AMGEN INC.,		
Plaintiff,	)	
vs.	)	CIVIL ACTION No. 05 CV 12227WCV
F. HOFFMANN-LA ROCHE LTD;	)	CIVIL ACTION No.: 05-CV-12237WGY
ROCHE DIAGNOSTICS GmbH; and HOFFMANN-LA ROCHE INC.	)	
Defendants.	)	

## **DEFENDANTS' MOTION FOR SUMMARY JUDGMENT** OF NONINFRINGEMENT OF THE '080 PATENT

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively "Roche") submit this motion for summary judgment of noninfringement, under the doctrine of issue preclusion (collateral estoppel) of claims 3, 4 and 6 of U.S. Patent No. 5,621,080 (the "'080 patent").

All of the asserted claims of the '080 patent contain the operative limitation "wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6." In prior litigation, the Federal Circuit construed this limitation to mean that the claimed product necessarily includes the 166 amino acid residues specified in Figure 6 of the patent. In addition, the Federal Circuit held that Amgen is barred by prosecution history estoppel from

<sup>&</sup>lt;sup>1</sup> Roche requested that Amgen withdraw the '080 patent some time ago. Amgen, however, refused on the basis of Amgen's pending petition for certiorari to the United States Supreme Court. On May 14, 2007, the Supreme Court denied certiorari. Roche then renewed its request. Amgen committed to providing a response by May 16<sup>th</sup>. On May 16<sup>th</sup> Amgen requested two more days to respond. On Friday, May 18<sup>th</sup>, having yet to receive a response, Roche informed Amgen that it would file this motion on Monday if no response was received by then.

arguing that this limitation in the claims of the '080 patent can cover a 165 amino acid protein under the doctrine of equivalents.

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Roche's accused product "CERA" is a new erythropoiesis stimulating agent ("ESA") that is chemically synthesized by combining a reactive succinimidyl ester of methoxy PEG-succinimidyl butanoic acid with epoetin beta. CERA does not "contain" EPO of any kind, be it 165 or 166 amino acids. Nonetheless, to the extent that Amgen asserts that CERA "contains" EPO, even Amgen maintains that CERA "contains" only 165 amino acids, not 166. Thus, Amgen claims infringement of the '080 claims only under the doctrine of equivalents. However, the Federal Circuit has already foreclosed this precise argument and Amgen is collaterally estopped by the prior holding.

Thus, Roche respectfully asks this Court to grant its motion for summary judgment of noninfringement of claim 3, 4 and 6 of the '080 patent. In support of this motion, Roche submits the accompanying memorandum of law, the Declaration of Kimberly J. Seluga, 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 that no agreement could be reached.

/s/ Julia Huston
Julia Huston

Dated: May 21, 2007

Boston, Massachusetts

Respectfully submitted,

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

By its attorneys,

/s/\_Julia Huston\_

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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/ Julia Huston Julia Huston

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