

## **Exhibit 20**

to the Declaration of Cullen N. Pendleton in Support of Amgen's Opposition to Roche's Motion for Summary Judgment that Claim 7 of the '349 Patent is Invalid Under 35 USC §112 and is Not Infringed

CONTAINS RESTRICTED ACCESS CONFIDENTIAL BLA/IND MATERIAL  
PURSUANT TO PROTECTIVE ORDER

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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 AMGEN INC., :  
 :  
 Plaintiff, :  
 :  
 v. :  
 :  
 F. HOFFMANN-LA ROCHE LTD, a Swiss : Civil Action No.: 05-12237 WGY  
 Company, ROCHE DIAGNOSTICS GmbH, a :  
 German Company and HOFFMANN-LA ROCHE :  
 INC., :  
 a New Jersey Corporation, :  
 :  
 Defendants. :  
 ----- X

**DEFENDANTS' RESPONSES AND OBJECTIONS TO PLAINTIFF AMGEN INC.'S  
FIRST SET OF INTERROGATORIES TO DEFENDANTS (NOS. 1-15)**

Defendants F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") make the following objections and responses to Plaintiff Amgen Inc.'s ("Amgen") First Set of Interrogatories (Nos. 1-15).

**GENERAL OBJECTIONS**

The following general objections apply to all of Defendants' responses and shall be incorporated in each response as if fully set forth therein. To the extent specific General Objections are cited in response to a specific interrogatory, those specific General Objections are provided because they are believed to be particularly applicable to the specific interrogatory and are not to be construed as waiver of any other General Objections applicable to the interrogatory.

Defendants object to each and every interrogatory to the extent it seeks information protected by the attorney-client privilege, the attorney work product doctrine and/or any other applicable privilege. All answers herein shall be subject to this objection, and no provision of information herein may act as a waiver of these objections.

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**J. Lack of Definiteness Under Section 112 – “capable upon growth in culture of producing erythropoietin in the medium of their growth in excess of 100 U of erythropoietin per  $10^6$  cells in 48 hours as determined by radioimmunoassay”**

Asserted claim 7 of the '349 patent depends from claims 1-6, each directed to vertebrate cells capable of producing erythropoietin in the medium of their growth. The claims require that claimed cells produce a specified number of “U of erythropoietin,” either 100, 500, or 1000, per 100,000 cells in 48 hours. Claims 1-6 further require that “U of erythropoietin” be determined by radioimmunoassay. It is Roche’s contention that the phrase as used in the claims is indefinite, cannot be properly defined in view of the patent specification and is otherwise scientifically inaccurate, as radioimmunoassay alone cannot measure erythropoietin units (“U”) as required by the claim phrase. The specification does not define “U of erythropoietin” nor does it disclose any method for measuring “U of erythropoietin.” Without further guidance that the specification fails to provide, the proper metes and bounds of this limitation cannot be determined. Because claim 7 depends from claims 1-6, each of which contains this limitation, claim 7 itself is indefinite under § 112 for failing to distinctly claim the subject matter in a manner that enables one skilled in the art to understand its true scope.

**INTERROGATORY NO. 10**

Separately, in claim chart form for each claim of Amgen’s patents-in-suit that you contend is invalid under 35 U.S.C. § 102, identify and describe on a limitation-by-limitation basis for each claim:

- (a) where, on a limitation-by-limitation basis, you contend each claim limitation is disclosed in the prior art;
- (b) how each such limitation is disclosed in the prior art, including specific references to pages, claims, columns and/or line numbers (if applicable) in each document supporting such contention;
- (c) all evidence on which you rely in support of each contention, including all documents, testimony, prior knowledge, or public uses tending to support your contention(s), and