UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

OPPOSITION TO ROCHE'S MOTION *IN LIMINE* TO PRECLUDE MENTION OF THE COURT'S GRANT OF SUMMARY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 5,955,422 OR ON ISSUES OF VALIDITY

Amgen hereby opposes Roche's Motion *in Limine* To Preclude Mention of the Court's Grant of Summary Judgment of Infringement of U.S. Patent No. 5,955,422 or on Issues of Validity. This Court's grant of Amgen's summary judgment motions is highly relevant and probative to issues in this case, including whether Roche infringes additional claims of Amgen's patents and Roche's invalidity defenses. As numerous courts have found, when prior grants of summary judgment are relevant to remaining claims, the jury should be made aware of those orders to ensure consistency.

Moreover, it is clear from Roche's Proposed Jury Instructions and Pretrial brief that Roche intends to relitigate the same undisputed factual findings that supported this Court's grant of summary judgment. For instance, Roche's Proposed Jury Instructions and Pretrial Brief indicate that Roche will assert that its peg-EPO product does not contain human erythropoietin. This directly conflicts with this Court's grant of Amgen's motion for summary judgment that peg-EPO infringes claim 1 of the '422 Patent, which requires that the product be "human

erythropoietin."[1] To allow Roche to reargue these findings would create juror confusion and potentially result in findings of fact that are inconsistent with this Court's findings. This result undermines the well-established "law of the case" doctrine and unfairly prejudices Amgen. Accordingly, this Court should deny Roche's motion.

I. This Court's grant of summary judgment for Amgen is directly relevant to claims the jury is deciding, and Roche should not be allowed to relitigate these issues.

This Court's summary judgment findings as to specific patent claims are highly probative of, and directly relevant to, the findings of fact the jury will be asked to decide. Under FRE 401 and 402 the Court's findings are admissible on those grounds alone. Moreover, these findings are particularly probative and relevant here because Roche has signaled an intent to relitigate these same issues and indeed, to seek to overturn this Court's summary judgment rulings at trial. By adopting a position at trial that contradicts this Court's summary judgment findings, Roche is attempting to put this Court's findings directly back in issue. Thus, at a minimum, the jury should be told about the Court's prior rulings as they tend to prove the very "fact that is of consequence to the determination of the action."[2]

There is no basis for Roche on the one hand to ask the jury to reach a factual finding that contradicts this Court's summary judgment rulings, while on the other hand, arguing that the jury should not be told of those rulings. Roche's attempt to mislead the jury into making factual findings that contradict the findings this Court has already made violates the principles of *stare decisis*, waiver, and "law of the case" and should be rejected on those grounds alone. In accordance with the principles of *stare decisis*, the jury can and should follow this Court's

[1] Without presuming to know the contents of this Court's written decision, which Amgen understands is forthcoming, Amgen submits this Opposition on the basis of the Court's August 27 and 28, 2007 Electronic Orders.

[2] *Amarin Plastics, Inc. v. Maryland Cup Corp*., 946 F.2d 147, 150 (1st Cir. 1991) (relevant evidence that proves a "fact that is of consequence to the determination of the action" is admissible).

determination that certain facts can no longer be disputed.[3] Indeed, principles of *stare decisis* require that the jury be informed of the Court's prior decision, and be provided with an instruction on *stare decisis*, as the Court's infringement findings are now the law of the case.[4]

Likewise, Roche's attempt to withhold this Court's findings from the jury, and to argue a contrary position to the jury, runs afoul of the "law of the case" doctrine. This doctrine is a "prudential principle that 'precludes relitigation of the legal issues presented in successive stages of a single case once those issues have been decided.'"[5] Thus, according to the "law of the case" doctrine, Roche may not relitigate the issues that this Court has already decided on summary judgment.[6] Nor may Roche seek to circumvent these decisions by introducing new arguments that it failed to raise at summary judgment and which are contrary to this Court's findings.[7]

A. This Court's Finding That Roche's peg-EPO Product Infringes Amgen's '422 Patent Is Relevant And Admissible

Despite this Court's August 28, 2007 Order that Roche infringes claim 1 of Amgen's '422 patent, Roche has contended in its Proposed Jury Instructions and its Proposed Verdict Form that its accused product does not infringe '422 claim 1.[8] Roche has indicated it will

[3] *Mendenhall v. Cedarapids*, 5 F.3d 1557, 1570 (Fed. Cir. 1993) (*Stare decisis* in essence "makes each judgment a statement of the law, or precedent, binding in future cases before the same court or another court owing obedience to its decision.). *See also Wang Lab. v. Oki Elec. Indus. Co.*, 15 F. Supp. 2d 166, 175 (D. Mass. 1998), citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390-391 (1996)

[4] *Id.*

[5] *United States v. Vigneau*, 337 F.3d 62, 67 (1st Cir. 2003) *citing*, *Field v. Mans*, 157 F.3d 35, 40 (1st Cir. 1998).

[6] *See also United States v. Medina*, 219 Fed. Appx. 20, 21-22 (1st Cir. 2007) (Under the relevant branch of the law of the case doctrine, "a legal decision made at one stage of a civil or criminal proceeding . . . remain[s] the law of that case throughout the litigation, unless and until the decision is modified or overruled by a higher court).

[7] *Arrieta-Gimenez v. Arrieta-Negron*, 859 F.2d 1033, 1037 (1st Cir. 1988) (argument not presented to district court in motion for summary judgment was waived).

[8] *See* Roche's Proposed Jury Instructions, p. 14; Defendant's Proposed Jury Verdict, p. 2.

contend at trial that its product does not infringe '422 claim 1 under the Reverse Doctrine of Equivalents, and because its activities are shielded by the safe-harbor exemption of 35 U.S.C. 271(e)(1).[9] This Court's determination that Roche's product infringes '422 claim 1 is highly relevant to these contentions of non-infringement that Roche will make at trial.

Roche also intends to ask the jury to find non-infringement and invalidity by rejecting the undisputed facts which support this Court's grant of summary judgment. Thus, in Roche's Opposition to Amgen's Motion for Summary Judgment that peg-EPO infringes claim 1 of the '422 Patent, Roche argued:

> Seeking to avoid prior art, Amgen now asserts that the human EPO of claim 1 is limited to structures that are obtainable from mammalian cells grown in culture. If Amgen is correct, it must prove that the structure of CERA is obtainable from mammalian cells grown in culture. CERA is a chemically synthesized product, which Dr. Lodish admitted could not be made by mammalian cells.[10]

In granting Summary Judgment on August 28, 2007, this Court rejected Roche's argument and found that Roche's peg-EPO product literally met the limitation of claims of the '422 patent "purified from mammalian cells grown in culture." Despite this Court's Order, however, Roche's Pre-Trial Brief states:

> [p]lainly, Roche's CERA is literally non-infringing [of the claims of the '933 Patent] because it is not a "product of . . . expression in a mammalian host cell," even under the broadest interpretation of a product-by-process claim. [citations omitted] Rather, CERA is a chemically synthesized compound that is created in the laboratory.

[9] Roche's Pre-Trial Br. at p. 24; Roche's Proposed Jury Instructions at p. 14. Roche litigated and lost the safe-harbor exemption issue in its motion to dismiss Amgen's complaint for lack of subject matter jurisdiction. In that Motion, Roche claimed that its activities were protected by 35 U.S.C. 271(e)(1) and that this deprived the Court of subject matter jurisdiction under the Declaratory Judgment Act. This Court denied Roche's motion and found that the Sec. 271(e)(1) safe-harbor did not shield Roche from Amgen's Declaratory Judgment Action. It appears from Roche's Proposed Jury Instructions, however, that Roche will seek to relitigate this decision of the Court as well.

[10] Roche's Opposition to Amgen's Motion for Summary Judgment of Infringement at p. 9.

> CERA is not and cannot be produced by living cells . . . . [11]

Roche's Pre-Trial brief indicates that it will attempt to relitigate the issue of whether the EPO in peg-EPO is obtained from mammalian host cells. This Court determined that the "human erythropoietin" in peg-EPO is made by mammalian cells. The jury should be made aware of this Court's finding so that Roche cannot confuse the issue or mislead the jury.

The Court also determined that Roche's peg-EPO product contains "human erythropoietin….purified from mammalian cells." But even though this element has been adjudicated against Roche, Roche alleges in its Pre-Trial Brief:

> CERA is distinct from the Epoetin beta and mPEG-SBA starting materials and CERA cannot be broken down into the starting materials. CERA differs from an erythropoietin glycoprotein product of a mammalian host cell not only in its structure but also in its resulting physiochemical, biological, and clinical properties.[12]

The claim limitation "a diluent, adjuvant or carrier" appears in the '933 claims, just as it appears in '422 claim 1. Presumably this Court rejected Roche's argument that peg-EPO does not infringe '422 claim 1 because the claim limitation "a diluent, adjuvant or carrier" is limited to a single diluent or adjuvant or carrier.[13] Nonetheless, in Roche's Proposed Jury Instructions it states:

> * * * All of the claims above share the following language: "A pharmaceutical composition **comprising** . . . a pharmaceutically acceptable **diluent, adjuvant or carrier**."
>
> Each member of the above Markush group (diluent, adjuvant, or carrier) is used *singly*. In other words, the above language would not encompass a pharmaceutical composition comprising a pharmaceutically acceptable diluent *and* a pharmaceutically acceptable adjuvant.[14]

Again, it is highly relevant for the jury to know that this Court has already found that peg-EPO

[11] Roche's Pre-Trial Br. at p. 7.

[12] Roche's Pre-Trial Br. at p. 7.

[13] Roche's Opposition to Amgen's Motion for Summary Judgment, p. 9.

[14] Roche's Proposed Jury Instructions at p. 46.

meets this claim limitation.

B. This Court's Finding That The '933, ' 349 and '422 Patents Are Not Invalid For Obviousness-Type Double Patenting Is Relevant And Admissible

In granting Amgen's Motion for Summary Judgment, this Court ruled as a matter of law that the asserted claims of the '933, '349, and '422 Patents are exempt from obviousness-type double-patenting in view of the claims of the '008 Patent because of the safe-harbor in 35 U.S.C. §121. Nonetheless, Roche has offered proposed jury instructions that state:

> Roche contends that the asserted claims of the patents-in-suit are invalid, as well as claims 4 and 5 of the '698 patent. * * *
>
> The claims of the patents-in-suit are obvious variations of the claims of Amgen's expired '008 patent, or the '868 patent and the '698 patent [15]

Roche's Pre-Trial Brief also indicates that Roche intends to assert its obviousness-type double patenting claims as to the '933, '349, and '422 Patents at trial:

- Claims 3, 7, 8, 9, 11, 12 and 14 Of The '933 Patent Are Invalid for Obviousness-Type Double Patenting Over the Claims of The '868 or '698 Patents[16]
- Claim 1 Of The '422 Patent Is Invalid for Obviousness-Type Double Patenting Over the Claims of The '868 or '698 Patents[17]
- Claim 7 Of The '349 Patent Is Invalid for Obviousness-Type Double Patenting Over the Claims of The '868 or '698 Patents.[18]

Thus, this Court's determination that the claims of the '933, '349, and '422 Patents are exempt from obviousness-type double patenting under 35 U.S.C. §121 is highly relevant and probative to rebut these contentions that Roche will apparently seek to re-litigate at trial.

Even if Roche can claim that obviousness-type double patenting related to claims of the

[15] Roche's Proposed Jury Instructions at p. 18.

[16] Roche's Pre-Trial Br. at p. 34.

[17] *Id*. at p. 40-41.

[18] *Id*. at p. 50.

'868 or '698 patent is a distinct issue, the Court's determination that the claims of the '933, '349, and '422 Patents are subject to the Section 121 safe-harbor is dispositive. The Section 121 safe-harbor also shields the claims of the '933, '349 and '422 Patents from this new obviousness-type double patenting attack because during prosecution the method claims of the '868 and '698 Patents were restricted into separate groups from the claims of the '933, '349 and '422 Patents.

C. This Court's Finding That The '933 and '349 Patents Are Not Invalid For Indefiniteness Is Relevant, Probative And Admissible

This Court's determination that the claims of the '933 and '349 Patents are not invalid for indefiniteness is highly probative to the contentions Roche intends to make at trial. This Court ruled on summary judgment that the asserted claims of the '933 Patent are not invalid because the claim term "non-naturally occurring" is definite under 35 U.S.C. §112, paragraph 2. Likewise, the Court ruled as a matter of law that the limitation "capable upon growth in culture of producing in excess of 100 U of erythropoietin per 10^6 cells in 48 hr as determined by radioimmunoassay" in claims 1-6 of the '349 Patent is definite under 35 U.S.C. §112, paragraph 2.

Despite the Court's rulings, Roche has requested that the Court provide the following instructions to the jury:

> For the issues of invalidity, you must determine: * * * whether the asserted claims were definite such that one skilled in the art could determine the precise limits of the claimed invention[19]
>
> Roche contends that the asserted claims of the patents-in-suit are invalid, as well as claims 4 and 5 of the '698 patent. * * * the asserted claims were indefinite such that one of ordinary skill in the art could not determine the precise limits of the claimed invention[20]

[19] Roche's Proposed Jury Instructions at p. 13.

[20] *Id*. at p. 18.

> Roche contends that the '422, '933, '698, '868 and '698 patents are invalid for indefiniteness.[21]

These instructions, combined with Roche's Proposed Verdict Form, indicate that Roche intends to assert at trial that Dr. Lin's patent claims, including the '933 and '349 claims, are indefinite. Such instructions and assertions are improper, and if made at trial could mislead the jury into invalidating the claims of the '933 and '349 patents as indefinite for the very reasons this Court has already rejected. The Court's rulings should be presented to the jury to prevent confusion and unfair prejudice to Amgen.

II. The introduction of this Court's summary judgment findings will not unfairly prejudice Roche, and excluding this evidence will mislead the jury and unfairly prejudice Amgen

Roche drastically overstates the prejudice it might face if the jury hears that this Court entered summary judgment of infringement or validity on particular claims before trial. "By design, all evidence is meant to be prejudicial; it is only *unfair prejudice* which must be avoided."[22] Moreover, "the discretion to exclude does not arise where the balance between the probative worth and the countervailing factors is debatable; there must be a significant tipping of the scales against the evidentiary worth of the proffered evidence."[23]

As set forth above, this Court's prior infringement findings are highly relevant to the issues to be addressed at trial, and are even more probative in light of Roche's intent to relitigate the same issues before the jury. Notably, Roche has not identified any specific *unfair* prejudice that it will face if the jury learns of this Court's prior infringement rulings. Moreover, there is a strong presumption that a limiting instruction would be sufficient to alleviate any such

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[21] *Id*. at 41.

[22] *United States v. Rodriguez-Estrada*, 877 F.2d 153, 155-156 (1st Cir. 1989) (emphasis added).

[23] *United States v. Aguilar-Aranceta*, 58 F.3d 796, 800 (1st Cir. 1995), *citing* Wright & Graham, supra, § 5221 at 309-10

prejudice.[24]

In *Century Wrecker Corp.*, a case cited by Roche in its Motion, the court concluded that under similar circumstances, a limiting instruction was entirely adequate.[25] Specifically, the court held that it was appropriate to alert the jury to the Court's infringement finding, and to instruct the jury that it was required to reach its own conclusions on the questions presented to it free from any influence from the court's determination of infringement.

Roche's argument that introducing this Court's prior findings will cause juror confusion fares no better. Roche's argument is based on the premise that unlike this Court, a jury will be confused and unable to distinguish among the Court's separate findings of infringement as to particular claims. As an initial matter, Roche's Motion is a remarkable retreat from its prior representations to this Court where it lauded the capacity of juries to sort through complex issues, including patent claims, and where it proclaimed that it "shares this Court's respect for a jury's abilities."[26]

More importantly however, Roche's arguments about juror confusion are wholly disingenuous in light of Roche's attempts to withhold relevant and admissible information from the jury. Roche's Motion is a strategically crafted attempt to foster, and indeed, capitalize on, jury confusion by permitting Roche to attempt to mislead the jury into making findings of fact contrary to this Court's decisions. Notably, for all its discussion of prejudice and potential jury confusion, Roche's Motion ignores the inevitable confusion and resulting unfair prejudice to Amgen if this Court's summary judgment findings were to be withheld from the jury. As the

[24] *See United States v Kilcullen* 546 F.2d 435 (1st. Cir. 1976), *citing* Fed. R. Evid. 105 (evidence may be admitted with a limiting instruction if inadmissible for one purpose).

[25] *Century Wrecker Corp. v. E.R. Buske Mfg. Co.*, 898 F. Supp. 1334 (D. Iowa 1995).

[26] Roche's Memorandum for July 17, 2007 Case Management Conference, p. 2, *citing Massachusetts Eye and Ear Infirmary v. QLT, Inc.*, 2007 U.S. Dist. LEXIS 50199 (D. Mass. July 10, 2007).

Century Wrecker court found, "confusion to the jury could result if the jury is asked to make a determination of the issues that remain within its province without being advised of the court's prior determination of infringement." [27]

For the reasons set forth above, this Court should deny Roche's Motion to Preclude Mention of The Court's Grant of Summary Judgment of Infringement of U.S. Patent No. 5,955,422 or on Issues of Validity.

[27] *See Century Wrecker Corp. v. E.R. Buske Mfg. Co.*, 898 F. Supp. 1334, 1347 (D. Iowa 1995)

Dated: September 3, 2007

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