UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

AMGEN INC.'S OBJECTIONS TO
DEFENDANTS' [PROPOSED] JURY INSTRUCTIONS

Plaintiff, Amgen Inc., hereby objects to the instructions set forth the in the Jury Instructions[1] proposed by Defendants F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche").

Amgen generally objects to Roche's jury instructions on the following grounds:

1. The instructions are not impartial and objective;
2. The instructions contain misstatements of law;
3. The instructions omit or mischaracterize Amgen's contentions;
4. The instructions misstate Roche's contentions;
5. The instructions omit reference to prior adjudications of this Court that are material to the issues the Jury must resolve; and
6. The instructions do not closely conform to the model instructions that are cited by Roche.

For these reasons and the reasons set out below, Amgen respectfully requests that this Court not follow the instructions proposed by Roche. In contrast, Amgen's Revised Post-Trial Instructions

[1] D.I. 917. Amgen further incorporates herein by reference its objections (DI 1074) filed to Roche's Proposed Supplemental Proposed Jury Instruction Concerning Source and Process Limitations.

follow the Federal Circuit Bar Association Model Jury Instructions and previously given instructions of this Court.

I. OBJECTION TO ROCHE'S PROPOSED INSTRUCTIONS § 1 – GENERAL INSTRUCTIONS

Amgen objects to Roche's jury instructions because they do not include appropriate instructions on testimony by deposition, exhibits as evidence, stipulations, or deliberations. Amgen further objects to Roche's general instructions because they are not impartial and objective.

Instruction 1.2 – Jurors' Duties

Amgen objects to this proposed instruction as it misstates the law, undermines the presumption of validity, is not impartial or objective, and is highly prejudicial to Amgen. This instruction does not mention the burden of proof, the presumption of validity, or the double presumption with prior art and arguments already considered by the PTO.

Amgen specifically objects to the second paragraph as undermining the presumption of validity by stating that the jurors must "decide whether Amgen's asserted patents ***are valid***." (emphasis added). Patents are presumed valid by statute under 35 U.S.C. § 282.

Amgen also objects to the second paragraph to the extent that it prejudicially and incorrectly summarizes the law regarding a finding of inequitable conduct into one statement that disregards the need to observe the totality of the circumstances, to separately find clearly and convincingly that the elements of materiality and intent are met, and the subsequent requirement to then balance a finding of intent to deceive with materiality. Amgen finally objects to the instruction as unfairly prejudicial and misstating the law in asking the jurors to determine if Amgen "buried material information" before the Patent Office.

Instruction 1.6 - Credibility Of Witnesses

Amgen objects generally to this proposed instruction because it is not impartial or objective and is highly prejudicial.

Amgen specifically objects to Roche's second paragraph regarding prior testimony. This statement is prejudicial in attempting to blur the lines between testimony from Amgen employees made during previous matters regarding subjects entirely different from the subjects at issue in this case. The instruction further fails to point out that earlier consistent statements may rehabilitate a witness.

II. OBJECTION TO ROCHE'S PROPOSED INSTRUCTIONS § 2 – THE PARTIES AND THEIR CONTENTIONS

Instruction 2.2 - Summary of Plaintiff's Contentions

Amgen objects generally to this proposed instruction because it mischaracterizes Amgen's contentions, is not impartial and objective and is highly prejudicial to Amgen. First, the instruction fails to state that the Court has adjudicated as a matter of law that '422 Patent, claim 1, has been adjudicated in favor of Amgen. Second, Amgen objects to Roche's statement that "Amgen contends that Roche has imported and is currently importing into the United States" Mircera. This misstatement attempts to depict Roche as having done nothing improper because it has not imported Mircera into the U.S., but is inaccurate as to Amgen's contention. Third, Amgen objects to Roche characterizing the status of its FDA application because Roche has failed to provide discovery on this point and Roche has publicly stated that it intends to launch the MIRCERA® product in the Fourth Quarter of this year. As such, Amgen objects to this instruction as highly prejudicial. Amgen is bringing a suit for declaratory judgment of infringement "when" Roche begins importation. Finally, the instruction fails to state that Amgen contends that Roche's allegation of invalidity and inequitable conduct are without merit.

Instruction 2.3 - Summary of Defendants' Contentions

Amgen objects to this proposed instruction because it mischaracterizes both Amgen's and Roche's contentions, contradicts the Court's prior rulings, misstates the law, instructs the jury on issues that are not in front of the jury, is irrelevant, is not impartial or objective, and would unfairly prejudice Amgen.

Amgen objects to the first paragraph as it is contradictory to the Court's adjudication that Roche infringes claim 1 of the '422 patent and the law of the case. Roche's contention that it does not infringe this claim would be extremely misleading and confusing to the jury.

Amgen objects to the second paragraph of this instruction because it improperly implies that there is 35 U.S.C. § 271(e)(1) protection against Amgen's declaratory judgment action for Roche's future commercial sales. This paragraph also misstates the role of Section 271(e)(1). Roche elicited no evidence supporting a defense under 35 U.S.C. § 271(e)(1) and the defense is irrelevant where Amgen seeks to reach only non-exempt activities. Reference during the charge to this defense would confuse and mislead the jury.

Amgen objects to the third paragraph as misleading and unfairly prejudicial to the extent that it includes instructions regarding obviousness-type double patenting ("ODP"), which this Court has removed from consideration by the jury, and definiteness, which is a question of law for the Court. Amgen objects to the last sentence of the third paragraph on prolonging a monopoly as such issue is not before the jury and the issue of choice has been ruled to be irrelevant to this matter.

Amgen objects to the fourth paragraph as irrelevant and unfairly prejudicial to Amgen because Roche has not presented any evidence supporting a defense of inequitable conduct.

If Roche puts on an inequitable conduct case:

Amgen objects to the fourth paragraph as unfairly prejudicial, not impartial, and not objective because it implies that Amgen, in fact, acted wrongfully and improperly, rather than stating that Roche "alleges" that Amgen acted wrongfully or improperly. This paragraph also improperly undermines Roche's high burden of proof.

Instruction 2.4 - Summary of Parties' Issues

Amgen objects to Roche's proposed instruction 2.4 because it mischaracterizes both Amgen's and Roche's contentions, contradicts the Court's prior rulings, includes issues that are not in front of the jury, is not impartial or objective, and would confuse the jury and unfairly prejudice Amgen.

Amgen objects to several of Roche's proposed invalidity issues that the jury must determine. First, Amgen objects to the identification of the theories of invalidity without reference to a particular claim or patent. Invalidity must be proved on a claim by claim basis. Second, Amgen objects to the following as they are listed but no longer at issue in this case:

- Whether the subject matter of an asserted claim was known publicly more than a year before the patent for the asserted claim was filed.
- Whether the subject matter of an asserted claim was sold in the U.S. more than a year before the patent for the asserted claim was filed.
- Whether the subject matter of an asserted claim was patented in the U.S. or a foreign country more than a year before the patent for the asserted claim was filed.
- Whether some of the claims-in-suit are mere obvious variations of Amgen's expired '008 patent, the '868 patent, or the '698 patent.
- Whether, during the prosecution of the patent application that led to the '349 patent, Amgen elected to proceed under 35 U.S.C. Sec. 103(b), and thus the '349 patent should have expired when the '008 patent expired.

Third, Amgen objects to the statements of contentions with respect to contentions on anticipation, obviousness, written description, enablement and indefiniteness as such statements are incomplete and contain erroneous statements of the law. For example, the instruction on enablement fails to state that the test is whether one of ordinary skill in the art could practice the invention claimed without "undue experimentation."

Amgen objects to Roche's mischaracterizations and misstatements of the law regarding the decisions that the jury must make on infringement and inequitable conduct. First, Amgen objects in that the statements on infringement fail to point out that infringement is on a claim by claim basis. Second, Amgen objects to the following:

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

Amgen objects to Roche's inclusion of any of these aforementioned issues as misstatements of the issue before the jury, irrelevant, not impartial or objective, and highly prejudicial to Amgen.

Finally, Amgen objects to the instruction on Section 271(e)(1) because it improperly implies that there is 35 U.S.C. § 271(e)(1) protection against Amgen's declaratory judgment action for Roche's future commercial sales. Roche elicited no evidence supporting a defense under 35 U.S.C. § 271(e)(1) and Amgen is not seeking to reach such activities in this suit. Reference during the charge to this defense would confuse and mislead the jury.

Instruction 2.5 - Issues Established By Prior Litigations

Amgen objects to Roche's proposed instruction 2.5 because it mischaracterizes prior adjudications, contradicts the Court's prior rulings, misstates and misapplies the law, is not impartial or objective, and would confuse the jury and unfairly prejudice Amgen. Amgen objects that this instruction is argumentative and states as fact what are substantive arguments that Roche must prove.

Amgen objects to Roche's instruction to the jury regarding "issue preclusion" as misstating the law. Moreover, an instruction on issue preclusion is irrelevant to a jury. If an issue has been fully determined previously and issue preclusion applies here, the Court should explain what that issue is, rather than embark on instructing the jury on the legal concept of issue preclusion.

Further, any admissions under Rule 36 is for the purpose of the pending action only and is not an admission for any other purpose nor may it be used against the party in any other proceeding.[2] The issues from prior proceedings that Roche seeks to admit are misleading and irrelevant. All of the excerpts relate to findings about patent claims and claim language that are not at issue in this proceeding. In addition, court orders from prior proceedings are inadmissible hearsay.

Amgen objects to Roche's assertions as to what has previously been adjudicated as binding. These assertions misstate the law, misstate facts, are irrelevant, and are highly prejudicial. Amgen objects to the following of Roche's assertions:

- Recombinant erythropoietin cannot be distinguished from urinary erythropoietin on the basis of glycosylation.

Roche's instruction completely misstates and contradicts the Court's findings by citing to a finding that has no relevance to the issues in this litigation. Roche's citation relates to the Court's finding in the TKT litigation concerning the definiteness of '933 claim 1, not at issue here, requiring "glycosylation which differs from that of urinary EPO," but which did not specify

[2] Federal Rule of Civil Procedure 36(b).

the particular urinary EPO to use as a comparator.[3] In this litigation the issue is whether the glycosylation of only one form of urinary EPO – the specific Goldwasser urinary EPO asserted as anticipatory prior art by Roche[4] – differs from the glycosylation of the claimed invention of '422 claim 1 and the '933 claims at issue here. In this litigation, there is no issue relating to urinary EPOs generally. And even as to the glycosylation of urinary EPOs, generally, Roche's instruction misleadingly ignores Court's finding in the TKT litigation that "one skilled in the art in 1983 would understand that 'the recombinant proteins are glycosylated differently than the naturally-occurring protein, and that these differences can be revealed by running an SDS-PAGE and doing a western blot. . . .'"[5]

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

This statement is irrelevant, prejudicial, and confusing to the jury because Roche's accused product is not an analog and not all of the claims have been examined and construed in this case. Further, this argument contradicts this Court's previous adjudication that the '422 patent infringed Amgen's patents. Therefore, any instruction like this is misleading to the jury and highly prejudicial to Amgen.

III. OBJECTIONS TO ROCHE PROPOSED INSTRUCTIONS § 3 – BURDEN OF PROOF

Amgen objects to this proposed instruction as not impartial and objective. The instruction elaborates on Amgen's burden of proof, but not Roche's and fails to make clear that

[3] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 155-56, 165 (D. Mass. 2001). As Amgen noted its Responses and Objections to Defendants' Omnibus Motion to Admit Party Admission and Previous Findings of Fact into Evidence (Docket No. 1130), the language that Roche cites to regarding glycosylation relates specifically to this Court's opinion in the HMR/TKT matter regarding claims 1, 2 and 9 of the '933 patent. In particular, this quote relates to the court's analysis of the limitation in claims 1, 2 and 9 of "glycosylation which differs from that of human urinary erythropoietin." In fact, the quote that Roche cites to does not end where Roche indicates in its paper, but continues "and that this failure is fatal to all three asserted '933 claims." As this Court is aware, Amgen does not assert any of these '933 claims in this proceeding. Prior findings regarding these unasserted claims have no relevance. Indeed after Amgen filed its opposition to these previous findings of fact, Roche withdrew its motion to admit them.

[4] To be clear, Roche's Dr. Bertozzi only relies on Dr. Goldwasser's urinary EPO, not other prior art urinary EPOs, as the basis for her opinions that '933 claims 3, 7-9, 11, 12, and 14 are anticipated. 9/14/07 Trial Tr. 1047:15-1050:3, 1052:14-1053:12.

[5] *Amgen, Inc.*, 126 F. Supp. 2d at 125.

Roche must satisfy the burden as articulated by the Court in its original preliminary charge on invalidity as stated on September 5, 2007, at Tr. 114:10-115:7 (must prove by clear and convincing evidence).

IV. OBJECTIONS TO ROCHE PROPOSED INSTRUCTIONS § 4 - VALIDITY DEFENSES

Amgen objects to this proposed instruction as prejudicial, subjectively unfair, and not impartial because it ignores the presumption of validity given to issued patents.[6] Moreover, the proposed instruction ignores the additional presumption when the same prior art and/or invalidity arguments were previously considered by the Patent Office examiner.[7] Roche's proposed instruction improperly seeks to undermine these presumptions with an instruction given by the Court as a matter of law. Finally, the proposed instruction lists Roche's invalidity contentions, but improperly and prejudicially excludes Amgen's contentions relating to the validity of the patents.

Amgen objects to this instruction as including defenses not raised by Roche or issues that have been removed from the jury, *viz. o*bviousness-type double patenting, indefiniteness, 35 U.S.C. § 103(b), and claims 4 and 5 of the '698 Patent.

Instruction 4.2 – Anticipation

Amgen objects to this instruction because it mixes Roche's contentions with its instruction on anticipation and thus is not impartial and objective. Amgen objects that this instruction also misstates the law.

Amgen objects to Roche's instruction that the '422 Patent is anticipated. The Court's JMOL decided this issue against Roche. Amgen further objects to Roche's instruction, "[i]f the prior art was ***properly before the PTO*** . . ." as injecting a subjective element as to whether material reviewed and considered by the PTO was properly before it.

[6] 35 U.S.C. § 282

[7] *See American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984).

Amgen further objects to Roche's instruction that "the presumption of validity of the patent is weakened because the rationale underlying the presumption – that the PTO, using its expertise, had approved the claim – is diminished."[8] Roche has not shown this language, which closely mirrors *KSR*'s dicta, is applicable here.[9] The *KSR* Court comment was based upon the facts in that case and was not meant to be a rule prospectively applied to all other patent cases and is contrary to 35 U.S.C. § 282.

Amgen objects that this instruction fails to instruct the jury regarding the second presumption for art considered by the PTO.

Amgen further objects to the following statement of source or process in Roche's instruction:

> A product-by-process claim covers the product, not the process. Amgen's product-by-process claims are anticipated if the products of those claims existed in the prior art. Whether such prior art products were produced by a process different from the process employed by Amgen, or are from a different source, is immaterial when determining the validity of Amgen's product-by-process claims. For that determination, the focus remains at all times on Amgen's claimed product and the products of the prior art. [10]

Roche fails to instruct the jury that source or process limitations can serve to define the structure of the claimed product where such limitations distinguish a claimed product over prior art. Moreover, to the extent that these source or process limitations distinguish the product over the prior art, they must be given the same consideration as traditional product characteristics.[11]

Roche's inherency instruction is also partial and misstates the law when it charges the jury that "[i]nherency, however, does not require that a person of ordinary skill in the art of the disclosure or occurrence of the anticipating subject matter would have recognized the inherent disclosure" because Roche does not provide the jury of when the inherency should be recognized.[12] As such, the jury may erroneously stray outside the relevant time frame, which is

[8] D.I. 917 at 21.
[9] *See KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1745 (2007)
[10] D.I. 917 at 21-22.
[11] *See* D.I. 918 at 63.
[12] D.I 917-22. Amgen reserves the right to file additional objections to any subsequently filed instructions by Roche.

whether at the time of the invention one of ordinary skill in the art would have recognized the inherency, if any.[13]

Roche should further make clear to the jury that it is Roche that has the burden of proving inherency by clear and convincing evidence rather than referring to the generality that a party claiming inherency has this burden. This leaves the jury with no doubt who has the burden of proof.

Instruction 4.3 – Effective Filing Date and Date of Invention

Amgen objects to Roche's instruction because it does not state the standards for Amgen to prove an earlier date of invention. Amgen further objects as it misstates the date of invention(s) and puts the burden on the wrong party as the burden is on Roche to prove clearly and convincingly all requisites for prior art.[14]

Instruction 4.4 – Prior Public Use

Amgen objects to this instruction because it does not state the test for public use, *i.e.*, public use in the United States more than one year before the application date.

Amgen objects to Roche's instruction because it includes claim 1 of the '422 Patent in light of the Court's JMOL decision. This issue is no longer before the jury. Furthermore, it misstates the public use requirement as it implies that any use by the inventor satisfies the public use requirement.

Instruction 4.5 – Prior Invention

Amgen objects to this instruction because it misstates the law of prior invention: the prior inventor must conceive and reduce to practice, both of which require a subjective, contemporaneous understanding by the inventor along with corroborating evidence.[15] Amgen also objects to this instruction because it does not accurately state the test under 35 U.S.C. §

[13] *See PharmaStem Therap., Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007).

[14] *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577-79 (Fed. Cir. 1996); *Loral v. Matsushita*, 266 F.3d 1358, 1361 (Fed. Cir. 2001)(burden of proof remains on defendant to establish prior art, plaintiff bears only a burden of production to antedate)

[15] *Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1339 (Fed. Cir. 2001); *Sandt Technology v. Resco*, 264 F.3d 1344, 1350 (Fed. Cir. 2001).

102(g)(2). The test is that Roche must establish by clear and convincing evidence that (1) another inventor did not abandon, suppress or conceal their invention, (2) reduced to practice their invention before the inventions by Dr. Lin, or conceived of an invention before Dr. Lin and diligently reduced it to practice, and (3) the prior reduction to practice or prior conception is supported by independent corroborating evidence.[16]

Amgen objects to Roche's instruction because it includes claim 1 of the '422 Patent in light of the Court's JMOL decision. This issue is no longer before the jury.

Instruction 4.6 – Prior Public Knowledge

Amgen objects to this instruction because it does not state the test accurately under 35 U.S.C. § 102(a) for what was publicly known. Amgen also objects to Roche's instruction because it includes claim 1 of the '422 Patent in light of the Court's JMOL decision. This issue is no longer before the jury.

Instruction 4.7 – Printed Publication

Amgen objects to Roche's instruction because it includes claim 1 of the '422 Patent in light of the Court's JMOL decision. This issue is no longer before the jury.

Amgen also objects to Roche's deviation from AIPLA Model Jury instruction 6.4 in omitting from its instruction, that "[t]he information must, however, have been maintained in some form, . . ." in order to give the Jury the context to determine whether material Roche wants the jury to consider constitutes a "prior publication."

Amgen further objects to the instruction, "[f]or a printed publication . . . sheds light on the knowledge such a person would have had," as overly complex and likely to confuse the jury. The instruction should also include a charge that it is Roche's burden to prove that a prior publication is enabling and whether it would have been within the knowledge of a person of ordinary skill in the art.

[16] *See Sandt Technology*, 264 F.3d at 1350.

Instruction 4.8 – Prior Patent

Amgen object to Roche's instruction because it includes claim 1 of the '422 Patent in light of the Court's JMOL decision. This issue is no longer before the jury. Moreover, Roche's instruction that the "unclaimed disclosures" of a prior art patent is presumed enabled is not supported by *Amgen Inc. v. Hoechst Marion Roussel, Inc*.[17] That case addressed claimed disclosures and was silent on unclaimed disclosures.[18]

Instruction 4.9 - Obviousness

Amgen objects to this proposed instruction because it is not impartial and objective, it is arbitrary and subjectively unfair, and it prejudicially and erroneously misstates the law.

Roche's instruction is arbitrary, subjectively unfair, prejudicial, and not objective because it states Roche's contentions that the claims are invalid as obvious, but fails to state Amgen's contentions that the claims are not obvious. Roche's instruction is also subjectively unfair, prejudicial, and erroneous as to the law because it improperly implies that the claimed subject matter would have been obvious, in fact, to one of ordinary skill in the art.

Amgen further objects to this instruction because it prejudicially and erroneously mischaracterizes the law, as follows:

- "The combination of ***familiar elements*** according to ***known methods*** is likely to be obvious when it does no more than yield ***predictable results***. When a patent simply arranges ***old elements*** with each performing the ***same function*** it had been ***known*** to perform and yields no more than one would expect from such an arrangement, the combination is obvious."

Although the words in this instruction may be found in case law, the instruction improperly invites the jury to ***assume***, without clear and convincing proof, that all of the elements of the claims were "old" and familiar, all of the methods were known, all of the functions were the same, and all of the results were predictable. These are determinations for the jury to make based on clear and convincing evidence and are not to be assumed as fact.

[17] 457 F.3d at 1307
[18] *Id.*

- "You must consider ***all of the prior art references*** and evaluate obviousness from the perspective of one of ordinary skill in the art ***at the time the invention was filed*** (not from the perspective of a layman or a genius in the art).

This portion of the instruction erroneously defines the point in time from which prior art and obviousness are to be evaluated. Contrary to the instruction, obviousness is determined as of the date of the inventions, not the filing dates of the patents.[19] Moreover, this portion of the instruction fails to inform the jury that what is "prior art" for the purposes of determining obviousness is a factual matter for them to decide.

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

This portion of the proposed instruction prejudicially mischaracterizes the law, which requires clear and convincing evidence of a reasonable probability of success to overcome the presumption of patent validity.[20]

- "Many techniques that require extensive time, money, and effort to carry out may nevertheless be arguably routine to one of ordinary skill in the art and do not equate to a conclusion that an expectation of success was unlikely."

This portion of the proposed instruction is objectionable as improper argument rather than an impartial and objective statement of the law. This portion of the proposed instruction misstates the law by leaving out the preceding, qualifying portion of the opinion: "the length, expense, and difficulty of the techniques used are [not] dispositive since many techniques that require extensive time, money, and effort to carry out may nevertheless be arguably "routine" to one of ordinary skill in the art."[21]

[19] 35 U.S.C. § 103(a).
[20] *Pfizer Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1367 (Fed. Cir. 2007).
[21] *Pfizer Inc.*, at 480 F.3d at 1367.

Instruction 4.10 - Obviousness Decision

Amgen objects to this proposed instruction because it is arbitrary and subjectively unfair and contains misstatements of the law. The proposed instruction improperly refers to "the prior publication, inventions, etc." without adequate legal definitions for the different types of prior art. The proposed instruction fails to state the requirement that, in order to support a conclusion of obviousness, there must be a suggestion or motivation to combine the teachings of the prior art.

First, the proposed instruction is incorrect on the issue of inherency and obviousness. That "which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown."[22] Such a retrospective view of inherence is not a substitute for some teaching or suggestion supporting an obviousness rejection.[23]

The proposed instruction further is neither impartial nor objective because it discusses only reasons to combine references to find an invention obvious. For instance, the instruction states that "it often may be the case that market demand, rather than scientific literature, will provide the motivation to create a particular combination that renders the claimed invention obvious." No counterbalance to this portion of the instruction is provided.

The proposed instruction misstates the law in improperly failing to point out that "the effects of demands known to the design community or present in the marketplace; the background knowledge possessed by a person having ordinary skill in the art; and the inferences and creative steps that a person of ordinary skill in the art would employ" are not to be used as reasons to combine prior art references, but rather to be used for the purpose of determining ***whether there was an apparent reason to combine*** the allegedly known elements in the fashion claimed by the patents at issue.[24]

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[22] *In re Sporman*, 363 F.2d 444, 448 (CCPA 1966).
[23] *See in re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989).
[24] *KSR*, 127 S. Ct. 1727, 1740-41 (2007).

Instruction 4.11 - Scope and Content of the Prior Art

Amgen objects to this proposed instruction as arbitrary and subjectively unfair because it fails to limit the prior art that the jury may consider to the prior art received into evidence. The proposed instruction also misstates the law because it fails to inform the jury that what is or is not "prior art" for the purposes of determining obviousness is a factual matter to be determined by the jury. The instruction does not state the test for analogous art.

Finally, the proposed instruction is incorrect on the issue of inherency and obviousness. That "which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown."[25] Such a retrospective view of inherence is not a substitute for some teaching or suggestion supporting an obviousness rejection.[26]

Instruction 4.12 - Objective Factors

Amgen objects to this proposed instruction because it is arbitrary and subjectively unfair in failing to even state that the limited factors listed are evidence of ***non-obviousness***. The proposed instruction also prejudicially and erroneously states the law because it provides only a partial list of the objective factors of non-obviousness that a jury may consider.

Amgen objects to this proposed instruction because it misstates the law in imposing on Amgen the requirement to prove "a nexus between the merits of invention and evidence of objective factors." To support this proposed instruction Roche cites to *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*[27] *PharmaStem*, however, merely states that there was "no indication that the praise for the inventors' work was based on any inventive contribution they made, as opposed to their proof . . . that fetal blood contains large numbers of stem cells."[28] It does not hold, as Roche contends, that "praise by others for the inventors' work must be directly tied to an actual inventive contribution rather than confirmation of what the state of knowledge in the art was already indicating." Moreover, Roche has not provided evidence to support a

[25] *In re Sporman*, 363 F.2d 444, 448 (CCPA 1966).
[26] *See in re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989).
[27] 491 F.3d 1342, 1365 (Fed. Cir. 2007).
[28] PharmaStem,

determination that praise by others for Dr. Lin's work was merely "confirmation of what the state of knowledge in the art was already indicating."

Amgen objects to the instruction because it improperly places a burden on Amgen to prove a nexus between the secondary factors of non-obviousness and the inventions. Amgen has a burden of production to provide evidence of a nexus, but the burden remains on Roche to prove invalidity by clear and convincing evidence.

Instruction 4.13 - Level of Ordinary Skill in the Art

Amgen objects to this proposed instruction for failing to state the parties' contentions as to the level of ordinary skill in the art. Amgen objects to this instruction as irrelevant and unfairly prejudicial to the extent that it recites factors showing the level of skill in the art that were not introduced at trial. Moreover, Roche's instruction lists factors, including prior art patents and publications, activities of others, and the sophistication of the technology, that are not included in the Federal Circuit Bar Association's Model Jury Instructions.

Instruction 4.14 - Factors Indicating Obviousness

Amgen objects to this proposed instruction as not impartial and objective because it provides a separate instruction on a single pro-defendant secondary factor relating to obviousness. Amgen objects to this proposed instruction because it is arbitrary and subjectively unfair in being titled "Factors Indicating Obviousness," while Instruction 4.12, which addresses factors indicating ***non-obviousness*** is merely titled "Objective Factors." The proposed instruction misstates the law in saying that "the simultaneous or near simultaneous invention by others of the patented subject matter ***is a secondary consideration supporting a conclusion of obviousness***." In fact, the law states that "[t]he fact of near-simultaneous invention, though not determinative of statutory obviousness, is strong evidence of what constitutes the level of ordinary skill in the art," and "[t]he possibility of near simultaneous invention by two or more

equally talented inventors working independently, . . . ***may or may not*** be an indication of obviousness when considered in light of all the circumstances."[29]

Instruction 4.15 - Derivation of Invention

Amgen objects to this proposed instruction as not impartial and objective because it provides a separate instruction on a single category of prior art. Amgen objects to the proposed instruction as substantially unfair because it fails to state that Roche must show derivation of the claimed invention by clear and convincing evidence.

Roche clearly misapprehends the application of Section102(f) and its jury instruction fails to identify the requirements of conception and reduction to practice, along with the requirement of a clear communication of this invention to Amgen.[30]

Instruction 4.16 - Enablement

Amgen objects to the proposed instruction because it includes Roche's contentions in what is supposed to be an impartial and objective instruction on the law. Amgen also objects to the instruction because it misstates Roche's contentions. At the September 24, 2007 hearing, the only claim for which Roche claimed that it had presented evidence on non-enablement was claim 7 of the '349 patent.[31]

Amgen objects to the proposed instruction as arbitrary, unfairly prejudicial, and not impartial or objective because it implies that the field of the invention is unpredictable for the purposes of determining enablement.

Finally, Amgen objects to the instruction's statement that it is "whether the written description would require undue experimentation," when the proper test is whether one of ordinary skill in the art with the specification in hand could practice the invention claimed without undue experimentation.

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[29] *Ecolochem, Inc. v. So. Cal. Edison Co,*, 227 F.3d 1361, 1379 (Fed. Cir. 2000).
[30] *See Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1344 (Fed. Cir. 2003).
[31] Trial Tr. at 1299:5-20.

Instruction 4.17 - Written Description

Amgen objects to the proposed instruction because it includes Roche's contentions in what is supposed to be an impartial and objective instruction on the law. Amgen also objects to the proposed instruction because it misstates Roche's contentions. Roche contends that some, but not all, of the asserted claims of the '933 patent lack written description.

Amgen objects as irrelevant the portion of the proposed instruction stating that the "written description is the 'technologic disclosure of the invention.'"

Amgen objects to the proposed instruction as unfairly prejudicial, subjectively unfair, and misstating the law in asserting that written description must "allow other inventors to develop and obtain patent protection for later improvements and subservient inventions that build on applicant's teachings." None of the case law cited by Roche supports this statement. Roche has taken a statement in Chisum on Patents § 7.04 regarding the ***purpose*** of the written description requirement and turned it into a ***requirement*** for written description.

Amgen objects to the proposed instruction as unfairly prejudicial, subjectively unfair, and misstating the law in re-stating long-standing case law in the negative. The written description is satisfied if a person of ordinary skill in the field, reading the patent application as originally filed, would recognize that the patent application described the invention as finally claimed in the patent. Roche incorrectly states that "the written description is ***not*** satisfied if a person of ordinary skill in the field . . . would ***not*** recognize that the patent application described the invention as originally claimed in the patent." Roche therefore improperly shifts the burden onto Amgen to prove that the written description requirement is met, rather than resting it on Roche to prove, by clear and convincing evidence, that written description requirement is not met.

Amgen objects to the proposed instruction as unfairly prejudicial and erroneously stating the law in asserting that the patent must contain a "complete" written description of the invention covered by any of its claims.

Instruction 4.18 - Indefiniteness

Amgen objects to this instruction as the issue is a matter of law, and not one for the jury to decide.

Amgen objects to the first sentence of the proposed instruction as indecipherable. Amgen objects to the first paragraph of the proposed instruction as prejudicial and subjectively unfair because it fails to state that Roche has the burden to prove indefiniteness of each of the asserted claims by clear and convincing evidence. Amgen also objects to this instruction because indefiniteness is a matter of law for the Court to determine.

Amgen objects to the second paragraph of the proposed instruction as irrelevant in merely stating that the "amount of detail required to be included in claims depends on the particular invention and the prior art." Amgen further objects to the second paragraph because it misstates the law in implying that patents, not claims, may be invalid for indefiniteness. In addition, Amgen objects to this paragraph as subjectively unfair and prejudicial because it implies that Amgen has the burden to prove the claims are definite, rather than that Roche has the burden to prove, by clear and convincing evidence, that the claims are indefinite.

Amgen objects to the third paragraph of the proposed instruction as irrelevant to the facts to be decided by the jury.

Amgen objects to the final paragraph of the proposed instruction as subjectively unfair and prejudicial in implying that the claims are not presumed to be definite.

Instruction 4.19 - Invalidity for Double Patenting

Amgen objects to this proposed instruction as improper and in conflict with the Court's ruling that double patenting is a question of law for the Court.

Instruction 4.20 - Biotechnological Process Election

Amgen objects to this proposed instruction as subjectively unfair, prejudicial, and inconsistent with Roche's contentions as stated during the September 24, 2007 hearing. During

that hearing Roche did not indicate that it contends that claim 7 of the '349 patent is invalid and/or unenforceable under 35 U.S.C. § 103(b).[32]

V. OBJECTION TO ROCHE'S PROPOSED INSTRUCTIONS § 5 - CONSTRUCTION OF CLAIMS

Instruction 5.1 – General Principles

Amgen objects to this proposed instruction because it improperly instructs the jury to engage in claim construction, which is a matter solely for the Court.

Instruction 5.2 – Dependent and Independent Claims

Amgen objects to Roche's proposed instruction 5.2 as it misstates the law regarding dependent claims, which would confuse the jury and unfairly prejudice Amgen. Specifically, Amgen objects to the statement "a dependent claim refers to at least one other claim in the patent and thus incorporates all the elements of that other claim, *plus additional elements*." Amgen objects that this instruction is vague as to what dependent claims are and as a result, would mislead the jury in determining the scope of Amgen's patents and prejudice Amgen.

Instruction 5.3 – Markush Groups

Amgen objects to Roche's proposed instruction 5.3 as it is irrelevant, and because it misstates the law, ignores the Court's prior rulings regarding Roche's Markush Group assertions that the claims of the suit are not limited to a single diluent, adjuvant or carrier, and would confuse the jury and cause undue prejudice to Amgen.

VI. OBJECTIONS TO ROCHE PROPOSED INSTRUCTIONS § 6 - INFRINGEMENT

Instruction 6.1 – General Principles

Amgen objects to instructing the jury that Amgen sued and alleged that "Roche's product and method for producing its product infringes the following claims in the patents-in-suit: . . . 'claim 1 of the '422 Patent.'" This is inaccurate. The Court determined as a matter of law that MIRCERA® infringes claim 1 of the '422 Patent. Roche's instruction will confuse the jury to

[32] Trial Tr. at 1299:5-21

believing that Amgen does not contend that MIRCERA® infringes the '422 Patent. Moreover, the law of the case doctrine precludes Roche from arguing to the jury otherwise. Roche's argument under 35 U.S.C. § 271(e)(1) as a basis for non-infringement has been waived for failing to argue this at summary judgment. Roche's Section 271(e)(1) argument is irrelevant. Amgen's declaratory relief seeks a determination from the jury of Roche's commercial activities which are outside provisions of Section 271(e)(1).

Moreover, Roche's instruction that "any person or business entity which makes, uses or sells … any product, apparatus or method legally protected by at least one claim of a patent within the United States before the patent expires, infringes the patent" ignores that importation of a product made by a patented process is infringement under 35 U.S.C. § 271(g).

Instruction 6.2 – Direct Infringement – Knowledge of Patent or Intent to Infringe Is Immaterial

Amgen objects to the instruction that "[i]t is not enough if Amgen has shown only the evidence allows for two but equal opposite conclusions." The jury is left with the impression that something more is needed but not what more is needed under Amgen's proof. For example, the jury may not know that if it is more likely the truth that Roche infringes, then Amgen has proven infringement. With Roche's instructions, the jury will evaluate the evidence without the proper context. The instruction is also unfairly prejudicial in comparison to Roche's instruction on the burden of proof to show invalidity.

Amgen also objects to the phrase "more likely than not that Roche has made, used, or sold the invention," in so far as the language does not focus the jury to whether Roche's accused product or process meets the requirements of the asserted claims of the patents-in-suit. Amgen also objects to this instruction as mischaracterizing the nature of this case, which is a declaratory judgment action. Amgen is not suing Roche for past infringement.

Instruction 6.3 – Inducing Patent Infringement

Amgen objects to this instruction for failing to provide the jury with an instruction that intent can be proven by direct or circumstantial evidence. Amgen further objects to the instruction limiting inducement to "patients" and thus excluding doctors.

Amgen objects to Roche's instruction "[i]f Roche provided instructions and directions to perform . . . this may be evidence of inducement to infringe."[33] Roche's language mischaracterizes the nature of this case, which is a declaratory judgment action. Amgen is not suing Roche for past infringement.

Roche's instruction on using "opinion of its counsel" for the jury to "negate the finding necessary for inducement of infringement" is improper and prejudicial. Roche has not raised reliance on the advice of counsel, waived its privilege, nor allowed Amgen any discovery on this matter, and thus such language should be stricken.

Instruction 6.4 – Literal Infringement

Roche's instruction, "[r]emember, the question is whether Roche's product or method infringes any claim of Amgen's patent-in-suit, and not whether Roche's product is similar or even identical to a product made by Amgen" is unnecessary in light of the preceding paragraph and the sentence immediately following this language, which instructs the jury to compare Roche's product to the claims of Amgen's patents.

Amgen also objects to the following: "[f]or Amgen's product-by-process claims, Amgen must prove that Roche's product possesses the same material structural and functional characteristics as the claimed product by process and also is made by a process employing each and everyone of the steps recited in the claims." Neither the *Scripps* nor *Atlantic Thermoplastics* cases cited by Roche support the use of such an instruction.[34] The Federal Circuit Bar's model jury instructions based on these two cases further do not support Roche's use of "same material

[33] D.I. 917 at 49.
[34] D.I. 917 at 53, n. 60 (citing *Scripps*, 927 F.2d at 1580; *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 846-47 (Fed. Cir. 1992).

structural and functional characteristics" instruction proposed by Roche. All that is required is that Roche's accused product has to meet the limitations of the claim.

Instruction 6.5 – Infringement of Dependent Claims

Amgen objects on the basis that Roche's instruction fails to provide the Jury with the context of the difference between an independent claim and dependent claim such as:

> An independent claim is a claim that does not refer to any other claim of the patent. An independent claim must be read separately from the other claims to determine the scope of the claim.
>
> A dependent claim is a claim that refers to at least one other claim in the patent. A dependent claim incorporates all of the elements of the claim to which the dependent claim refers, as well as the elements recited in the dependent claim itself.[35]

Instruction 6.6 – Material Change

Amgen objects to this instruction because it is not impartial and objective and misstates the law. This instruction covers only part of the test for infringement under 35 U.S.C. § 271(g). This instruction turns the test for infringement under § 271(g) on its head, making it a test for material change rather than a test for infringement.

Amgen objects to Roche's instruction "[i]n the chemical context, a material change in a compound is most naturally viewed as a significant change in the compound's structure and properties." There is no support in *Eli Lilly & Co. v. American Cyanamid Co.*, for this instruction, particularly in the context of dealing with large and complex molecules as is the case with recombinant human EPO.[36]

Amgen objects to Roche's following instruction as unfairly prejudicial, not impartial, and misstating the law:

"The following factors support a finding of material change:

- that subsequent processes confer an additional, distinct, and valuable property to the product of the patented process

[35] AIPLA's Model Patent Jury Instructions 3.6.
[36] 82 F.3d 1568 (Fed. Cir. 1996).

- that subsequent processes confer superior properties relating to the basic utility of the product of the patented process, *e.g.*, increased potency
- that subsequent processes confer significant structural differences to the product of the patented processes such as the removal and/or addition of certain chemical groups of a compound
- that subsequent processes applied to the product of a patented process are complex and involve multiple steps"[37]

But the *Eli Lilly* court did not identify the above "factors" invented by Roche. Rather, Roche selectively quotes the *Eli Lilly* court's analysis of the specific facts of that case, as opposed to any "factors" of general application. Importantly, these "factors" were not identified in the precedential *Eli Lilly* Federal Circuit decision. [38] Contrary to the impression left by Roche's proposed instruction, the Federal Circuit in *Eli Lilly* expressly declined "to define with precision what classes of changes would be material and what would not. . . ." Rather, § 271(g) has to be resolved on a case-by-case basis.[39] Roche's instruction is therefore legally incorrect because it would confuse the jury by conflating facts from another case with the legal rule itself.

Moreover, these instructions are exclusive, suggesting to the jury that it need only consider these factors in its determination of materially changed. Roche fails to explain how *Eli Lilly*'s statement concerning a small molecule applies here. Amgen objects to this instruction as not impartial and objective because no examples are provided of changes that are not material.

Amgen further objects to Roche's instruction, "[a]dditionally, even if individual steps of subsequent processes administered to the product of a patented process involve relatively routine chemical reactions, that does not preclude a finding of material change." Again, this instruction is partial and implies to the jury that routine change may make significant changes in this case.

[37] D.I. 917 at 53-54.
[38] *Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568 (Fed. Cir. 1996).
[39] *Bio-Technology Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1561 (Fed. Cir. 1996) ("The statute does not specify what products will be considered to have been 'made by' the patented process, apparently because Congress wanted the courts to resolve this critical question of proximity to the product of the patented process on a case-by-case basis. See S. Rep. No. 83, 100th Cong., 1st Sess. 46 (1987) ('Inevitably the courts will have to assess the permutations of this issue of proximity to or distance from the process on a case-by-case basis.'); *id.* at 49 ('The Committee expects the courts to exercise careful judgment in distinguishing those products that are too far removed from the patented process, and those that have been changed only in insignificant ways.').".

Roche's use of language from *Eli Lilly* involving a small molecule does not support the use of the instruction in this case.

Roche's instruction contains another legal error. Roche suggests that the appropriate comparison is between the "product of the patented process" and the "the imported product."[40] The appropriate legal test, however, is whether the product of the process — not the imported product — has been materially changed by subsequent processes prior to importation. The two-part test in § 271(g) focuses on the differences, if any, between the EPO product of the claimed process and the EPO in peg-EPO, not differences between the product of the claimed process and the totality of the imported product.

The statutory language makes this clear. Section 271(g) asks whether the product of the process — not the imported product — has been materially changed by subsequent processes prior to importation. Alternatively, the statute asks whether the product of the process has become merely a trivial and nonessential component of the imported product. If, as Roche contends, the relevant legal inquiry were to compare the product of the process (EPO) with the totality of the imported product (peg-EPO), the second statutory test would be superfluous. Tellingly, Roche does not even mention the second statutory test in its instruction. If Roche's view were the relevant legal analysis, then a "material change" would occur every time a product of a claimed process was incorporated into a larger product, and there would be no purpose served by inquiring whether the incorporated product had become a "trivial and non-essential component" of the imported product. But that is not the law.

The recent decision in *Oki America, Inc. v. Advanced Micro Devices, Inc.*[41] is instructive. In that case, the patent claim at issue related to a process for making a semiconductor wafer with smooth edges. As a result, the semiconductor wafers had less debris leading to less defects in the semiconductor chips that were diced from the wafers. Moving for summary judgment of non-

[40] "To determine material change, one must look to the substantiality of the change between the product of the patented process and the imported product." Roche's Proposed Jury Instructions, Docket No. 917 at 53.
[41] No. C-04-03171, 2006 WL 2711555 (N.D. Cal. Sept. 21, 2006).

infringement, the defendant conceded it used the claimed process outside the United States. However, it argued that it materially changed the product of the process (semiconductor devices from a wafer substrate lacking certain debris) by performing subsequent processing steps. The court, however, rejected the argument:

> Oki also argues that the numerous other wafer processing steps (mask placement, photolithography, resist development and removal, dicing, encapsulation) required for fabrication would anyway constitute a material change. As stated above, however, ***the product is a device lacking certain debris, and this aspect of the product remains unchanged by any subsequent processing***. . . . The ***subsequent processing steps***, such as photolithography, resist development and removal, dicing, and encapsulation, ***do of course make material changes to the physical and electrical properties of the semiconductor substrate, but these changes do not impact the product of Allen process, a debris-free device***.[42]

Here, prior to importation, Roche makes EPO using Lin's claimed processes and then pegylates the EPO, by attaching a peg chain to the EPO polypeptide. The peg chain forms a single amide bond at either the N-terminal alanine or the side chain of an internal lysine.[43] This reaction does not alter the amino acid sequence or the carbohydrate composition of the glycoprotein.[44] In fact, in efforts to gain FDA approval, Roche told the FDA the EPO in peg-EPO is "identical" to the EPO that is used as a starting material in the pegylation process. Thus, like the debris-free wafer in *Oki*, the EPO product of the process is not "changed" as a result of subsequent processing.

Finally, Amgen objects because infringement under Section 271(g) should be explained at the very outset.

Instruction 6.7 – Infringement by Doctrine of Equivalents

Amgen objects on the basis that Roche instructs the jury that it has an option of considering infringement under the doctrine of equivalents if the jury does not find literal infringement. The instruction should inform the jury that they "may find" infringement under the doctrine of equivalents if the jury does not find literal infringement.

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[42] *Id.* at *14 (emphasis added).
[43] Trial Tr. at 2460:16-25.
[44] Trial Exh. 53 at 4027 ("Both EPO starting material and RO0503821 have the identical amino acid sequence and composition of the carbohydrate moiety.").

Amgen objects to this instruction as neither impartial nor objective and misstating the law. Amgen objects to Roche's use of "exceptional circumstances" as to when the doctrine of equivalents is improper. Roche's instruction suggests to the jury that this is likely not applicable and/or not a favored way of finding infringement. These objections also apply to Roche's statement, "[a]gain, however, application of the doctrine of equivalents is the exception, not the rule." The doctrine of equivalents is not considered only in exceptional cases and any such reference should be stricken.

The following instruction is partial and takes *London v. Carson Pirie Scott & Co.*, out of context:

> Patent claims must be clear enough so that the public has fair notice of what was patented. Notice permits other parties to avoid actions which infringe the patent and to design around the patent. On the other hand, the patent owner should not be deprived of the benefits of his patent by competitors who appropriate the essence of an invention while barely avoiding the literal language of the patent claims.[45]

London also explained the policy that:

> On the other hand, the patentee should not be deprived of the benefits of his patent by competitors who appropriate the essence of an invention while barely avoiding the literal language of the claims. *See Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 856-57, 9 U.S.P.Q.2d (BNA) 1289, 1291 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1068, 109 S. Ct. 2069, 104 L. Ed. 2d 634 (1989) (citing the additional opinions in *Pennwalt* as exhaustively discussing these competing policies). Accordingly, the doctrine of equivalents emerged. Although designing or inventing around patents to make new inventions is encouraged, piracy is not. Thus, where an infringer, instead of inventing around a patent by making a substantial change, merely makes an insubstantial change, essentially misappropriating or even "stealing" the patented invention, infringement may lie under the doctrine of equivalents. *See Graver Tank*, 339 U.S. at 609-10, 85 U.S.P.Q. (BNA) at 331; *Lockheed Aircraft Corp. v. United States*, 213 Ct. Cl. 395, 553 F.2d 69, 82, 193 U.S.P.Q. (BNA) 449, 461 (1977).

Roche's omission of the above passage from *London* leaves the jury without the reason for the doctrine of equivalents.[46]

Amgen also objects to Roche's instruction:

> The evidence in support of a finding of equivalency must be specific and precise.

[45] 946 F.2d 1534, 1538 (Fed. Cir. 1991).
[46] D.I. 917 at 55 (citing *London*, 946 F.2d at 1538).

> Generalized testimony as to an overall similarity between the claims and Roche's product or process will not suffice. That is to say, you cannot find infringement by the doctrine of equivalents if Roche's product comes close to one of Amgen's claims. The doctrine of equivalents must be applied to individual elements of the claim, not to the claimed product or process as a whole.

Roche's instruction springs from a case which dealt with analyzing a trial court's JMOL decision.[47] Roche does not explain how that is applicable here, and such an instruction is likely o mislead the jury.

Instruction 6.8 – Limitations on Doctrine of Equivalents – Prior Art

Amgen objects to this instruction as partial and likely to confuse the jury.

Roche's instruction, "[a]ccordingly, to find infringement under the doctrine of equivalents you must find that Amgen has proven that it could have obtained from the Patent Office hypothetical claims similar to the asserted claims at issue, but broad enough to literally cover the accused product and method" is inappropriate and misstates the law. First, Roche improperly shifts the burden to Amgen. The burden of proof that the hypothetical claim encompasses the prior art falls on Roche.[48] As such, Roche invites the jury to commit error by shifting the burden onto Amgen for this hypothetical claims analysis.

Second, *Wilson Sporting Goods,* as cited by Roche, addressed the hypothetical claim analysis because there was a dispute on a specific prior art reference with respect to the doctrine of equivalence.[49] Roche's generalized statement is improper. The test from *Wilson Sporting Goods* prevents equivalents used in a hypothetical claim that would literally encompass the prior art.[50] The characterization of the test provided by Roche would require that the claim satisfy 35 U.S.C. § 112.

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[47] *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996).
[48] *See Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1323 (Fed. Cir. 2000) (holding that the argument that a hypothetical claim literally covering the accused device would be unpatentable is a defense to infringement under the doctrine of equivalents, for which the accused infringer bears the burden of proof).
[49] *Wilson Sporting Goods v. David Geoffrey & Assocs.*, 904 F.2d 677, 685 (Fed. Cir. 1990).
[50] *See id.*

Instruction 6.9 – Limitations on Doctrine of Equivalents – Prosecution History Estoppel

Amgen objects to this instruction as improper where there is no decision by the Court that prosecution history estoppel applies and whether prosecution history estoppel applies is a matter of law.[51] The AIPLA instructions that it is modeled after also instructed the court that prosecution history applies and what ranges are estopped from being claimed by the patentee under the doctrine of equivalents.[52] The situation is not applicable here and Roche's instructions invite the jury to err.

Instruction 6.10 – Limitations on Doctrine of Equivalents – Claim Elements May Not Be Read Out of Existence

Amgen objects to this instruction because it is a misstatement of law and an erroneous description of the cited cases. The *Hilton Davis* case cited by Roche does not state this proposition;[53] neither does *Novartis*.[54] The *Novartis* case held that an accused equivalent could not be an equivalent because it would vitiate the definition of a term in view of the specification.

Amgen also objects to this instruction because it is inapplicable to this case and likely to confuse the jury. The instruction itself is defective providing the jury with no guidance on how this should be applied. Thus, Roche invites the jury to commit error prejudicial to Amgen.

Instruction 6.11 – Limitations on Doctrine of Equivalents – Applied on an Element by Element Basis

Amgen objects to this instruction as cumulative and unnecessary because Roche's instructions 6.4 and 6.7 already provide an instruction to the jury that covers this topic. This instruction is not impartial and objective in providing a separate instruction on these issues; it unfairly highlights them in comparison to pro-patentee instructions.

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[51] *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 152 L. Ed. 2d 944, 122 S. Ct. 1831 (2002); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 304 F.3d 1289 (Fed. Cir. 2002).
[52] *See* AIPLA Model Jury Instructions 3.10.
[53] *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997).
[54] *See Novartis Pharms. Corp. v. Abbott Labs.*, 375 F.3d 1328, 1339 (Fed. Cir. 2004).

Instruction 6.12 – Limitations on Doctrine of Equivalents – Subject Matter Dedicated to the Public

Amgen objects to this instruction as improperly, prejudicially, and incorrectly implying that subject matter in a patent cannot be claimed in later continuation applications. Amgen also objects to the relevance of this instruction, as Roche has made no allegations in this case that subject matter has been dedicated to the public. Moreover, the instruction itself is defective and provides the jury with no guidance on how this should be applied. Thus, Roche invites the jury to commit error prejudicial to Amgen.

Instruction 6.13 – Reverse Doctrine of Equivalents

Amgen objects to this instruction and any instruction on the reverse doctrine of equivalents because Roche has failed to make a prima facie showing that would entitle it to such an instruction. As the Court stated, "When I come to charge the jury, I'm not going to say anything about reverse doctrine of equivalents for the good and sufficient reason that that's an affirmative defense and we'll see whether we get to the jury on that, though theoretically it's possible."[55]

Moreover, Roche's proposed jury instruction misstates the law and impermissibly lowers the bar for proving reverse doctrine of equivalents. Roche provides no basis for the statement in the instruction that "this determination is made by considering the original intended scope of the patent and the 'spirit and intent' of the claims, keeping in mind the particular context of the patent, the prior art, and the particular circumstances of the case."

Also, in its doctrine of equivalents instruction, Roche characterizes the doctrine of equivalents as applying in "exceptional circumstances," and again characterized it as the "exception, not the rule." Roche's omission here misleads the jury into concluding that the reverse doctrine of equivalents applies on a regular basis when the doctrine truly is applied in rare circumstances.

[55] Trial Tr. at 2325:25-2326:4.

Next, Roche's instruction, "[a] new product or process that uses a new technology that makes a real difference in how the process works or what is produced would not infringe under the reverse doctrine of equivalents (e.g. changes to a drug's biologic or therapeutic effects)," mischaracterizes the law. Roche's use of "real difference" lowers from *Graver Tank's* holding that the change must be "so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way."[56]

Roche's inclusion of "(*e.g*. changes to a drug's biologics or therapeutic effects)" is not impartial and suggests to the jury that were there such differences the jury should find that reverse doctrine of equivalents applies.

Roche's inclusion of "a prima facie (on its face)" misstates the law and prejudices Amgen by leading the jury to end the inquiry if a *prima facie* case is established.

Further, Amgen will suffer prejudice if it cannot mention the Court's prior ruling that MIRCERA infringes claim 1 of the '422 Patent, were Roche to present arguments and evidence that the reverse doctrine of equivalents applies in this case.

Instruction 6.14 – Safe Harbor Exemption

Amgen objects to this instruction as irrelevant and in violation of the law of the case doctrine. Amgen's declaratory relief action concerns Roche's commercial activities which are outside the provisions of the Section 271(e)(1) "safe harbor." Moreover, the Court has already determined as a matter of law that MIRCERA® infringes claim 1 of the '422 Patent. Roche waived its right to make such an argument when it failed to argue this at summary judgment.

Instruction 6.15.1 – Infringement of U.S. Patent No. 5,441,868

Amgen objects to this instruction as misstating the law. This instruction does not properly describe the effect of "comprising." The instruction also incorrectly assumes that Amgen is asserting infringement under 35 U.S.C. § 271(a). The court construed, ""cells transformed or transfected with an isolated DNA sequence encoding human erythropoietin" and

[56] *Graver Tank & Mfg. Co., v. Linde Air Prod. Co.*, 339 U.S. 605, 608-09 (1950).

not "mammalian host cells" to mean "cells that have been genetically modified with isolated DNA containing genetic instructions for human erythropoietin or later generations of these cells that have inherited those instructions."

Amgen objects that the instruction does not recite the claim language of the asserted claims in its entirety to the jury. Amgen objects that the instruction does not recite the Court's entire claim construction for some terms.

Finally, Amgen objects to the statement of materially changed as it is an erroneous statement of the law because it fails to focus on any change to the product claimed. Roche's instruction suggests that the appropriate comparison is between the product of the patented process and the imported product.[57] The appropriate test is whether the product of the process — not the imported product — has been materially changed by subsequent processes prior to importation. The two-part test of Section 271(g) focuses on the differences, if any, between the EPO of the claimed process and the EPO in peg-EPO, not differences between the product of the claimed process and the imported product. The statutory language makes this clear. First, the statute asks whether the product of the process — not the imported product — has been materially changed by subsequent processes prior to importation. Alternatively, the statute asks whether the product of the process has become merely a trivial and nonessential component of the imported product.

Instruction 6.15.2 – Infringement of U.S. Patent No. 5,547,933

Amgen objects that the entire claim language of the asserted claims is not being read to the jury in its entirety. The court construed, "wherein said cells are CHO cells" and not "CHO cells" to mean "a cell from the ovary of a chinese hamster." Amgen further objects to Roche's instruction of "an effective amount a glycoprotein product effective for erythropoietin" in that it does not provide the Court's full construction.

[57] "To determine material change, one must look to the substantiality of the change between the product of the patented process and the imported product." (D.I. 917 at 53.)

Amgen objects that this instruction asks the jury to look at the process limitations rather than the structure that results from the process steps. Amgen also objects because this instruction improperly states that Amgen asserts that Roche directly infringes the method of treatment claims.

Finally, Amgen objects to the extent the instruction states or implies that MIRCERA must satisfy the claim limitations themselves. The legal issue is whether MIRCERA comprises the elements of the asserted claims. As the Federal Circuit explained in *A.B. Dick Co. v. Burroughs Corp.*,[58]

> "It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device. For example, a pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write."

The infringement inquiry requires the court to determine if each claim limitation is present in the accused product, not whether each feature or component of the accused product is present in the claim.[59] The presence of additional elements in the accused product or process that are not recited in the claims does not negate infringement.[60]

Instruction 6.15.3 – Infringement of U.S. Patent No. 5,618,698

Amgen objects that the entire claim language of the asserted claims is not being read to the jury in its entirety. Roche's instruction for claim 9 of the '868 Patent is improper. Claim 9 is dependent of the process according to claims 2, 4, and 6. Roche's instruction that the Claim 9 cannot be infringed if it does not meet the requirements of claims 7 and 8 is improper. This instruction also improperly states that Amgen is asserting infringement under 35 U.S.C. § 271(a).

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[58] 713 F.2d 700, 703 (Fed. Cir. 1983).
[59] *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482-83 (Fed. Cir. 1984); *see also Nazomi Communications, Inc. v. Arm Holdings, PLC*, 403 F.3d 1364, 1372 (Fed. Cir. 2005).
[60] *Amstar*, 730 F.2d at 1482 ("Modification by mere *addition* of elements of functions, whenever made, cannot negate infringement without disregard of the long-established hornbook law….")

Roche's instruction suggests that the appropriate comparison is between the product of the patented process and the imported product.[61] The appropriate test is whether the product of the process — not the imported product — has been materially changed by subsequent processes prior to importation. The two-part test of Section 271(g) focuses on the differences, if any, between the EPO of the claimed process and the EPO in peg-EPO, not differences between the product of the claimed process and the imported product. The statutory language makes this clear. First, the statute asks whether the product of the process — not the imported product — has been materially changed by subsequent processes prior to importation. Alternatively, the statute asks whether the product of the process has become merely a trivial and nonessential component of the imported product.

Instruction 6.15.4 – Infringement of U.S. Patent No. 5,756,349

Amgen objects that the entire claim language of the asserted claims is not being read to the jury. Amgen objects that this instruction misstates the law with respect to "comprising." Amgen also objects that this instruction improperly states that Amgen is asserting infringement of the method claims under 35 U.S.C. § 271(a).

Roche's instruction suggests that the appropriate comparison is between the product of the patented process and the imported product.[62] The appropriate test is whether the product of the process — not the imported product — has been materially changed by subsequent processes prior to importation. The two-part test of Section 271(g) focuses on the differences, if any, between the EPO of the claimed process and the EPO in peg-EPO, not differences between the product of the claimed process and the imported product. The statutory language makes this clear. First, the statute asks whether the product of the process — not the imported product — has been materially changed by subsequent processes prior to importation. Alternatively, the

[61] "To determine material change, one must look to the substantiality of the change between the product of the patented process and the imported product." (D.I. 917 at 53.)
[62] "To determine material change, one must look to the substantiality of the change between the product of the patented process and the imported product." (D.I. 917 at 53.)

statute asks whether the product of the process has become merely a trivial and nonessential component of the imported product.

Instruction 6.15.5 – Infringement of U.S. Patent No. 5,955,422

Amgen objects to Roche's attempt to re-litigate this issue before the jury. On August 28, 2007, the Court determined that MIRCERA® infringes claim 1 of the '422 Patent. As such, Roche is bound by the Court's determination under the law of the case doctrine. Moreover, Section 271(e)(1) does not apply. Amgen's declaratory relief concerns Roche's commercial activities which fall outside this provision. Roche further waived this argument by not making the argument during summary judgment.

VII. UNENFORCEABILITY (INEQUITABLE CONDUCT)

Instruction 7.1 – Inequitable Conduct – Generally

Amgen objects to Roche's proposed instruction 7.1 as it misstates the law, is not impartial or objective, undermines the presumption of validity, is argumentative, and is irrelevant to the issues in this case. As such, Roche's proposed instruction 7.1 would be confusing to the jury and is highly prejudicial to Amgen.

Amgen specifically objects to the entire first paragraph as it undermines the presumption of validity by making unsupported factual allegations about the inadequacy of the PTO and Examiners. Amgen objects to this paragraph as it misstates the facts regarding the PTO, misstates the law regarding Examiners' duties, is irrelevant, is not impartial or objective, and is highly prejudicial to Amgen.

Amgen objects to Roche's second paragraph as misstating the law regarding the PTO's reliance upon the patent applicant for information. Amgen objects to Roche's assertions regarding the duty of candor and good faith as misstatements of the law, argumentative, and not impartial or objective. Amgen objects to the examples of violations of the duty of candor as argumentative, irrelevant and misleading to the jury as to the issues in this case. Specifically, Amgen objects to Roche's statement that "the United States Patent and Trademark Office ("PTO") must rely on the patent application for information. . . ." Roche offers no case law or

statute to support this assertion. Amgen further objects that Roche's footnotes, case cites, and parentheticals to this paragraph are argumentative, misstate the law from the MPEP, misstate the law and facts of the cases cited therein, are irrelevant to the actual facts and law at issue in this case, and are misleading to the jury. Roche cites cases with different factual scenarios that are inapplicable to this case. As such, this paragraph and the footnotes are misleading to a jury and highly prejudicial to Amgen.

Amgen objects to Roche's fifth paragraph as misplaced within this section and as such, is not impartial or objective. This paragraph, which describes Roche's burden for establishing inequitable conduct, should be at the forefront of this section.

Instruction 7.2 – Materiality

Amgen objects to Roche's proposed instruction 7.2 as it misstates the law, is not impartial or objective, is argumentative, misstates contentions made by Roche, and is irrelevant to the issues in this case. As such, Roche's proposed instruction 7.2 would mislead the jury and prejudice Amgen.

Amgen objects to Roche's first paragraph as it is argumentative, misstates the law regarding materiality and the concept of "burying" as it relates to materiality, and is misleading to the jury. Roche offers no statute or case to support this assertion regarding burying. As such, this instruction is not impartial or objective, and is highly prejudicial to Amgen. Amgen is filing a motion in limine on this issue.

Amgen objects to the second paragraph as it misstates the law and is not impartial or objective. Amgen objects to Roche's failure to include an explanation that evidence that is cumulative is not required to be submitted to the PTO. Amgen further objects to Roche's assertion that "[i]nformation is material if the reference 'more explicitly and clearly' discloses limitations also found in submitted prior art," as it misstates the law stated by the Federal Circuit and is inapplicable to the facts in this case. Roche has not asserted that any art was not produced that was more clear than art that was produced.

Amgen objects to the third paragraph as not impartial or objective and argumentative, nor is this paragraph a statement of the law regarding "materiality." By listing at least eight general and repetitive terms for "information" that Roche contends Amgen withheld, Roche is attempting to impart an untrue and unfair impression in the jury that Amgen withheld a great deal of information from the PTO, if any, without making its case. Such instruction would be highly prejudicial to Amgen as Roche's contentions bear are irrelevant to the instruction of "materiality."

Instruction 7.3 – Intent

Amgen objects to Roche's proposed instruction 7.3 at it misstates the law, is argumentative, neglects to state the proper burden or legal standard for determining intent, is not impartial or objective, and is misleading to the jury and highly prejudicial to Amgen.

Amgen objects to Roche's first paragraph as argumentative. Specifically, Amgen objects to Roche's assertion that intent is found when material information is "buried within a mass of less relevant information." Such statement is irrelevant to the legal instruction as to "intent," and is misleading to the jury regarding any alleged action by Amgen. Rather, Roche overstates the case law regarding "burying," which is merely one factor that is considered in totality and "can be probative" of bad faith, but is not absolute evidence of bad faith.[63]

Amgen objects to Roche's second paragraph as it misstates the law, is argumentative, is not impartial or objective, and neglects to recite that it is Roche's burden to show intent by clear and convincing evidence. Amgen objects to each of Roche's attempts to instruct the jury through specific (and often irrelevant or incorrect) examples of intent. Specifically, Roche states that "[i]ntent to deceive also can be inferred when a party or its counsel fails to correct a representation made to the Examiner, ***even*** after learning that it was incorrect." Roche's use of "even" misstates the law and would confuse the jury into believing that any mistake made, including unknowing or inadvertent mistakes, would evidence an intent to deceive. This

[63] *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995).

misstatement of law would mislead the jury and prejudice Amgen. Amgen also objects to Roche's misstatement of the law that "[i]ntent can also be inferred from evidence that the patentee submitted the material information to other entities, such as the FDA." Roche neglected to state that such disclosure to the FDA must be "simultaneous" with the failure to submit the same information to the PTO in order to evidence any intent to deceive, and that that action was coupled with other egregious actions by the patent applicant.[64] As such, Amgen objects to this instruction as irrelevant as it does not factually compare. Amgen further objects to the inclusion of the instruction that "shielding material information from counsel or other individuals who owe the duty of good faith and candor is also indicative of intent to deceive." This statement is entirely irrelevant to any allegation from Roche and would only serve to prejudice Amgen by misleading the jury into believing this might have occurred. Amgen objects to Roche's footnotes and parenthetical recitation of the holdings in the cases cited therein as misstatements of law and fact, and objects to them as argumentative.

Amgen further objects to this entire section as it fails to include impartial and objective instructions relating to Roche's burden of proof to show intent, as well as the fact that neglect, mistakes, oversight, carelessness or erroneous judgment is not evidence of intent to deceive. As such, Roche's entire section 7.3 is misleading and extremely prejudicial to Amgen.

Instruction 7.4 – Balancing of Materiality and Intent

Amgen objects to Roche's proposed instruction 7.4 as not impartial or objective, and misleading to the jury and highly prejudicial to Amgen. Amgen specifically objects to Roche's instruction that "omitting a highly material piece of information requires less proof of intent, thereby allowing you to infer intent." This example of how the jury could balance materiality and intent is not a neutral example, but rather, makes an unfair inference that if Amgen did omit a document, it was "highly material" and that intent can simply be inferred, rather than shown by

[64] *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005) (citing *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989) ("inference of deceptive intent was supported by "damning" evidence that included applicant having submitted material information to the FDA while simultaneously withholding it from the PTO")).

Roche. Amgen objects that this would be highly prejudicial to Amgen.

VIII. CONCLUSION

For the reasons stated above, Amgen respectfully requests that the Court give Amgen's preliminary jury instructions that are set forth in Amgen's Pre-Trial and Post-Trial Jury Instructions.[65]

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Respectfully Submitted,

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[65] (D.I. 918).

CERTIFICATE OF SERVICE

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

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