

**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

**ORAL ARGUMENT REQUESTED**

**ROCHE'S MOTION FOR SUMMARY JUDGMENT  
THAT CLAIM 1 OF THE '422 PATENT IS INVALID UNDER 35 U.S.C. § 112**

Defendants F. Hoffman-La Roche LTD, Roche Diagnostics GmbH and Hoffmann-La Roche, Inc. ("Roche") respectfully move for summary judgment that claim 1 of U.S. Patent 5,955,422 ("the '422 patent"), owned by Plaintiff Amgen, Inc. ("Amgen"), is invalid under 35 U.S.C. §112, ¶1 for lack of adequate written description and as indefinite under 35 U.S.C. §112, ¶2.

When Dr. Lin filed his series of patent applications with the United States Patent and Trademark Office directed to human erythropoietin ("EPO"), he told the Patent Office -- and the world -- that he was the first to disclose the amino acid sequence of human EPO, claiming to have made and possessed a human EPO with a 166 amino acid sequence. Now, nearly 24 years later in litigation, Amgen impermissibly relies on knowledge other than the information set forth in Lin's disclosure to assert that claim 1 of the '422 patent claims "a protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine" -- *i.e.*, a protein with a 165 amino acid sequence. This is not allowed under 35 U.S.C. §112, ¶1.

There is no question that Lin's specification does not adequately describe the amino acid sequence of EPO isolated from human urine. In prior litigation, Amgen unequivocally admitted to this Court that, even though example 10 of the '422 application may inherently produce a human EPO with 165 amino acids, there is no adequate written description of human EPO as it has been construed, and that the 165 amino acid sequence would constitute new matter that would have required filing a continuation-in-part application to describe. Moreover, not until 1987, when scientists at Genetics Institute published the 165 amino acid sequence of human erythropoietin was the protein publicly described by the amino acid sequence that Amgen now claims.

The construction of "human erythropoietin" also renders claim 1 of the '422 patent indefinite. One of skill in the art, reading the Lin disclosure, would not be able to ascertain what amino acid sequence Amgen claims as human EPO. The use of "such as" in defining human EPO denotes that the 165 amino acid sequence of human urinary EPO is merely one example of human EPO. Amgen has argued that several working examples in the specification also describe human EPO; however (1) each of these examples has an amino acid sequence that differs from that of EPO isolated from human urine, and (2) several of the disclosed amino acid sequences are wrong. Therefore, one of skill in the art reading Lin's disclosure cannot determine the proper scope of the claim.

Accordingly, Roche respectfully requests that this Court grant is notion for summary judgment that claim 1 of the '422 patent is invalid for lack of written description and as indefinite. In support of this motion, Roche submits the accompanying memorandum of law, the Declaration of Krista M. Rycroft including exhibits, and a Rule 56.1 Statement of Undisputed Material Facts.

**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 counsel for Amgen does not assent.

DATED: Boston, Massachusetts  
June 11, 2007

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

/s/ Nicole A. Rizzo  
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