UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' OPPOSITION TO AMGEN'S CROSS-MOTION TO PRECLUDE ROCHE FROM INTRODUCING THE STATEMENTS LISTED IN EXHIBIT A OF ITS MOTION *IN LIMINE* TO INVOKE ISSUE PRECLUSION AS TO FINDINGS FROM PRIOR LITIGATION

Defendants F. Hoffmann-La Roche, Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively "Roche") respectfully oppose Amgen's Cross-Motion to Preclude Roche from Introducing the Statements Listed in Exhibit A of its Motion *in Limine* to Invoke Issue Preclusion as to Findings from Prior Litigation [D.N. 820]. Because Amgen's requested relief will deprive the jury of conclusively established, relevant evidence, it should be denied.

I. ROCHE PROPERLY SEEKS TO INTRODUCE CONCLUSIVE, RELEVANT EVIDENCE

Roche properly seeks to introduce conclusively established, relevant evidence that will assist the jury in its factfinding. As discussed in detail in Roche's Reply in Support of Motion *in Limine* to Invoke Issue Preclusion as to Findings from Prior Litigation [D.N. 952-2] and below, the two factual issues identified in Roche's motion—(1) that rEPO cannot be distinguished from

uEPO on the basis of glycosylation, and (2) that the common specification of the patents-in-suit does not support claims to analogs of EPO beyond the few disclosed in the patent specifications— satisfy the four requirements of issue preclusion.

Amgen, apparently dissatisfied with the prior findings concerning these issues, attempts to prevent the jury from benefiting from a full record by asserting a combination of baseless claims of prejudice and by promoting the notion that well-established findings on key issues in this dispute will cause confusion.[1] Amgen's claim that it will be forced to rebut this evidence with its own evidence is misleading and completely at odds with the concept of and policy behind issue preclusion. Because these issues have already been decided, the operation of issue preclusion means that Amgen is simply not entitled to relitigate them in any event.

The two findings Roche seeks to provide to the jury are relevant to this litigation under Fed. R. Evid. 401. There is no unfair prejudice in giving these established facts to the jury. Indeed, it is the role of the Court to provide the jury with similarly pre-established information about the facts and the law, such as claim construction, stipulated facts and jury instructions.

II. THE FACTUAL ISSUE "rEPO CANNOT BE DISTINGUISHED FROM uEPO ON THE BASIS OF GLYCOSYLATION" IS RELEVANT TO THIS LITIGATION AND WAS DECIDED IN PRIOR LITIGATION

In the present case, Roche has asserted numerous defenses, including anticipation and obviousness. In particular, Roche contends that the rEPO of the claims-in-suit is anticipated by or obvious in light of naturally occurring EPO, i.e., uEPO. Amgen will undoubtedly attempt to show that its claimed rEPO is distinguishable from the prior art uEPO. If Amgen were to

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[1] Amgen's reliance on *Greycas, Inc. v. Proud* is puzzling. In that case, the Seventh Circuit Court of Appeals noted that the judgment in question was "merely some evidence of the degree" to which the defendant's conduct harmed the plaintiff and differentiated it from a traditional collateral estoppel dispute. *Greycas, Inc. v. Proud*, 826 F.2d 1560, 1566-67 (7th Cir. 1987). Furthermore, that court upheld admitting as as evidence a judgment that fixed property rights and suggested that the catch-all exception to the hearsay rule alleviated concerns about hearsay. *Id.*

attempt to do so by arguing that the glycosylation of the claimed rEPO differed from that of prior art uEPO, Amgen would be re-litigating the identical factual issue that has been fully litigated and finally decided against Amgen in the prior litigation. That different claims or different patents were involved in the prior litigation is of no avail to Amgen, since the factual issue is identical. *Amgen, Inc. v. Genetics Institute, Inc.,* 877 F.Supp. 45 (D. Mass. 1995), *aff'd Amgen, Inc. v. Genetics Institute, Inc.,* 98 F.3d 1328 (Fed. Cir. 1996). The doctrine of issue preclusion only requires that the identical issue have been previously litigated; it does not require that the issue have been litigated in the identical context. Indeed, if the issue had been litigated in the identical context, the doctrine of claim preclusion would be the appropriate doctrine, not issue preclusion.

In *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 165 (D. Mass. 2001), this Court held that "Claims 1, 2, and 9 of the '933 patent are not infringed, and, if this finding is error, those claims are invalid for lack of an adequate written description, indefiniteness, and lack of enablement." Essential to this holding was the factual finding that rEPO cannot be distinguished from uEPO on the basis of glycosylation. *Id.* at 155 ("[T]he glycosylation of human urinary erythropoietin is a standardless standard. As a result, making comparisons between the glycosylation of recombinant EPO and that of human urinary EPO is virtually impossible."). The Federal Circuit affirmed this Court's holding that the '933 patent is invalid. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1358 (Fed. Cir. 2003). In doing so, the Federal Circuit adopted this Court's finding that rEPO cannot be distinguished from uEPO on the basis of glycosylation. *See, e.g., id.* at 1341-1342.

("A further point is that a judgment, insofar as it fixes property rights, should be admissible as the official record of such rights, just like other documents of title….").

III. THE FACTUAL ISSUE "THAT THE COMMON SPECIFICATION OF THE PATENTS-IN-SUIT DOES NOT SUPPORT CLAIMS TO ANALOGS OF EPO BEYOND THE FEW DISCLOSED IN THE PATENT SPECIFICATIONS" IS RELEVANT TO THIS LITIGATION AND WAS DECIDED IN PRIOR LITIGATION

Roche has asserted that Amgen's patents are invalid for lack of enablement and failure of written description. In particular, Roche intends to show that '349 claim 7 is not fully enabled or described. Roche is not barred from trying this defense before the jury; the question of whether or not Roche's product is an analog does not prevent Roche from pursuing such a 35 U.S.C. § 112, 1st ¶ defense. Since the previously litigated issue that the common specification of the patents-in-suit does not support claims to analogs of EPO beyond the few disclosed in the patent specifications is relevant to Roche's defense and is identical in the prior and current litigations, issue preclusion is appropriate.

Amgen has argued that this issue—which was thoroughly litigated and finally decided in the *Chugai* litigation—is irrelevant to the current litigation because "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." D.N. 896, p. 6. However, the nature of Roche's accused product is irrelevant to the validity of Amgen's claims. For example, if one were to attempt to practice the subject matter of '349 claim 7, the radioimmunoassay technique of that claim would measure fragments of EPO; however, these fragments of EPO are EPO analogs that are not fully enabled or described by the patent specification.

Accordingly, Amgen's sole basis for seeking to keep the jury from this decided issue — namely, that "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"—is ill-founded and does not, in any way, address whether the issue is identical in the two litigations. As a result, Amgen's entire opposition on this issue collapses.

Thus, whether the enablement and written-description requirements are fully satisfied for '349 claim 7 is a defense that Roche is allowed to pursue and intends to pursue at trial. Furthermore, contrary to Amgen's arguments which mischaracterize the Court's summary judgment rulings (and are detailed at D.N. 952-2), the issue of whether EPO analogs are fully enabled and described is still a relevant issue in the current case, and furthermore, this issue is identical to the issue in the *Chugai* case.

CONCLUSION

For the reasons set forth above, Amgen's cross-motion should be denied and Roche's motion *in limine* D.N. 820 should be granted. Amgen should be prevented from re-litigating these two issues: (1) that rEPO cannot be distinguished from uEPO on the basis of glycosylation, and (2) that the common specification of the patents-in-suit does not support claims to analogs of EPO beyond the few disclosed in the patent specifications. These determinations are directly relevant to the claims in the instant litigation and have been fully and finally litigated by Amgen in prior proceedings.

Dated: September 4, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
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