

# **EXHIBIT H**

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

**REDACTED**

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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

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**DEFENDANTS’ SECOND SUPPLEMENTAL 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 Second Supplemental 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

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Amgen is now judicially estopped from denying that the claims of the '008 invalidate the asserted claims of the patents-in-suit.

Importantly, Amgen is not shielded from this double patenting attack under 35 U.S.C. § 121 because among other things, Section 121 provides a safe harbor to patents issued from divisional applications whereas the patents-in-suit issued from continuations of the application that became the '008 patent. Moreover, Amgen did not maintain consonance with the restriction requirements. See *Bristol-Myers Squibb Co. v. Research Corp. Tech.*, 361 F.3d 1343, 1348 (Fed. Cir. 2004); *Geneva*, 349 F.3d at 1381; *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1579 (Fed. Cir. 1991). (“Consonance requires that the line of demarcation between ‘independent and distinct inventions’ that prompted the restriction requirement be maintained. . . . Where that line is crossed the prohibition of the third sentence of Section 121 does not apply.”).

Evidence supporting this contention can be found at Interference File History Nos. 102,096 and 102,097, *Fritsch v. Lin*, 21 U.S.P.Q.2d 1731 (Bd. Pat. App. & Interf. 1991), *Fritsch v. Lin*, 21 U.S.P.Q. 2d 1737 (Bd. Pat. App. & Interf. 1992), and *Amgen, Inc. v. Chugai Pharms.*, 927 F.2d 1200 (Fed. Cir. 1991).

**B. Lack Of Inventorship and Derivation Under Sections 102(f) and 116**

As stated above, Defendants have maintained that the DNA and host cell claims of the '008 render obvious the asserted claims of the patents-in-suit. To the extent that Amgen denies this contention and argues that the asserted claims require separate inventive contribution, then those asserted claims would be invalid for lack of inventorship and derivation under 35 U.S.C. §§ 102(f) and 116.

Specifically, during Interference Proceedings Nos. 102,096 and 102,097, it was adduced that all of the work done at Amgen relating to expression of the EPO gene in mammalian host

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DATED: February 26, 2007

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

By its attorneys,

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**CERTIFICATE OF SERVICE**

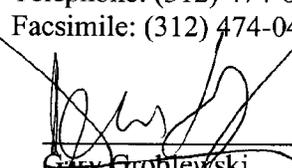
I hereby certify that a copy of this document was served upon the attorneys of record for the plaintiff (as listed below) by overnight mail on the above date.

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