

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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AMGEN INC., )  
 )  
 Plaintiff, )  
 )  
 v. )  
 )  
 F. HOFFMANN-LA ROCHE, LTD )  
 ROCHE DIAGNOSTICS GmbH )  
 and HOFFMANN-LA ROCHE INC. )  
 )  
 Defendants. )

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CIVIL ACTION No.: 05-CV-12237WGY

**OFFER OF PROOF REGARDING CLAIMS OF U.S. PATENT NO. 5,441,868 AND NO. 5,618,698 THAT INVALIDATE CLAIMS OF U.S. PATENT NO. 5,547,933, NO.5,756,349, AND NO. 5,955,422 REGARDING OBVIOUSNESS-TYPE DOUBLE PATENTING**

Defendants F. Hoffmann-La Roche, Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively “Roche”) respectfully submit this Offer of Proof regarding claims of U.S. Patent No. 5,441,868 (“the ‘868 patent”) and No. 5,618,698 (“the ‘698 patent”) that invalidate claims of U.S. Patent No. 5,547,933, (“the ‘933 patent”), No. 5,756,349 (“the ‘349 patent”), and No. 5,955,422 (“the ‘422 patent”) based on obviousness-type double patenting (“ODP”).

Claims 1, 2, 4, and/or 5 of the ‘868 patent render claims 3, 7, 8, 9, 11,12, and 14 of the ‘933 patent, claim 7 of the ‘349 patent, and claim 1 of the ‘422 patent invalid for ODP.

Claims 6, 7, 8, and/or 9 of the ‘698 patent render claim 7 of the ‘349 patent and claim 1 of the ‘422 patent invalid for ODP.

The issue of ODP includes factual determinations that are suitable for the jury. As the U.S.P.T.O. Manual of Patent Examining Procedure (“M.P.E.P.”) states:

Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985).

Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

- (A) Determine the scope and content of a patent claims relative to claim in the application at issue;
- (B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue;
- (C) Determine the level of ordinary skill in the pertinent art; and
- (D) Evaluate any objective indicia of nonobviousness.

The conclusion of obviousness-type double patenting is made in light of these factual determinations.

M.P.E.P. Section 804 (II)(B)(1) (8<sup>th</sup> Edition) (Rev. 4) (October 2005).

In accordance with the Court's remarks at the September 7 hearing, Roche will provide further briefing on this and other ODP issues before the close of the validity case.

Dated: September 7, 2007

Respectfully submitted,

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

*By their Attorneys*

/s/ Keith E. Toms

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### **CERTIFICATE OF SERVICE**

I certify that, on the above date, 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.

/s/ Keith E. Toms

Keith E. Toms