## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

AMGEN, INC.,

Plaintiff,

v.

F. HOFFMANN-LA ROCHE Ltd, a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN-LA ROCHE INC., a New Jersey Corporation,

Defendants.

Civil Action No. 05-12237 WGY U.S. District Judge Young

## ROCHE'S MOTION IN LIMINE TO PRECLUDE AMGEN FROM ARGUING THAT LIN DESCRIBED HUMAN EPO WITH THE 1-165 AMINO ACID RESIDUES OF FIG. 6

Amgen should be precluded from arguing and offering testimony that the Lin specification describes human EPO with the amino acid sequence of 1-165 of Figure 6. Although the 165 amino acid sequence that Amgen asserts is "the amino acid sequence of EPO isolated from human urine" may be a subset of Figure 6, the Federal Circuit has already held that the specification and its figures describe human EPO only as an amino acid sequence of 166 residues. Under *stare decisis* an "issue of law that is contained in a final judgment is binding in all future cases on ... courts that owe obedience to that court." *U.S. v. Rodriguez-Pacheo*, 475 F.3d 434, 441 (1st Cir. 2007). Thus, this Court is bound by the Federal Circuit's interpretation of the Lin specification. *Amgen, Inc. v. F. Hoffman-La Roche Ltd.*, 494 F. Supp. 2d 54, 61 (D. Mass. 2007).

Amgen's asserted claims are all directed to human EPO or a process for making human EPO, which the specification expressly describes as having 166 amino acid residues. The disclosure states that "FIG. 6 thus serves to identify the primary structural conformation (amino acid sequence) of mature human EPO as including 166 specified amino acid residues (estimated

M.W.=18,399)." (Trial Ex. 1, '933 patent, col. 21:3-6). In *Amgen v. HMR/TKT*, the Federal Circuit construed Figure 6 and its related passages holding that "[i]f, then, as the specification states, 'the primary structural conformation (amino acid sequence) of mature human EPO as including 166 amino acid residues,' it is simply illogical for Amgen to argue that that means anything other than, at minimum, the 166 amino acids in Figure 6." *Amgen, Inc. v. HMR/TKT*, 314 F.3d 1313, 1345 (Fed. Cir. 2003). Thus, because the appellate court already determined this issue, *stare decisis* precludes Amgen from arguing a contrary position here.

For these reasons, Amgen should be precluded from presenting evidence and arguing that the Lin specification describes human EPO as an amino acid sequence with the 1-165 residues of Figure 6.

## **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 could be reached.

DATED: September 13, 2007

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) participants on the above date.

/s/ Thomas F. Fleming
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