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 PROCESS LIMITATIONS DISTINGUISH THE PRIOR ART FROM ITS '933 PRODUCT-BY-PROCESS CLAIMS

During the prosecution of the '933 patent, Amgen admitted that its claims were drafted as "product-by process" claims and in this litigation Amgen has not argued otherwise.[1] (Trial Ex. 2011, '933 file history at 2011.251-252 ("All product claims in the subject application are now product-by-process claims ... [that] specifically define the erythropoietin of the subject invention as a 'glycoprotein product of the expression of an exogenous DNA sequence in a eukaryotic host cell...."). Federal Circuit precedent states that product-by-process claims are not patentable simply by reciting a new process for making a known product and Amgen cannot argue that the recited process imparts a novel structure.

Here, the Court has defined human erythropoietin -- the product claimed by the asserted product-by-process claims of the '933 patent -- solely by the amino acid sequence, and "declined

[1] The asserted claims of the '933 patent -- claims 3, 7, 8, 9, 11, 12 and 14 -- are all product-by-process claims or dependent therefrom.(Trial Ex. 1, '933 patent, claim 3).

to work" limitations of "glycosylation" and "a description of the structure of erythropoietin" "into the construction." *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 494 F. Supp. 2d. 54, 63 (D. Mass. 2007). Amgen has not argued -- and cannot argue -- that "expression in a mammalian host cell" imparts a novel amino acid sequence to Amgen's claimed product as compared to prior art human EPO. Indeed, this Court has already held that "additional molecules" such as carbohydrate that can be attached to EPO "are not part of the amino acid structure that comprises the claimed product." *Id.*

As a result, the only basis to argue patentability is the process limitations themselves. However, such reliance directly contradicts controlling law. The Federal Circuit has repeatedly held "that one cannot avoid anticipation [or obviousness] by an earlier product disclosure by claiming the same product more narrowly, that is, by claiming the product as produced by a particular process." *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317 (Fed. Cir. 2006); *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). In other words, "[i]f the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *SmithKline*, 439 F.3d at 1317; *see also Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991) ("In determining patentability we construe the product as not limited by the process stated in the claims"). That is because "once a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process." *SmithKline*, 439 F.3d at 1316.

In accordance with clear and consistent Federal Circuit law, the process limitation "of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin" cannot confer patentability to claim 3 of the '933 patent or any of

its dependent claims. Amgen should be precluded from taking a contrary position and presenting irrelevant and confusing evidence to the jury which is contrary to the claims as a matter of law.

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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