with a "source element." The sentence is misleading or confusing because Amgen does not provide a written description or any definition of "human erythropoietin" or how one of skill in the art would determine its structure if it is limited by a source limitation. Roche further objects because Amgen did not apply the "source element" in its motion for summary judgment of infringement of '422 claim 1 and should not be permitted to now invoke the "source element" to distinguish prior art. A claim must be construed in the same manner for infringement and validity.[1]

Roche requests that the Court give Roche's proposed instruction on this issue. *See* Defendants' Proposed Jury Instructions [D.N. 917 and D.N. 1030].

[1] Although this Court has previously ruled on infringement of Claim 1 of the '422 patent, the portion relating to '422 Claim 1 is still relevant. First, the claim construction is still relevant to the validity inquiry because the claim should be construed the same way for both infringement and validity. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003)("It is axiomatic that claims are construed the same way for both invalidity and infringement"). Second, Roche contends that it still has defenses to infringement, including under the Reverse Doctrine of Equivalents and the safe harbor of 35 U.S.C. § 271(e).

D. "Comprising" Claims

> The beginning portion, 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 the 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.

In addition to the General Objections, and without waiving any, Roche specifically objects to Amgen's proposed instruction because it appears to allow the jury to interpret the claims-in-suit, which task is solely for this Court. *Markman v. Westview Instruments, Inc*., 517 U.S. 370, 390-91 (1996).

Roche also objects because the instruction fails to account for the "material change" doctrine under 35 U.S.C. § 271(g) and the Reverse Doctrine of Equivalents. Under these inquiries, an accused product or process may not infringe--even though the claim uses the terms "comprises" or "comprising" and even though the accused product or process includes additional components or steps--because the additions so far change the product or process that it cannot be deemed an infringement. *See, e.g*., *Eli Lilly & Co. v. American Cyanamid Co*., 66 F. Supp. 2d 924, 931-32 (S.D. Ind. 1999) (Barker, C.J.) (discussing the "material change" inquiry under § 271(f)); *Amgen, Inc. v. Hoechst Marion Roussel, Inc*., 339 F. Supp. 2d. 202, 287 (D. Mass. 2004) (Young, C.J.) (discussing Reverse Doctrine of Equivalents), *aff'd in part*, *rev'd in part*, *vacated in part on other grounds*, 457 F.3d 1293 (Fed. Cir. 2006).

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.

Roche does not specifically object to this instruction per se but does reserve its right to object to and/or appeal the Court's various claim constructions.

OBJECTIONS TO AMGEN'S INFRINGEMENT INSTRUCTIONS
(Section XIII of Amgen's Instructions)

XIII. INFRINGEMENT [MODIFIED]

A. PATENT 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.

In addition to the General Objections, and without waiving any, Roche specifically objects because this instruction is slanted in favor of the plaintiff rather than presenting a neutral recitation of the law. For example, in the fourth paragraph, the instruction emphasizes what is infringement without also instructing the jury how it can find that Roche does not infringe (e.g., "That's infringement"). The instruction should include a statement that if Amgen fails to show that each and every limitation of a claim is found in MIRCERA, then there is no infringement.

Roche further objects to the second paragraph (concerning additional elements and improvements) to the extent it unfairly suggests to the jury that it should not consider how MIRCERA is different from the product of the claimed processes. For example, MIRCERA has a longer "half life," enabling it to be administered much less frequently. That and similar comparisons help to highlight how MIRCERA has different molecular structures, functions, and properties from the EPO products of the asserted claims. In turn, this information is relevant to Roche's defenses that MIRCERA (a) is "materially changed" and thus does not infringe under 35 U.S.C. § 271(g); (b) does not infringe under the Doctrine of Equivalents; and (c) does not infringe under the Reverse Doctrine of Equivalents. *See, e.g., Eli Lilly & Co. v. American Cyanamid Co*., 66 F. Supp. 2d 924, 931-32 (S.D. Ind. 1999) (increased efficacy of new compound over patented compound helped to show that product was materially changed); *Genentech, Inc. v. The Wellcome Foundation Ltd*., 29 F.3d 1555, 1569 (Fed. Cir. 1994) (accused protein, formed through recombinent DNA technology, did not infringe under doctrine of equivalents because, inter alia, it had a far longer "half-life" and other clinical advantages, thus showing that it achieved a different result); *Amgen, Inc. v. Hoechst Marion Roussel, Inc*., 339 F. Supp. 2d. 202, 287 (D. Mass. 2004) (Young, C.J.) (recognizing that the reverse doctrine of equivalents supports innovation--especially in the area of biotechnology where blocking patents are common--because it offers some chance of protection to those that make substantial changes or radical improvements to inventions"), *aff'd in part*, *rev'd in part*, *vacated in part on other grounds*, 457 F.3d 1293 (Fed. Cir. 2006).

Roche further objects to the characterization of Amgen's burden of proof. First, the burden should not be described as a "fair" preponderance of the evidence, which prejudicially suggests that the jury should apply a fairness standard to infringement. Furthermore, it fails to

mention that Amgen bears the burden of proving whether or not the imported product has been "materially changed." In other words, in its assertion of various process claims, Amgen must prove that any imported product resulting from those process claims was not materially changed.

Finally, Roche objects because the instruction fails to state that if the jury finds that an independent claim is not infringed, then it must also find that any claim dependent there from is not infringed. *Wolverine World Wide v. Nike Inc*., 38 F.3d 1192, 1199 (Fed. Cir. 1994).

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to Amgen's instruction because it fails to instruct the jury that, to infringe a product-by-process claim, Amgen must prove that Roche's product has the same material structure and functional characteristics as the claimed product-by-process and is made by a process employing each and every one of the steps recited in the claims. *See Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1580 (Fed. Cir. 1991); *Atlantic Thermoplastics Co. v. Fate Corp*., 970 F.2d 834, 846-47 (Fed. Cir. 1992). Amgen, however, has failed to identify those structures or characteristics, let alone where in the patent they are required. *See SmithKline v. Geneva Parma, Inc*. 2002 U.S. Dist. LEXIS 25275 at *20 (E.D. Pa. 2002) ("[W]e decline to

recognize product properties that are not required by the patent claims or specification.")(emphasis added). Moreover, in stating that a product-by-process claim is written in terms of "the process by which the product is made, not by reference to the particular structure or function of the claimed product," Amgen misleadingly and incorrectly converts a product claim into a pure process claim. A product-by-process claim, however, is still a product claim. *SmithKline Beecham Corp. v. Apotex Corp*., 439 F.3d 1312, 1317 (Fed. Cir. 2006) ("Regardless of how broadly or narrowly one construes a product-by-process claim, it is clear that such claims are always to a product, not a process").

Roche further objects to the instruction regarding "additional elements" as improperly suggesting that the jury should not consider the differences in MIRCERA, which are relevant to defenses such as "material change" and the reverse doctrine of equivalents. *See* Roche's objection to XENIA above.

In addition, the use of the words "describes" and "described. " A claim does not describe but rather "defines" an invention. *Markman v. Westview Instruments, Inc*., 517 U.S. 370, 373 (1996). Amgen's term improperly suggest that a patent claim functions as a teaching tool (which is the role of the patent's specification) rather than as a boundary marker. As such, Amgen's term improperly suggest that a claim can be broadened at the whim of the jury when, in many cases, a claim should be read narrowly. *Athletic Alternatives, Inc. v. Prince Mfg., Inc*., 73 F.3d 1573, 1581 (Fed. Cir. 1996) ("Where there is an equal choice between a broader and a narrower meaning of a claim, . . . we consider the notice function of the claim to be best served by adopting the narrower meaning").

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 nonessential 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.

In addition to the General Objections, and without waiving any, Roche specifically objects to Amgen's proposed instruction because it fails to state that Amgen has the burden to show that the accused product is not materially changed and, instead, implies that Roche has the

burden to show that the product has been materially changed. *See Genentech, Inc. v. Bushranger Mannheim GmbH*, 47 F. Supp. 2d 91, 108 (D. Mass. 1999) (Saris, J.) (patentee bears burden of proof on "material changed" issue).

Roche further objects to the instruction to the extent it prevents the jury from considering how MIRCERA is different from the product of the claimed processes. For example, MIRCERA has a longer "half life," enabling it to be administered much less frequently. That and similar comparisons help to highlight how MIRCERA has different molecular structures, functions, and properties from the claimed products. In turn, this information is relevant to Roche's defenses that MIRCERA (a) is "materially changed" and thus does not infringe under 35 U.S.C. § 271(g); (b) does not infringe under the Doctrine of Equivalents; and (c) does not infringe under the Reverse Doctrine of Equivalents. *See, e.g., Eli Lilly & Co. v. American Cyanamid Co*., 66 F. Supp. 2d 924, 931-32 (S.D. Ind. 1999) (increased efficacy of new compound over patented compound helped to show that product was materially changed); *Genentech, Inc. v. The Wellcome Foundation Ltd*., 29 F.3d 1555, 1569 (Fed. Cir. 1994) (accused protein, formed through recombinent DNA technology, did not infringe under doctrine of equivalents because, inter alia, it had a far longer "half-life" and other clinical advantages, thus showing that it achieved a different result); *Amgen, Inc. v. Hoechst Marion Roussel, Inc*., 339 F. Supp. 2d. 202, 287 (D. Mass. 2004) (Young, C.J.) (recognizing that the reverse doctrine of equivalents supports innovation--especially in the area of biotechnology where blocking patents are common--because it offers some chance of protection to those that make substantial changes or radical improvements to inventions"), *aff'd in part*, *rev'd in part*, *vacated in part on other grounds*, 457 F.3d 1293 (Fed. Cir. 2006).

Amgen's instruction also improperly refers to the accused product as "EPO" and "EPO product" rather than as "MIRCERA." That description is scientifically inaccurate. Indeed, MIRCERA is not "EPO" or an "EPO product" at all. Rather, it is an erythropoietin stimulating agent ("ESA"). MIRCERA is a new and different compound and is not created simply by the "attachment of polyethylene glycol," as Amgen asserts. Rather, MIRCERA results from chemical reactions in which bonds are broken, atoms are removed and others substituted, and new bonds are formed to create new molecules.

Roche's process includes more than simply attaching polyethylene glycol. Other processing steps also help materially change the accused product. Thus, the jury should not be told, in essence, to ignore the other processes. Roche likewise objects to the similar implication is Amgen's proposed instruction that the "attachment of peg" is somehow the only subsequent processing step used by Roche.

Finally, Roche objects because Amgen's proposed instruction suggests that there can be a significant change only if the change in structure or properties "changes the basic utility of the EPO product" While change in the utility of a compound is one measure of "material change," other changes can also show "material change." For example, if the subsequent processes confer significant structural differences to the product, such as the addition or removal of certain chemical groups, that alone can show material change, regardless of whether the basic utility has been affected. *See Eli Lilly & Co. v. American Cyanamid Co*., 82 F.3d 1568, 1572-73 (Fed. Cir. 1996).

Roche requests that the Court instead instruct the jury per Roche's proposed instructions on material change and on these claims. *See* D.N. 917.

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to Amgen's proposed instruction because it includes several materially incorrect statements of law. First, the instruction improperly refers to hypothetical future direct infringement. For example: "In this case, Amgen asserts that Roche will induce others to infringe the methods of treatment . . . " and "There can be no inducement of infringement unless someone will directly infringe the patent." There can be no liability for hypothetical future infringement. *See Benitec Australia, Ltd. v. Nucleonics, Inc*., 495 F.3d 1340, 1346-47 (Fed. Cir. 2007) (affirming dismissal of declaratory judgment action because accused infringer had not yet started making, using, or selling a product other than for purposes of testing the product under the safe harbor of 35 U.S.C. § 271(e)(1) and thus there could be no case or controversy). And

there can be no indirect infringement unless there has first been a direct infringement. *Water Techs. Corp. v. Calco, Ltd*., 850 F.2d 660, 668 n. 7 (Fed. Cir. 1988) ("Direct infringement is a prerequisite to finding induced infringement").

Second, the instruction fails to instruct that if Roche had a good faith basis for believing that it does infringe, that good faith basis could negate the required showing of a specific intent to cause an infringement. *DSU Med. Corp. v. JMS Co*., 471 F.3d 1293, 1307 (Fed. Cir. 2006) (en banc) ("To the contrary, the record contains evidence that ITL did not believe its [accused product] infringed. Therefore, it had no intent to infringe").

B. DOCTRINE OF EQUIVALENTS [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.

In addition to the General Objections, and without waiving any, Roche specifically objects because Amgen is not entitled to invoke the doctrine of equivalents for the asserted claims because it has not overcome prosecution history estoppel. Based on the file histories of the patents-in-suit, which have been entered into evidence, each of the asserted claims was the result of amendments that narrowed its scope. As a result, there is a presumption that there are no equivalents of these claims. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*,

525 U.S. 722, 740 (2002). Amgen has submitted *no evidence* rebutting this presumption, such as proof that the alleged equivalent would have been unforeseeable at the time of the narrowing amendment. *Id.*

Furthermore, Amgen now concedes that infringement under the doctrine of equivalents must be considered on a limitation by limitation basis, rather than based on the claim as a whole. *See Terlep v. Brinkmann Corp.*, 418 F.3d 1379, 1384-85 (Fed. Cir. 2005). Amgen's previously proposed instruction did not make this distinction. But Amgen has failed to submit evidence of equivalents on a limitation by limitation basis and thus is not entitled to an instruction on the doctrine of equivalents. *See, e.g., Prentiss & Carlisle Co. v. Koehring-Waterous Div. of Timberjack, Inc.*, 972 F.2d 6, 10 (1st Cir. 1992) (affirming district court's refusal to give requested instruction, stating that "[a] jury instruction should not be given if there is not sufficient evidence to support it").

Roche also objects because the instruction oversimplifies and misstates application of the doctrine of equivalents. "The doctrine of equivalents comes into play only when actual literal infringement is not present." *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1361 (Fed. Cir. 1983); *see also, e.g., ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1581 (Fed. Cir. 1988) ("When literal infringement is not found, the equitable doctrine of equivalents comes into play"). Thus, the jury should first be instructed that it should not apply the doctrine of equivalents unless it has first found that Roche has not literally infringed the given claim. Roche requests that the Court instead give Roche's proposed instruction on the doctrine of equivalents. *See* Roche's proposed instructions Nos. 6.7 - 6.12 [D.N. 917 at pp. 55-61].

Roche further objections because the instruction fails to include limitations on application of the doctrine of equivalents, as recited in Roche's Proposed Instruction Nos. 6.7 - 6.12

[Document 917 at pp. 55-61]. These limitations include, for example, that (a) application of the doctrine is the exception and not the rule, (b) the doctrine may not be used to broaden a claim such that it would be obvious in view of the prior art, and (c) the doctrine may not be used to read a claim element or step out of existence.

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.

Because Amgen has now deleted or moved these instructions, specific objections are unnecessary. Roche, however, reserves the right to object should Amgen revise or refile these instructions.

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to Amgen's proposed instruction because it mischaracterizes Roche's arguments concerning non-infringement. MIRCERA is not simply an improved EPO product, as Amgen would have the Court and jury believe. Rather, it is a new and different molecule. (Indeed, it is not an EPO product at all but rather is an erythropoietin stimulating agent, or "ESA.") As such, the instruction improperly suggests that the jury should ignore the differences of MIRCERA. Such differences are relevant to the "material change" doctrine under 35 U.S.C. § 271(g), the doctrine of equivalents, and the Reverse Doctrine of Equivalents. Under these inquiries, differences with a patented product may be so significant that the accused product or process does not infringe. *See, e.g.*, *Eli Lilly & Co. v. American Cyanamid Co*., 66 F. Supp. 2d 924, 931-32 (S.D. Ind. 1999) (Barker, C.J.) (discussing the "material change" inquiry under § 271(g)); *Amgen, Inc. v. Hoechst Marion Roussel, Inc*., 339 F. Supp. 2d. 202, 287 (D. Mass. 2004) (Young, C.J.) (discussing Reverse Doctrine of Equivalents), *aff'd in part*, *rev'd in part*, *vacated in part on other grounds*, 457 F.3d 1293 (Fed. Cir. 2006). Indeed, contrary to Amgen's instruction, obtaining a patent on Roche's different product, MIRCERA, may support a finding of non-infringement under the Reverse Doctrine of Equivalents. *See Amgen v. Hoeschst Marion Roussel*, 339 F. Supp. 2d at 300 ("attainment of a patent may aid in making a *prima facie* case in support of the reverse doctrine of equivalents"). Likewise, Roche's patents may also be relevant to non-infringement under the doctrine of equivalents. *National Presto Indus., Inc. v. West Bend Co*., 76 F.3d 1185, 1192 (Fed. Cir. 1996) ("The fact of separate patentability is relevant and is entitled to due weight).

G. DETERMINATION OF INFRINGEMENT

This instruction has been incorporated into subsection A.

H. INDUCING INFRINGEMENT

This instruction has been incorporated into subsection A.

Because Amgen has deleted these instructions from its previous version, specific objections to these sections are no longer necessary. Roche, however, reserves the right to object should Amgen revise or refile these instructions

OBJECTIONS TO AMGEN'S INSTRUCTIONS ON VALIDITY
(Section XIV of Amgen's Instructions)

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.

Roche's objections to this portion of the instruction are stated below, after subpart A.

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to this instruction because it contains repetitious, argumentative statements on the issue of presumption of validity that will mislead and confuse the jury. For example, the term "Dr. Lin's patents" and similar terms improperly appeals to sentiment. The patents should be referenced by their number (e.g., "the '422 patent") or, simply, as the "patents-in-suit" and should not be personalized. The term "attacking" in the first sentence also is slanted, unfairly, in favor of the patentee.

Amgen's use of the terms "added burden," "higher burden of proof," and "presumption of validity is strong" are incorrect statements of the law. The presumption of validity is a procedural device—it does not constitute "evidence" that needs to be weighed against Roche's evidence of invalidity. The presumption simply places the burden of persuasion on Roche. Moreover, the burden does not change and does not become stronger or weaker. . *See, e.g., Alco Stnd. Corp. v. Tennessee Valley Authority*, 808 F.2d 1490, 1497 (Fed. Cir. 1986); *Lear Siegler, Inc. v. Aeroquip Corp*., 733 F.2d 881, 885 (Fed. Cir. 1984).

Amgen's repeated use of the phrases "because the Patent Office issued" and "clear and convincing" improperly suggest that Roche will not be able to meet its burden and thus unfairly prejudice Roche. It is also prejudicial in this instruction to compare Roche's burden on validity with Amgen's burden for infringement.

Roche further objects to the proposition in the fourth sentence of the first paragraph, which asserts that the "presumption of validity . . . relates to each patent as a whole . . . ." This sentence misleadingly and improperly suggests that the presumption of validity attaches to the entire patent as opposed to each claim individually. As such, the jury could be mislead into

believing that, for example, if one claim is valid, then all claims must be valid. In fact, the law is that the validity of each claim must be assessed individually, independent of the other claims. *See, e.g., Dana Corp. v. American Axle & Mfg., Inc.*, 279 F.3d 1372, 1376 (Fed. Cir. 2002).

Roche also objects to the last two sentences in the third paragraph because they are needless, confusing repetitions of the straightforward premise that a juror "must consider each asserted claim . . . separately." Roche objects to the entire last two paragraphs for the same reason—they are a needless, confusing repetition of the straightforward premise that a patent is presumed to be valid and Roche must prove invalidity with clear and convincing evidence. Moreover, the phrase in the last sentence "can no longer be accepted as valid" misleadingly suggests that a given claim was previously determined to be valid when, in fact, that is not the case.

Roche requests that the Court give Roche's proposed post-trial instruction on this issue, which accurately and fairly describes the presumption of validity.

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 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.

In addition to the General Objections, and without waiving any, Roche specifically objects to this instruction because it misstates and confuses the written description, enablement, and definiteness requirements of 35 U.S.C. § 112 ¶¶ 1-2. Roche further objects to this instruction because the third paragraph is a needless, confusing repetition of Amgen's previous instructions on burden of proof (Instruction XI).

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to the last two sentences of the second paragraph (beginning "In order to be prior art . . .") because they inaccurately describe the requirements for prior art under 35 U.S.C. § 102. Prior art also includes, among other things, public use, offers to sell, and sales. *See* 35 U.S.C. § 102(b). This type of prior art does not need to be, as the first sentence states, "available. . . without restriction" or, as the second sentence states, part of the "general knowledge in the field." Indeed, a reference need not be widely known to render a patent claim anticipated or obvious. *See, e.g.*, *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) (the hypothetical person of ordinary skill in the art "is presumed to be aware of all the pertinent prior art"); *Hart v. L.A. Baarcke*, 396 F. Supp. 408, 412 (S.D. Fla. 1975) (Roettger, J.) ("One foreign publication, no matter how obscure, may be sufficient to invalidate a patent claim . . ."); Donald S. Chisum, 2 *Chisum on Patents* § 5.04[1][b] (one of ordinary skill "is presumed to have perfect knowledge of all the pertinent prior art--however obscure the source").

In addition, a printed publication is prior art when it is available to the segment of the public that is *interested* in its content not, as the second sentence states, to the "segment of the public most likely to make use of" its content. *See In re Klopfenstein*, 380 F.3d 1345, 1351 (Fed. Cir. 2004) ("a reference, 'however ephemeral its existence,' may be a 'printed publication' if it 'goes direct to those whose interests make them likely to observe and remember whatever it may

contain that is new and useful'") (citation omitted). Furthermore, for prior art purposes, "[p]ublication does not require dissemination in books or journals." *E.I. Du Pont de Nemours & Co. v. Cetus Corp.,* 1990 Dist. LEXIS 18382 at *4 (N.D. Cal. 1990) (unreported). Additionally, publicly accessible submissions to government entities constitute printed publications. *See Amer. Stock Exchange, LLC v. Mopex, Inc.,* 250 F. Supp. 2d 323, 329-30 (S.D.N.Y. 2003) (finding World Equity Benchmarks Application submitted to the SEC to be prior art).

Moreover, under § 102(e), a patent is a prior art reference as of its filing date, although its existence is not yet known until the patent issues. *See Hazeltine Research, Inc. v. Brenner*, 382 U.S. 252 (1965). Likewise, there is no requirement under § 102(g) that a prior art reference be "public" at all to be considered prior art. *See Int'l Glass Co. v. United States*, 408 F.2d 395, 402 (Ct. Cl. 1969); *see also E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.,* 849 F.2d 1430, 1437 (Fed. Cir. 1988) ("Nor does § 102(g) contain a 'known to the art' requirement apart from the requirement of no abandonment, suppression or concealment"). Nor is there any requirement that prior art under § 102(f) (derivation) be public. It must only be made available to the patent applicant. *See Oddzon Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1403-04 (Fed. Cir. 1997) ("subject matter derived from another not only is itself unpatentable to the party who derived it under § 102(f), but, when combined with other prior art, may make a resulting obvious invention unpatentable to that party under a combination of §§ 102(f) and 103").

Roche also objects to use of the phrase "more than one year before the application for the patent was filed" in the fifth and sixth paragraphs because it will confuse the jury. Should the Court choose to use this phrase, Roche requests that the Court also instruct the jury that "more than one year before the application for patent was filed means before November 30, 1983." *See* Defendants' Proposed Jury Instructions, Nos. 4.1.2-4.1.4, at 19 (D.N. 917)

Roche further objects to the seventh and eighth paragraphs because it is unclear whether the phrase "before the inventor made the invention" refers to the date the patent issued or the date the application was filed. Roche requests that the Court clarify for the jury that this phrase refers to the date the application was filed. *See, e.g.,* 35 U.S.C. § 102(e) ("described in…a patent granted on an application for patent by another filed in the United States before the invention by the applicant"). *See also* Defendants' Proposed Jury Instructions, No. 4.2 (5th Bullet and Last Bullet), at 20-21 (D.N. 917).

Roche objects to the penultimate paragraph because the jury should consider evidence that may be dated after Amgen's invention date if it shows what was prior art, such as §102(f) and (g) prior art.

Roche also objects to the reference to "Amgen employees" in the penultimate paragraph, as Dr. Goldwasser's work clearly constitutes prior art and, given Dr. Goldwasser's close association with Amgen—including being an expert witness in the present litigation—the jury is likely to be confused as to whether Dr. Goldwasser qualifies as an employee of Amgen.

In addition, Roche objects to the statement in the penultimate paragraph that the jury can decide what is and is not prior art. This is an incorrect statement of the law. Whether a document is a prior publication is a question of law. *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1330 (Fed. Cir. 2004); *Reading & Bates Constr. Co. v. Baker Energy Res. Corp.*, 748 F.2d 645, 649-50 (Fed. Cir. 1984). Furthermore, there is no reasonable basis for Amgen to argue that any of the prior art being asserted by Roche does not qualify as prior art, and thus, the instruction suggests to the jury that it can ignore prior art that is properly before the jury. (Amgen disputes as to what the prior art teaches or suggests, but there should be no factual dispute as to whether

the prior art qualifies as prior art.) In addition, the penultimate paragraph includes needless repetition.

Amgen also objects to the instruction that the '008 patent does not constitute prior art as that will confuse the jury, since the '008 patent, like the patents-in-suit, contains nearly ten columns of discussion on the background of the invention. In addition, Example 1 of the '008 patent and the patents-in-suit describes §102(f) prior art by Goldwasser. These "teachings" can provide a reason for combining elements because they may discuss the "need[s] or problem[s] known in the field of the endeavor at the time of invention." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007). Moreover, Amgen is bound by its admissions in the patent specifications concerning the prior art. *See PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007) ("Admissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness"). Accordingly, Amgen also objects to this instruction because it ignores the admissions and descriptions of the prior art set forth in the patents-in-suit.

Roche objects to the last paragraph as being unduly repetitive with other instructions and because it suggests that some of the prior art properly being provided to the jury does not qualify as prior art, even though there is no reasonable basis for Amgen to argue that any of the prior art being asserted does not qualify as prior art.

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.

In addition to the General Objections, and without waiving any, Roche specifically objects because Amgen has failed to introduce sufficient evidence that its date of invention is any earlier than November 30, 1984. *See Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576-77 (Fed. Cir. 1996) (patent's invention date is effective filing date of application absent evidence showing inventor's prior actual reduction to practice). Because the evidence does not support this charge, it should not be given. *See, e.g., Prentiss & Carlisle Co. v. Koehring-Waterous Div. of Timberjack, Inc.*, 972 F.2d 6, 10 (1st Cir. 1992) (affirming district court's refusal to give requested instruction, stating that "[a] jury instruction should not be given if there is not sufficient evidence to support it").

Roche also objects to the reference to "the DNA sequence of human EPO" and the contention that it "was conceived and reduced to practice no later than October 1983." First of all, "the DNA sequence of human EPO" was the subject of the now-expired '008 patent, which is

not one of the patents-in-suit. In addition, Amgen has failed to introduce sufficient evidence to support such a contention.

Roche also object to the reference to "Dr. Lin's other inventions," as there is no evidence that Dr. Lin conceived or reduced to practice any invention other than "the DNA sequence of human EPO." Indeed, all the evidence shows that Dr. Lin did not conceive or reduce to practice any other invention.

Roche also objects to the clause "and is especially likely to occur in the unpredictable arts such as biology" in the fourth paragraph because it is argumentative and is an inaccurate statement of the doctrine of simultaneous conception and reduction to practice. *See, e.g.*, *Hitzeman v. Rutter*, 243 F.3d 1345, 1357 (Fed. Cir. 2001) ("It is not necessary that all biotechnology inventions…be characterized by simultaneous conception and reduction to practice.").

Roche further objects because the instruction omits that Amgen must prove both conception and reduction to practice of the invention to prove an earlier date of invention.

Roche requests that the Court give Roche's proposed post-trial instruction on this issue, which accurately and fairly describes conception and reduction to practice.

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to this instruction because it inaccurately states the rules concerning prior invention. In particular, the instruction fails to state that prior invention may occur when a third party was the first to conceive of the invention and exercised reasonable diligence in reducing the invention to practice—even though the third party's reduction to practice occurred after the patentee's reduction to practice. *Dow Chem. Co. v. Astro-Valcour, Inc.,* 267 F.3d 1334, 1339 (Fed. Cir. 2001). In addition, the instruction incorrectly states that the prior invention must be made public. But there is no requirement under § 102(g) that a prior invention be "public" at all to be considered prior art. *See Int'l Glass Co. v. United States*, 408 F.2d 395, 402 (Ct. Cl. 1969); *see also E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.,* 849 F.2d 1430, 1437 (Fed. Cir. 1988) ("Nor does § 102(g) contain a 'known to the art' requirement apart from the requirement of no abandonment, suppression or concealment").

Roche requests that the Court give Roche's proposed post-trial instruction on this issue, which accurately and fairly describes prior invention. *See* Defendants' Proposed Jury Instructions, No. 4.5 [D.N. 917 at 25].

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to use of the phrase "more than one year before Dr. Lin filed his original priority patent application . . ." in this instruction because it will confuse the jury. Should the Court choose to use this phrase, Roche requests that the Court also instruct the jury that "more than one year before the priority application for patent was filed means before November 30, 1983." *See* Defendants' Proposed Jury Instructions, No. 4.1, ¶ 3 [D.N. 917 at p. 19].

Furthermore, and as similarly noted in Roche's Objections to Amgen's Instruction C (Prior Art: Definition), a printed publication is prior art no matter how obscure it may be. *See, e.g.*, *Standard Oil Co. v. American Cyanamid Co*., 774 F.2d 448, 454 (Fed. Cir. 1985) (the hypothetical person of ordinary skill in the art "is presumed to be aware of all the pertinent prior art"); *Hart v. L.A. Baarcke*, 396 F. Supp. 408, 412 (S.D. Fla. 1975) (Roettger, J.) ("One foreign

publication, no matter how obscure, may be sufficient to invalidate a patent claim . . ."); Donald S. Chisum, 2 *Chisum on Patents* § 5.04[1][b] (one of ordinary skill "is presumed to have perfect knowledge of all the pertinent prior art--however obscure the source"). Thus, a printed publication is prior art when it is available to the segment of the public that is *interested* in its content--not, as the second sentence states, to the "portion of the public most likely to use it." *See In re Klopfenstein*, 380 F.3d 1345, 1351 (Fed. Cir. 2004) ("a reference, 'however ephemeral its existence,' may be a 'printed publication' if it 'goes direct to those whose interests make them likely to observe and remember whatever it may contain that is new and useful'") (citation omitted).

Roche also objects to the instruction that unpublished writings are not prior art. That is an inaccurate statement of law. Unpublished writings may be prior art under 35 U.S.C. §§ 102(f) or (g). For example, under § 102(f), unpublished or concealed writings are part of the prior art. *See OddzOn Prods. Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1403-04 (Fed. Cir. 1997) (holding confidential prior art under § 102(f) was prior art for purposes of obviousness). *See also* Roche's objections to Amgen's proposed instruction XIV.c above (showing that unpublished prior art still qualifies as prior art for the validity analysis).

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to this instruction because it complicates the straightforward "known or used" requirements of 35 U.S.C. § 102(a) with a needless four-part test and inaccurate statements about those requirements. In particular, 35 U.S.C. § 102(a) does not require that the "known or used" invention be patented, as stated in the first sentence. Also, contrary to the statement in the last sentence, and as similarly noted in Roche's Objections to Amgen's Instruction F (Prior Art: Printed Publication), under 35 U.S.C. § 102(f), unpublished or concealed writings qualify as prior art. *See OddzOn Prods. Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1403-04 (Fed. Cir. 1997) (holding unpublished prior art under § 102(f) was prior art for purposes of obviousness). *See also* Roche's objections to Amgen's proposed instruction XIV.c above (showing that unpublished prior art still qualifies as prior art for the validity analysis).

Furthermore, the assertion that "Prior knowledge or use outside the United States cannot be relied upon to invalidate a patent claim" will mislead or confuse the jury into thinking that no foreign prior art can ever invalidate a patent when, in fact, many forms of prior art from foreign countries, such as foreign patents, printed publications, and published patent applications, can be used to invalidate a U.S. patent. *See* 35 U.S.C. § 102(a), (b), and (e).

Roche requests that the Court give Roche's proposed post-trial instruction on this issue, which accurately and fairly describes the "known or used" requirements of §102(a). *See* Defendants' Proposed Jury Instructions, No. 4.6, [D.N. 917 at p.26].

H. ANTICIPATION [MODIFIED]

> 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.

In addition to the General Objections, and without waiving any, Roche specifically objects to this instruction because whether prior art is enabling is a question of law based on underlying factual findings. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1342-43 (Fed. Cir. 2005). Furthermore, there is a presumption that the prior art reference (at least a prior art patent) is enabling. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003).

Roche also objects to the first paragraph because saying that there is anticipation "if someone else has already made the same invention" suggests that the prior art must be identical to what is disclosed in the patents-in-suit, whereas the relevant question is whether the prior art falls within the scope of the claim.

Roche also objects to the instruction because it does not make clear that the entire scope of the claimed invention must not be anticipated; if any embodiment falling within the scope of the claim is anticipated, the entire claim is considered anticipated.

In addition, Roche objects to the first sentence of the third paragraph because it inaccurately states the law concerning inherent anticipation. The sole requirement for inherent anticipation is that the missing descriptive matter is necessarily present. *See Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1321 (Fed. Cir. 2004) ("to the extent the district court's statement meant that one of ordinary skill needed to recognize at the time of the [prior art patent] the inherent characteristics or results of [the prior art patent's] embodiments, it was incorrect").

In addition, Roche objects to the last paragraph as it applies the law of anticipatory publications to all types of prior art. Prior art activities like public use under §102(b) or actual reduction to practice under §102(g) do not need to "enable" a third party to be able to replicate that activity. *See In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (for a "public use" or "on sale" finding, there is no requirement for an enablement inquiry) (citing *J.A. LaPorte, Inc. v. Norfolk Dredging Co*., 787 F.2d 1577, 1583 (Fed. Cir. 1986)).

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to this instruction to the extent that it will mislead and confuse the jury regarding the effect of process limitations in product-by-process claims. In particular, this instruction omits the different standard for invalidation of product-by-process claims. The process for making a known product of a product-by-process claim does not distinguish the prior art unless that process also happens to confer on the product some new characteristics that change the structure of the product and that is required by the patent. *See Smithkline Beecham Corp. v. Apotex Corp*., 439 F.3d 1312, 1315 (Fed. Cir. 2006); *SmithKline v. Geneva Pharma, Inc.* 2002 U.S. Dist. LEXIS 25275 at *20 (E.D. Pa. 2002) ("[W]e decline to recognize product properties that are not required by the patent claims or specification.")(emphasis added); *see also In re Luck*, 476 F.2d 650, 653 (C.C.P.A. 1973). Thus, Roche requests that the Court further instruct the jury on product-by-process claims using Roche's proposed post-trial instruction on this issue, which correctly states the law regarding the anticipation of product-by-process claims. *See* Defendants' Proposed Jury Instructions, No. 4.2 [D.N. 917 at pp. 21-22) and Supplemental Proposed Jury Instructions [D.N. 1030, 1030-2].

Roche further objects because the instruction misstates the parties' burdens. Amgen must show that the process or source limitations distinguish the structure of the prior art compositions. Amgen, however, has failed to distinguish the prior art. Furthermore, Amgen has introduced

experimental data to rebut Roche's case that the asserted claims of the patents-in-suit are distinguishable over the prior art that Roche has presented in its invalidity case, but the technology for generating the experimental data was not available before November 30, 1984. Because the technology for generating the experimental data was not available before that date, it cannot be used in the anticipation or obviousness analyses. *See In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed.Cir. 1986); *Elf Atochem N. Amer., Inc. v. LaRoche Indus., Inc.*, 85 F. Supp. 2d 336, 343 (D. Del. 2000); *National Research Dev. Corp. v. Great Lakes Carbon Corp.*, 410 F. Supp. 1108, 1124 (D. Del. 1975).

Roche also objects to Amgen's instruction because it fails to instruct the jury on "the rule that a claimed product shown to be present in the prior art cannot be rendered patentable solely by the addition of source or process limitations." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 at n.20 (Fed. Cir. 2003). Rather the claimed product can be patentable (*e.g.,* novel or non-obvious) only if the source or process imparts some new structure to the claimed product that distinguishes it from the prior art product. *See Markman* Order [D.N. 613] at 18. In other words, it is not the process or source that must be new or non-obvious but the *product* itself. *Id.*; *see also SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1318-19 (Fed. Cir. 2006); 3 *Chisum on Patents* § 8.05[3] (2007 ed.) ("Even though a product may be claimed in terms of the process of making it, the product still must be new in structural terms in order to meet the novelty requirement"). If the product is not new (*e.g.*, if the process or source does not confer on the product a novel structure), then it is not patentable.

Roche also objects to the last paragraph because it only refers to "Dr. Goldwasser's EPO product," whereas Roche is relying on other prior art in addition to "Dr. Goldwasser's EPO product." Furthermore, Roche objects to the phrase "to the products claimed in each of those

claims" in the last paragraph because it implies that the prior art should only be compared to actual commercial EPO products, such as Epogen, whereas the prior art should be compared to the entire scope of the claim.

J. ANTICIPATION – PURIFIED COMPOUNDS

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

In addition to the General Objections, and without waiving any, Roche specifically objects to this instruction because it is irrelevant and unnecessary and, therefore, will mislead and confuse the jury. In particular, Roche does not rely on EPO found in nature to show anticipation of the claimed products and processes. Instead, Roche's proof regarding the lack of novelty of Amgen's product claims are based on (a) purified or isolated forms of EPO and (b) prior art methods for purifying uEPO—not on a "less-pure" form of EPO that, arguably, might occur in nature.

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to this instruction because it contains repetitious, argumentative statements on the issue of obviousness that will mislead and confuse the jury. For example, Amgen restates Roche's burden of clear and convincing evidence numerous times—unfairly suggesting that Roche will not be able to meet its burden. In addition, Amgen argues that "obvious to try" is an inaccurate test for obviousness—a statement that is contrary to the U.S. Supreme Court's recent holding in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007). Indeed, Amgen's instruction reads as if it was written before the U.S. Supreme Court's decision in *KSR*. In *KSR*, the Supreme Court warned that the so-called "teaching, suggestion, or motivation" test is not controlling and should not be over-emphasized or applied rigidly. 127 S. Ct. at 1741, 1743. According to *KSR*, a person of ordinary skill in the art faced with a finite number of possible combinations "has good

reason to pursue the known options within his or her technical grasp"—making the anticipated success the "product not of innovation but of ordinary skill and common sense." *KSR*, 127 S.Ct at 1742. It is not necessary to "seek out precise teachings directed to the subject matter of the challenged claim…for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 1741.

Further, the instruction precludes reliance on the teachings of the patents-in-suit. The patents-in-suit, however, contain nearly ten columns of discussion on the background of the invention. These "teachings" can provide a reason for combining elements because they may discuss the "need[s] or problem[s] known in the field of the endeavor at the time of invention." *KSR*, 127 S. Ct. at 1742. Moreover, Amgen is bound by its admissions in the patent specifications concerning the prior art. *See PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007) ("Admissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness").

Further, Amgen discusses obviousness in terms of "reasonable expectation" of success. The correct standard, needed only when there is some degree of unpredictability in the art, is reasonable *probability* of success. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) ("obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success").

Roche objects to the detailed listing of "[i]mportant evidence of non-obviousness." Amgen has not introduced evidence concerning many of the secondary considerations of non-obviousness, let alone a nexus between the evidence and the claimed products or processes. *See* Roche's Bench Memorandum Regarding Amgen's Failure to Demonstrate the Requisite Nexus Regarding Secondary Considerations of Non-Obviousness [D.N. 1273]. Accordingly, Amgen is

not entitled to an instruction on these secondary considerations. *See, e.g., Prentiss & Carlisle Co. v. Koehring-Waterous Div. of Timberjack, Inc.*, 972 F.2d 6, 10 (1st Cir. 1992) (affirming district court's refusal to give requested instruction, stating that "[a] jury instruction should not be given if there is not sufficient evidence to support it"); *See also PharmaStem Therapeutics, Inc. v. Viacell, Inc*., 491 F.3d 1342, 1365 (Fed. Cir. 2007) ("The problem with that evidence is that there was no indication that the praise for the inventors' work was based on any inventive contribution they made.")

In addition, Roche objects to the statement that the jury can decide what is and is not prior art. This is an incorrect statement of the law. Whether a document is a prior publication is a question of law. *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1330 (Fed. Cir. 2004); *Reading & Bates Constr. Co. v. Baker Energy Res. Corp.*, 748 F.2d 645, 649-50 (Fed. Cir. 1984). Furthermore, there is no reasonable basis for Amgen to argue that any of the prior art being asserted by Roche does not qualify as prior art, and thus, the instruction suggests to the jury that it can ignore prior art that is properly before the jury. (Amgen disputes as to what the prior art teaches or suggests, but there should be no factual dispute as to whether the prior art qualifies as prior art.) In addition, the statement regarding what constitutes prior are includes needless repetition from prior instructions.

Roche also objects to the instruction that jury cannot consider what Dr. Lin and other scientists expected. This evidence is probative as to whether there was a reasonable *probability* of success.

Roche also objects to the instruction because it does not make clear that the entire scope of the claimed invention must not have been obvious; if any embodiment falling within the scope of the claim would have been obvious, the entire claim is considered obvious.

Roche further objects to phrases such as "the inventor, Dr. Lin," as such phrases improperly suggest that inventions were made when, in fact, Roche challenges the validity of the patents (*i.e.*, that there were no patentable inventions).

Roche repeats its objections to Amgen's prior art instructions because they fail to instruct the jury that unpublished prior art qualifies as prior art for the obviousness analysis. *See* Roche's objection to Amgen's proposed instruction XIV.C. above.

Roche requests that the Court give Roche's proposed post-trial instruction on this issue, which accurately and fairly describes the obviousness determination. *See* Defendants' Proposed Jury Instructions, No. 4.9-4.14 [D.N. 917 at pp. 29-35].

L. OBVIOUSNESS: SCOPE AND CONTENT OF THE PRIOR ART [WITHDRAWN]

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

N. OBVIOUSNESS: LEVEL OF ORDINARY SKILL [WITHDRAWN]

O. OBVIOUSNESS: MOTIVATION TO COMBINE [WITHDRAWN]

P. OBVIOUSNESS: OBJECTIVE INDICATIONS CONCERNING OBVIOUSNESS [WITHDRAWN]

Q. OBVIOUSNESS: SUMMARY [WITHDRAWN]

R. [PROVISIONAL INSTRUCTION] OBVIOUSNESS-TYPE DOUBLE PATENTING[2] [WITHDRAWN]

Because Amgen has either withdrawn these instructions or incorporated them elsewhere, specific objections are no longer necessary. Roche, however, reserves the right to object should Amgen revise or refile these instructions

[2] Because the Court is hearing the obviousness type double patenting issue without a jury, this instruction should not be necessary. Roche does not waive any arguments.

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to the last paragraph because the discussion of the "accused product" inappropriately conflates infringement with validity. Roche requests that the Court give Roche's proposed post-trial instruction on this issue, which accurately and fairly describes the written description determination. *See* Defendants' Proposed Jury Instructions, No. 4.17 [D.N. 917 at 39-40].

A reference to the accused product in an instruction regarding patent validity will confuse and mislead the jury. Roche also objects to the third paragraph two because it includes needless, confusing repetition of the second paragraph.

Roche also objects to the phrase in the second paragraph that ". . . the applicant in fact possesses a means to make and use the claimed invention at the time of the application . . ." The written description requirement concerns whether an inventor was in possession of the invention itself, not merely the means to make or use the invention.

Roche also objects to the discussion in the third paragraph that the specification can "inherently" satisfy the written description. If the description is not "written," the description cannot satisfy the written description requirement of §112.

Roche also objects to the instruction because it does not make clear that there must be a written description for the full scope of the claimed invention.

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 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. 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 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.

In addition to the General Objections, Roche objects to the first paragraph because it does not address the non-enablement of '422 claim 1 and '933 claims 9, 11, 12, and 14, which all require "a pharmaceutical composition" (and in the case of '933 claim 11 and 14, also require administration to a kidney dialysis patient). The patents do not enable sufficiently purifying the rEPO to permit it to be used as a pharmaceutical composition; therefore, these claims cannot be considered enabled Roche requests that the Court give Roche's proposed post-trial instruction on this issue, which accurately and fairly describes the enablement determination. *See* Defendants' Proposed Jury Instructions, No. 4.16 [D.N. 917 at 37].

Roche objects to the instruction because it does not make clear that the full scope of the claimed invention must be enabled.

Roche also objects to the third paragraph as including needless, confusing repetition from the second paragraph. Roche further objects to use of the word "many" in the second sentence of paragraph four ("a conclusion that is reached by weighing many factual considerations") because it is argumentative and improperly suggests that Roche will not be able to meet its burden. Last,

Roche objects to use of the phrase "or unpredictability" in the last sentence of the fourth paragraph ("the predictability or unpredictability of the art") because use of the second term contradicts the first term and, accordingly, misleads and confuses the jury.

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to paragraph one because it does not refer to the '698 patent.

Roche also objects to the third paragraph because it includes needless, confusing repetition from paragraph two which will confuse and mislead the jury.

Roche requests that the Court give Roche's proposed instruction on indefiniteness, which accurately reflects the law. *See* Roche's Proposed Instruction No. 4.18 [D.N. 917 at p. 41]

OBJECTIONS TO AMGEN'S PROVISIONAL INSTRUCTIONS ON INEQUITABLE CONDUCT
(Section XV of Amgen's Instructions)

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to Amgen's instruction because it misstates and misapplies the law regarding inequitable conduct and omits several key issues involved in a proper analysis of inequitable conduct. First,

the applicant's violation of his or her duty of disclosure is not negated by mere submission of information to the Patent Office. The Federal Circuit has made clear that mere submission of information is not a defense against inequitable conduct when an applicant buries material information or presents the information in a manner so that the examiner would be likely to ignore it and permit the application to issue as a patent. *See eSpeed Inc. v. BrokerTec USA LLC*, 480 F.3d 1129, 1138 (Fed. Cir. 2007); *see also* MPEP § 2002.03 (5th ed. Rev. 3, May 1986) ("nonidentification of an especially relevant passage buried in an otherwise less or non-relevant text could result in a holding of 'violation of duty of disclosure'").

Amgen's proposed instruction understates the duty of each individual involved in prosecuting a patent (including, for example, Amgen's employees and attorneys, not just Dr. Lin) to provide all material information known to that individual to the USPTO. That duty is one of candor and good faith, which Amgen neglects to mention.

. The jury should be informed that when a patent applicant takes steps to bury material information, it has engaged in inequitable conduct. *See eSpeed Inc. v. BrokerTec USA LLC*, 417 F. Supp. 2d 580 (D. Del. 2006) (Jordan, J.) (submission made amidst more than two thousand pages of materials was a "blizzard of paper" characterized as "consistent with an intent to hide" and supporting a finding of inequitable conduct), *aff'd*, 480 F.3d 1129 (Fed. Cir. 2007); *Golden Valley Microwave Foods Inc. v. Weaver Popcorn Co, Inc.*, 837 F.Supp. 1444, 1477 (N.D. Ind. 1992)(Lee, J.), *aff'd* 11 F.3d 1072 (Fed. Cir. 1993) (holding duty of candor violated where applicant or attorney discloses reference "in such a way as to 'bury' it or its disclosure in a series of disclosures of less relevant prior art references, so that the examiner would be likely to ignore the entire list and permit the application to issue"); *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F.Supp. 948, 965 (S.D. Fla. 1972) (Mehrtens, J.) ("…purpose of this

misrepresentation was to bury the Wollard patent in a long list of allegedly old prior art patents …. Such conduct violates the required standard of candor and fair dealing with the Patent Office."), *aff'd*, 479 F.2d 1328 (5th Cir. 1973). Roche respectfully requests that the Court instruct the jury with its Proposed Instruction 7.1 [D.N. 917 at 76-78].

Roche further objects to the last two sentences of the second paragraph (beginning "Finally, and importantly, the intent to deceive cannot be inferred . . ."). These sentences improperly suggest that proof of intent must be direct and cannot be circumstantial or based on inferences. That is not the case. The Federal Circuit has reiterated that "[t]here is no requirement that intent to deceive be proven by direct evidence; in fact, it is rarely proven by such evidence." *eSpeed Inc.*, 480 F.3d at 1138. Mere denials of intent to mislead may not be sufficient to overcome circumstantial evidence of intent to deceive. *LaBounty Mfg., Inc. v. United States Int'l Trade Comm.*, 958 F.2d 1066, 1076, (Fed. Cir. 1992). Thus, as a matter of law, the jury is entitled to infer intent from various factors, including:

> • the materiality of a reference. See *Cargill Inc. v. Canbra Foods Ltd.*, 476 F.3d 1359,1367 (Fed. Cir. 2007) ("We have never held that materiality is irrelevant to the question of intent"); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs*., 394 F.3d 1348 (Fed. Cir. 2005) ("intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information");
>
> • evidence that applicant could not have made the same patentability arguments had information been disclosed. See *LaBounty Mfg. v. United States ITC*, 958 F.2d 1066, 1076 (Fed. Cir. 1992); *Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1379(Fed. Cir. 2006); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1275 (Fed. Cir. 2001);
>
> • evidence that the patentee submitted material information to other entities, such as FDA. See *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005); *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989);
>
> • burying material information. See *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995)("Burying a particularly material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith."); *eSpeed Inc.*

v. BrokerTec USA LLC, 417 F. Supp. 2d 580, 598 (D. Del. 2006) (the "blizzard of paper is therefore more consistent with an intent to hide than to disclose").

The applicant's duty of disclosure and candor also requires the applicant to ensure that the relevant art was before the examiner. Amgen, however, may have submitted information to one branch of the PTO but not to the Examining Corp which is charged with issuing the patents-in-suit. Pursuant to the Code of Federal Regulations, an applicant must disclose material information directly to the examiner to discharge the duty of good faith and candor and the duty of disclosure. *See* 37 CFR 1.4(b) ("Since each file must be complete in itself, a separate copy of every paper to be filed in a patent application, patent file, or other proceeding must be furnished for each file to which the paper pertains, even though the contents of the papers filed in two or more files may be identical."); 37 CFR 1.4(c) ("Since different matters may be considered by different branches or sections of the United States Patent and Trademark Office, each distinct subject, inquiry or order must be contained in a separate paper to avoid confusion and delay in answering papers dealing with different subjects."). It is not enough that the applicant submit relevant information to another, separate branch of the PTO (such as the Board of Patent Appeals and Interferences) yet not disclose the same material information to the examiner charged with potentially issuing the application as a patent. *See, e.g.*, *Gen. Elec. Co. v. United States*, 206 USPQ 260, 280 (Ct. Cl. 1979); *A.B. Dick Co. v. Burroughs Corp.*, 617 F. Supp. 1382, 1397 (N.D. Ill. 1985), *aff'd* 798 F.2d 1392 (Fed. Cir. 1986); *Li Second Family Ltd. Partnership v. Toshiba Corp.*, 231 F.3d 1373, 1377-81 (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.

In addition to the General Objections, and without waiving any, Roche specifically objects to Amgen's instruction that the applicant's legal arguments cannot support a finding of inequitable conduct. A characterization of references, and legal arguments relating to those references, may in fact mislead a patent examiner and thereby constitute inequitable conduct. It is entirely possible that arguments can constitute "material information" for purposes of an inequitable conduct charge. *See, e.g., Li Second Family Ltd. Partnership v. Toshiba Corp.*, 231 F.3d 1373 (Fed. Cir. 2000) (patentee's arguments that claims were entitled to the benefit of

earlier filing dates constituted an "affirmative misrepresentation"); *Semiconductor Energy Lab., Co. v. Samsung Elecs. Co.*, 24 F. Supp.2d 537, 542 (E.D. Va. 1998) ("where, as here, material misrepresentations are made in a position advocated to the PTO with intent to mislead, inequitable conduct does exist"); *A.B. Dick Co. v. Burroughs Corp*., 617 F. Supp. 1382, 1393 (N.D. Ill. 1985)(Shadur, J.) (counsel's argument regarding the prior art and the claimed invention was a "affirmatively misleading representation"). Amgen's instruction is therefore likely to mislead the jury and should not be given.

Furthermore, the instruction on materiality neglects to instruct the jury that "[a]n applicant should know information is material when the examiner repeatedly raises an issue to which the information relates." *Cargill Inc. v. Canbra Foods Ltd.*, 476 F.3d 1359, 1366 (Fed. Cir. 2007).

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to this instruction because it is incomplete. Amgen's proposed instruction fails to advise

the jury that direct evidence of intent is rarely found. The instruction also fails to provide examples of the facts and circumstances from which intent may be inferred. *See Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005); *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989).

Furthermore, Amgen's proposed instruction is incomplete because it fails to explain that shielding material information from other individuals who owe the duty of good faith and candor also indicates an intent to deceive. *Novo Nordisk Pharms., Inc. v. Bio-Technology Gen. Corp.*, 424 F.3d 1347, 1361-62 (Fed. Cir. 2005); *FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 526 n. 6 (Fed. Cir. 1987); *Synthon IP, Inc. v. Pfizer, Inc.*, 472 F. Supp. 2d 760, 779-80 (E.D. Va. 2007) (Ellis, J.). This tenet is well-established in patent law but would not likely be apparent to the jury without specific guidance.

Finally the jury should understand that burying material information supports intent to deceive. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995) ("[B]urying' a particular material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith."); *eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 417 F. Supp. 2d 580, 598 (D. Del. 2006) (Jordan, J.) (the "blizzard of paper is therefore more consistent with an intent to hide than to disclose."). Roche respectfully requests that the Court instruct the jury with its Proposed Instruction 7.3 [D.N. 917 at 81-82].

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.

In addition to the General Objections, and without waiving any, Roche specifically objects to this instruction because the second paragraph, which provides a range for materiality, is unclear and likely to confuse the jury into believing that there is a particular formula for balancing materiality and intent. Roche respectfully requests that the Court instruct the jury with its Proposed Instruction 7.4 [D.N. 917 at p.83].

OBJECTIONS TO AMGEN'S SUPPLEMENTAL PROPOSED JURY INSTRUCTIONS
(D.N. 1074-2)

XII.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. Claim 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 [*sic*], 1329 (Fed. Cir. 2003).

This instruction is merely a verbatim repeat of Amgen's proposed instruction XII.C., which is addressed above. Accordingly, Roche incorporates its objections stated above into this supplemental objection.

XIV. I. ANTICIPATION -- EFFECT OF PROCESS OR SOURCE LIMITATIONS

> Where the structure and/or function of a claimed product is novel, in other words new and not found in the prior art, the 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 limitations help to distinguish the claimed product over prior art. Product claims may include process steps to wholly or partially define the claimed product. Similarly, product claims may include source limitations to wholly or partially define the claimed product. To the extent that these sources or process limitations distinguish a novel product over the prior art, they must be given the same consideration as traditional product characteristics.
>
> During prosecution of the '422 and '933 patents, the examiner accepted that the claimed products were novel, and that process or source limitations within the issued claims properly defined the scope of the claimed inventions. To establish that the source limitation 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 the identical product previously existed in the prior art. So, for

> example, Roche must prove by clear and convincing evidence that the claimed product, recombinant EPO purified from mammalian cells grown in culture, is identical to a prior art EPO product, such as Dr. Goldwasser's EPO product purified from urine.
>
> Similarly, to establish that the process limitations of claims 3, 7-9, 11, 12 and 14 of the '933 patent do not distinguish the claim over the prior art, Roche must first prove by clear and convincing evidence that the claimed product in each of those claims is not novel.

In addition to the General Objections, and without waiving any, Roche specifically objects to Amgen's instruction because it fails to instruct the jury on "the rule that a claimed product shown to be present in the prior art cannot be rendered patentable solely by the addition of source or process limitations." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 at n.20 (Fed. Cir. 2003). In footnote 20 of its decision, the Federal Circuit has made clear how this issue is to be handled regarding these patents, and Amgen is bound by that ruling. Rather the claimed product can be patentable (*e.g.,* novel or non-obvious) only if the source or process imparts some new structure to the claimed product that distinguishes it from the prior art product. *See Markman* Order [D.N. 613] at 18. In other words, it is not the process or source that must be new or non-obvious but the *product* itself. *Id.*; *see also SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1318-19 (Fed. Cir. 2006); 3 *Chisum on Patents* § 8.05[3] (2007 ed.) ("Even though a product may be claimed in terms of the process of making it, the product still must be new in structural terms in order to meet the novelty requirement"). If the product is not new (*e.g.*, if the process or source does not confer on the product a novel structure), then it is not patentable.

Roche further objects to the first and last sentences of the second paragraph ("During prosecution of the '422 and '933 patents . . . ." and "So, for example . . .") because they are argumentative and are more properly characterized as evidence for Amgen to argue rather than a neutral instruction on the law. Roche requests that the Court give Roche's proposed instructions

on source and product-by process limitations in D.N. 917 and 1030.

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Boston, Massachusetts

Respectfully submitted,
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CERTIFICATE OF SERVICE

I certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

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