UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, vs. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, AND HOFFMANN-LA ROCHE INC., Defendants	CIVIL ACTION No.: 05-CV-12237WGY

ROCHE'S MOTION *IN LIMINE* TO PRECLUDE AMGEN INC. FROM ARGUING THAT SOURCE LIMITATIONS DISTINGUISH THE PRIOR ART FROM ITS '422 PATENT CLAIM 1

Amgen should be precluded from asserting that claim 1 of the '422 patent is patentable over the prior art where the only proffered distinction is the source of the claimed erythropoietin because:

- This Court and the Federal Circuit have made clear that a claim is not patentable solely by virtue of a source limitation.
- This Court has recognized that purported structural differences from the prior art based on unclaimed attributes, such as glycosylation, clearance rate or in vivo potency are irrelevant.
- Even if these purported differences were relevant, Amgen has shown time and again that it cannot meet its burden.
- Evidence and arguments on this issue will unnecessarily confuse the jury.

Claim 1 of the '422 patent reads: "A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is *purified from mammalian cells grown in culture*." ('422 patent, claim 1) (emphasis added). Amgen can not dispute that "purified from

mammalian cells grown in culture" is a source limitation. *Amgen v. HMR/TKT*, 314 F.3d 1313, 1329 (Fed. Cir. 2003) ("the limitation 'purified from mammalian cells grown in culture' in claim 1 clearly limits the source of the EPO....The limitation *only* speaks to the source of the EPO") (emphasis added).

As this Court has recognized, "the Federal Circuit made clear that a finding of non-obviousness cannot be rendered solely on source or process limitations." *Amgen v. HMR/TKT*, 339 F. Supp. 2d 202, 335 n.163 (D. Mass. 2004); *see also Amgen v. HMR/TKT,* 314 F.3d 1313, 1356 (Fed. Cir. 2003) ("source limitations cannot impart novelty to old compositions"); *SmithKline Beecham Corp. v. Apotex Corp*., 439 F.3d 1312, 1317 (Fed. Cir. 2006).

Assuming, as Amgen does, that source limitations can confer patentability when they impart a novel structure to the product, this is the exception to the rule, and Amgen has the burden to "convincingly show" that the source limitation imparts novel structure. *In re Moeller*, 117 F.2d 565, 567 (C.C.P.A. 1941). Amgen has repeatedly tried and failed to meet this burden and should not now be allowed to confuse the jury with irrelevant evidence and arguments that run contrary to the law. For example, when Amgen tried to show that its claimed r-EPO differed from u-EPO in *Amgen v. HMR/TKT*, this Court held that "the glycosylation of human erythropoietin is a standardless standard." *Amgen v. HMR/TKT*, 126 F. Supp. 2d 69, 155 (D. Mass. 2001). Moreover, this Court later noted that Amgen "claims that EPO molecules derived from Dr. Lin's cell cultures differ in glycosylation, degradation, clearance rates, in vivo potency, and therapeutic effect." *Amgen. v. HMR/TKT*, 339 F. Supp. 2d at 335 n.163. As this Court recognized, there is no "convincing case law recognizing [such] unclaimed product attributes as differences in this part of the analysis." *Id.*

In accordance with this memorandum, Roche submits that Amgen should be precluded

from offering evidence and arguments, and from further questioning Dr. Spinowitz, regarding any novelty purportedly conferred by the source limitation in claim 1. The law makes clear that this is irrelevant and, in this case, will only serve to confuse the jury.

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 that no agreement was reached.

Dated: September 11, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

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CERTIFICATE OF SERVICE

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

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