

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

ORAL ARGUMENT REQUESTED

DEFENDANTS’ MOTION FOR SUMMARY JUDGMENT THAT AMGEN IS ESTOPPED FROM ASSERTING INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS OF THE ASSERTED CLAIMS OF THE ‘698 AND ‘868 PATENTS

Defendants F. Hoffmann-La Roche, Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively, “Roche”) respectfully move for summary judgment that Amgen is estopped from asserting that the term “mature erythropoietin amino acid sequence of FIG. 6” in claims 4-9 of U.S. Patent No. 5,618,698 (the ‘698 patent) and the term “encoding human erythropoietin” in claims 1 and 2 of U.S. Patent No. 5,441,868 (the ‘868 patent) are infringed by Roche under the doctrine of equivalents.

The asserted claims of the ‘698 patent describe a process for producing “a glycosylated erythropoietin polypeptide” which employs “DNA encoding the mature erythropoietin amino acid sequence of FIG. 6.” The term “mature erythropoietin amino acid sequence of Fig. 6” also appears in U.S. Patent No. 5,621,080 (the ‘080 patent). In previous litigation, this Court construed the term, in the context of the ‘080 patent, as requiring “an erythropoietin glycoprotein comprising the fully realized erythropoietin amino acid sequence of Figure 6 which depicts 166 amino acids.” The Court further held that the phrase should have the same meaning in both the

'080 and the '698 patents. Additionally, the Federal Circuit held that because the phrase was added to the claims of the '080 patent for patentability reasons following a patent office interview, Amgen was estopped from maintaining that the words "mature erythropoietin amino acid sequence of FIG. 6," as used in the '080 patent, could cover an EPO product containing a 165 amino acid sequence under the doctrine of equivalents.

The phrase "mature erythropoietin amino acid sequence of FIG. 6" was added to the application for the '698 patent for patentability reasons at the very same time and as a result of the very same patent office interview that resulted in the addition of those words to the '080 patent. Having thus narrowed the claims, Amgen should be estopped -- as in the case of the '080 patent -- from contending that the term "mature erythropoietin amino acid sequence of FIG. 6" is satisfied under the doctrine of equivalents.

The phrase "an isolated DNA sequence encoding human erythropoietin" was added to the claims of the '868 patent to overcome a rejection by the examiner. Having thus narrowed the claims in response to the examiner's rejection, Amgen should be estopped from asserting that the term "encoding human erythropoietin" is satisfied under the doctrine of equivalents.

Thus, Roche respectfully asks this Court to grant its motion for summary judgment that Amgen is estopped from asserting that the term "mature erythropoietin amino acid sequence of FIG. 6" in the claims of the '698 patent and the term "an isolated DNA sequence encoding human erythropoietin" in the claims of the '868 patent are met under the doctrine of equivalents.

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: Boston, Massachusetts
July 3, 2007

Respectfully submitted,

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

By their Attorneys,

/s/ Nicole A. Rizzo

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO # 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel: (617) 443-9292
nrizzo@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
Tel: (212) 836-8000

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) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Nicole A. Rizzo

Nicole A. Rizzo

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