

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

**OPPOSITION TO ROCHE’S MOTION *IN LIMINE* TO INVOKE
ISSUE PRECLUSION AS TO FINDINGS FROM PRIOR LITIGATION
AND CROSS-MOTION TO PRECLUDE ROCHE FROM INTRODUCING THE
STATEMENTS LISTED IN EXHIBIT A OF ITS MOTION TO THE JURY.**

Roche’s Motion *in Limine* seeks to estop Amgen from defending the validity of the patent claims-in-suit based on prior judicial rulings that found different claims indefinite or not enabled. But the prior rulings addressed specific claim language that is not found in any of the claims-in-suit and specific facts not presented by Roche’s case here so estoppel does not apply. None of the claims-in-suit include the “sufficiently duplicative” language of claim 7 of the ‘008 patent, which was construed as an attempt to “claim all possible genetic sequences that have EPO-like activity.” Likewise, none of the claims-in-suit include the “glycosylation which differs from that of human urinary erythropoietin” language of ‘933 claims 1 and 2, which this Court found to be indefinite in the *HMR/TKT* case because the claims did not recite a standard for urinary EPO. In trying to attack the validity of the claims-in-suit, Roche must deal with the specific language and scope of the asserted claims and not simply pursue a “guilty by association” strategy.

Moreover, the factual issues previously decided on these different claims are distinct from the issues raised by Roche in this case. As this Court has already correctly determined in

finding infringement of ‘422 claim 1, Roche’s peg-EPO product comprises human EPO and not an analog of EPO. Consequently, Roche’s argument that Amgen cannot claim analogs is irrelevant — and untrue as even Roche admits that Amgen is entitled to claim some analogs. With respect to the indefiniteness of urinary EPO, the prior judicial statements are irrelevant because none of the claims or Roche’s defenses invoke the universe of urinary EPOs. In fact, this court has already rejected Roche’s indefiniteness attacks on the asserted ‘933 claims when it recently granted Amgen’s Motion for Summary Judgment that Dr. Lin’s Asserted Claims are Definite, Adequately Described and Enabled.

Furthermore, Roche’s request that this Court admit as “conclusive evidence” Roche’s cherry-picked list of “statements” excerpted from various court-decisions is baseless. Roche has no support for this request. Its citation to a single case where the court considered admitting evidence of a prior criminal antitrust conviction into a civil antitrust trial is unavailing. That case in no way supports Roche’s claim that it can engage in quilt-making from prior court decisions and submit as “conclusive evidence” its patch work of excerpts from prior findings on unrelated patent claims that are not at issue in this proceeding. Moreover, because those statements are irrelevant to the issues in this case, would so confuse the jury as to what they are supposed to decide and be prejudicial to Amgen, these excerpts should not be introduced at trial at all.

Amgen cross-moves for an order precluding the introduction of the statements listed in Exhibit A.

I. Amgen Cannot Be Collaterally Estopped by Prior Rulings on Unrelated Limitations of Prior Claims

The premise of Roche’s Motion that its requested relief is a matter of “issue preclusion,” is entirely without merit. Issue preclusion is intended to prevent relitigation of the same issues in

a subsequent case.¹ The doctrine applies only if: (1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) the party against whom estoppel is invoked had a full and fair opportunity to litigate the issue in the first action.² Plainly, the issues in this case are not identical to the issues in the prior cases. The claims are different, the claim language is different, and the factual issues raised are different.

The two issues identified in Roche's motion that (i) rEPO cannot be distinguished from uEPO on the basis of glycosylation, and (ii) the common specifications of the patents-in-suit do not support claims to analogs of EPO beyond the few disclosed, are inappropriate for issue preclusion. As a threshold matter, Amgen does not assert in this litigation any of the patent claims that were at issue in the findings referenced by Roche. It is black letter law that under the doctrine of claim differentiation each claim of a patent is presumed to be valid and is to be treated as a complete and independent invention that is presumptively different in scope.³ Indeed, for this reason the Federal Circuit and other courts have held that when patent claims are not substantially identical — and here the claims are plainly different on their face — collateral estoppel cannot apply.⁴

¹ *Freeman United Coal Mining v Co., v. Office of Workers' Compensation Program*, 20 F.3d 289 (7th Cir. 1994) (doctrine "intended to protect the parties from the burden of relitigating the same issue following a final judgment").

² *Amgen, Inc. v. F. Hoffman-LaRoche LTD.*, 2007 U.S. Dist. LEXIS 47886, *7 (D. Mass. July 3, 2007) citing *In re Freeman*, 30 F.3d 1459 (Fed. Cir. 1994).

³ *Wenger Manufacturing, Inc. v. Coating Machinery Systems, Inc.*, 239 F.3d 1225, 1233 (Fed. Cir. 2001) ("under the doctrine of claim differentiation, each claim in a patent is presumptively different in scope"); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1137 (Fed. Cir. 1985) (holding that it is "well settled that each claim of a patent is entitled to presumption of validity and is to be treated as a complete and independent invention").

⁴ *Interconnect Planning Corp.*, 774 F.2d at 1136 -1137 (Fed. Cir. 1985) (a district court's interpretation of patent claim language cannot be used as collateral estoppel in a later litigation where claims were not substantially identical); *Plastic Container Corp. v. Continental Plastics of Oklahoma, Inc.*, 607 F.2d 885, (continued...)

A. Roche’s Proposed Findings from the *HMR/TKT* Litigation Are Unrelated to Issues in this Matter.

With respect to Roche’s first claim about distinguishing rEPO from uEPO based on glycosylation, Roche confuses the issue by conflating arguments raised in the *HMR/TKT* litigation regarding the term “human urinary erythropoietin.” In the *HMR/TKT* litigation the court held that claims 1 and 2 of the 933 patent indefinite because of their limitation “having a glycosylation which differs from that of human urinary erythropoietin.” But the findings in that case were specific to the context of “human urinary erythropoietin.” As this Court is well aware, the issue was whether a skilled artisan could reasonably determine which of many different possible preparations of urinary EPO provided the benchmark against which to assess the recited differences in glycosylation or molecular weight.

In this litigation Amgen is not asserting any claims that recite “human urinary erythropoietin,” nor is Roche asserting the universe of urinary EPOs as a defense to any claim. In its attacks on the ‘422 and ‘933 claims, Roche has centered on the Goldwasser uEPO that was administered to three patients. As will be shown at trial, Goldwasser’s uEPO does not invalidate these claims because it does not meet all the limitations of the claims. Nothing about the prior decision in *HMR/TKT* that “urinary erythropoietin” is indefinite in the context of claims 1 and 2 of the ‘933 patent precludes Amgen from showing in this litigation that the claimed subject matter of claim 1 of the ‘422 patent and claim 3 of the ‘933 patent is different from Goldwasser’s uEPO, including in its glycosylation.

Significantly, this Court has already rejected Roche’s faulty argument – *twice*. Roche moved for summary judgment on these very same grounds claiming that findings from the

894 (10th Cir. 1979) (collateral estoppel appropriate if unadjudicated claim “merely restates and when none of the unadjudicated claims defines an invention separate and apart from the invention described in the adjudicated claims.”)

HMR/TKT litigation rendered claim 1 of the 422 patent invalid for indefiniteness.⁵ As set forth in Amgen’s opposition to this motion, the source limitation of claim 1 of the ‘422 patent “purified from mammalian cells grown in culture” is vastly different to the language of the claims found indefinite in the *HMR/TKT* litigation regarding human urinary erythropoietin.⁶ The Court denied Roche’s motion for summary judgment over a month ago.⁷

Moreover, Roche’s issue preclusion assertion is entirely inconsistent with this Court’s recent grant of Amgen’s Motion for Summary Judgment that claims in the ‘933 patent directed to “non-naturally occurring” products were definite.⁸ Roche had made the same arguments in its opposition to Amgen’s motion for summary judgment that it makes here: that these findings from the *HMR/TKT* litigation rendered the term “non-naturally occurring” indefinite.⁹ As Amgen explained in its memorandum in support of its motion for summary judgment, the claims in the ‘933 patent directed to “non-naturally occurring” relate to whether a skilled artisan could determine if an accused glycoprotein product was obtained from a source that naturally contains the glycoprotein without human intervention.¹⁰ This is indisputably different than the findings in the *HMR/TKT* litigation, which is why this Court appropriately granted Amgen summary judgment on this issue.

⁵ See Docket No. 482.

⁶ See Docket No. 580, pp. 14-16.

⁷ See Docket No. 762, Electronic Order issued July 17, 2007 denying, among other motions, Roche’s Motion for Summary Judgment that Claim 1 of the ‘422 Patent is Invalid Under 35 U.S.C. Sec. 112.

⁸ See Electronic ORDER entered Aug. 27, 2007 GRANTING except for human erythropoietin Motion for Summary Judgment that Dr. Lin’s Asserted Claims are Definite, Adequately Described and Enabled.

⁹ See Docket No. 630, pp. 4-7.

¹⁰ See Docket No. 532, p. 7.

B. Roche's Proposed Findings from the *Chugai* Litigation Have No Relevance to the Claims at Issue.

Issue preclusion is also inappropriate as to Roche's claim about EPO analogs. Amgen is not asserting a claim regarding analogs as part of this litigation because Roche's accused product is not an analog; it has exactly the same amino acid sequence as human erythropoietin. The findings Roche relies on from the *Chugai* litigation are related solely to the extent that Amgen's patents cover EPO analogs. These issues are entirely irrelevant to any of Amgen's claims in this litigation. As this Court correctly found in finding that Roche's peg-EPO product infringes '422 claim 1, peg-EPO comprises human EPO and is not an EPO analog under any generally accepted definition of an analog.¹¹

Moreover, this Court already rejected Roche's claim when it held that Amgen's patents are described and enabled and that Amgen does not have to enable an infringing product.¹² Roche claimed in opposition to Amgen's Motion for Summary Judgment that Dr. Lin's Asserted Claims are Definite, Adequately Described and Enabled that based on the arguments from the *Chugai* case Amgen's patents did not enable peg-EPO.¹³ This Court appropriately rejected that assertion and found Amgen's claims to be enabled.¹⁴ Thus, any issue about the enablement of EPO analogs is irrelevant, and has been decided by the Court as it pertains to the issues raised by Roche.

¹¹ See Electronic ORDER entered Aug. 28, 2007 'Amgen's Motion for Summary Judgment is ALLOWED as to infringement of the '422 patent...'

¹² See Electronic ORDER entered Aug. 27, 2007 GRANTING except for human erythropoietin Motion for Summary Judgment that Dr. Lin's Asserted Claims are Definite, Adequately Described and Enabled.

¹³ See Docket No. 630, pp. 16-18.

¹⁴ See Electronic ORDER entered Aug. 27, 2007 GRANTING except for human erythropoietin Motion for Summary Judgment that Dr. Lin's Asserted Claims are Definite, Adequately Described and Enabled.

II. This Court Should Preclude Roche From Reading Its Cherry-Picked Excerpts of Prior Findings To The Jury.

Roche further suggests that this Court should allow them to parse through prior findings from previous cases to which Amgen was a party, and present a compilation of excerpted statements to the jury as “conclusive evidence.” Roche has no legal support to justify this extraordinary exercise in quilt-making. The one case Roche cites, *Emich Motors Corp. v. General Motors Corp.*¹⁵, is inapposite. In *Emich*, the Supreme Court addressed whether under the Clayton Act, a prior *criminal antitrust conviction* may be introduced in a subsequent *civil antitrust case* dealing with the *very same conduct*.¹⁶ Significantly, the prior criminal conviction was *prima facie* evidence of civil Clayton act liability. Here, *Emich* has no application. Roche is claiming that prior findings on different patent claims should be read to the jury as “conclusive evidence” of the validity of other patent claims.¹⁷ This is vastly different than the holding in *Emich*. Because the prior findings are irrelevant to the issues here, allowing Roche to read them to the jury would be so prejudicial and confusing that the Court should preclude Roche from doing so.

A. Rule FRE 801 and 403 Preclude Roche From Introducing Misleading Excerpts of Prior Court Findings

Roche’s proposal to introduce excerpts of various court decisions is also inadmissible under FRE 801. Statements from civil judgments of prior proceedings cannot be used as

¹⁵ 340 U.S. 558, 571 (1951)

¹⁶ “The issue we must determine, as defined in our order granting review, is ‘whether the Court of Appeals erred in construing §5 of the Clayton Act...as not permitting: (a) the admission in the instant case of the indictment in the antecedent criminal case against respondents, nor (b) the judgment therein to be used as evidence that the conspiracy of which respondents had been convicted occasioned Emich Motors’ cancellation.’” *Id.* at 569.

¹⁷ Notably, under *Emich*, the prior findings would not be “conclusive evidence” in this case as Roche suggests, but rather *prima facie* evidence. *Id.* at 568, 569, 570-571. *See also, Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481 (1968).

evidence because the judgment is hearsay that does not fall within any exception to the hearsay rule.¹⁸ Instead, these are extrajudicial statements from prior court proceedings.¹⁹ They cannot, as Roche suggested, be offered as “conclusive evidence.”

Furthermore, it would also be inappropriate to allow these statements to be presented to the jury because they are misleading and unduly prejudicial. FRE 403 prohibits offering such a compilation because it is an inaccurate portrayal of prior findings that would create a misleading and incomplete picture of Amgen’s prior patent litigation. Roche, by cherry-picking out-of-context statements from prior court opinions *that found in Amgen’s favor*, is inappropriately trying to suggest to the jury that the weight of prior judicial findings were against Amgen. In other words, Roche seeks to create an erroneous and misleading impression that Amgen did not prevail in its prior patent lawsuits. At the same time, Roche is moving to preclude Amgen from relying on these prior decisions. This is precisely the type of prejudice that FRE 403 was designed to avoid.

The excerpts are also inadmissible under FRE 403 because they will not assist the jury, and, to the contrary, will cause unnecessary confusion. If Roche is allowed to read to the jury from court opinions addressing claims that are not at issue here, there is a significant likelihood that the jury will not understand that these prior findings related to different claims. Amgen will be forced to rebut this purported evidence with its own testimony and argument, spending unnecessary time differentiating the pending claims from the patent claims advanced in prior litigation. This is an unnecessary waste of the Court’s and the jury’s time.

¹⁸ See *Greycas, Inc v. Proud*, 826 F.2d 1560, 1567 (7th Cir. 1987) (we are aware that, with immaterial exceptions, . . . civil judgments are said not to be usable in subsequent proceedings as evidence of the facts underlying the judgment; for as to those facts, the judgment is hearsay).

¹⁹ *Id.*

For the foregoing reasons, this Court should deny Roche's Motion to Invoke Issue Preclusion as to Findings from Prior Litigation. In addition, Amgen moves that this Court preclude Roche from introducing the statements listed in Exhibit A of its Motion *in Limine* to the jury.

Date: August 30, 2007

Respectfully Submitted,
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CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and no agreement was reached.

/s/ Michael R. Gottfried
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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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BST99 1550186-3.041925.0056