

UNITED STATES DISTRICT COURT
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

DEFENDANTS' RESPONSES AND OBJECTIONS TO PLAINTIFF AMGEN INC.'S
THIRD SET OF INTERROGATORIES TO DEFENDANTS (NO. 26)

Defendants and Counterclaim-plaintiffs F. Hoffmann-La Roche Ltd., Roche Diagnostics
GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") hereby object and respond to
Plaintiff and Counterclaim-defendant Amgen Inc.'s ("Amgen") Third Set of Interrogatories (No.
26).

GENERAL OBJECTIONS

The following general objections apply to all of Roche's responses and shall be
incorporated in each response as if fully set forth therein ("General Objections"). 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.

Amgen's consistent pattern of failing to apprise the United States examiners of material information from European proceedings is similarly shown through its failure to disclose arguments that were raised during the opposition proceedings to its Kirin-Amgen European Patent Application No. 0 148 605 regarding the high materiality of errors in the data corresponding to Example 10 of its US patent application. (European Tech. Board of Appeals 11/21/1994 (“[A]s admitted by the Respondents, the carbohydrate analysis performed in Example 10 was erroneous.”); *see also* 9/6/2000 Borun Trial Tr. 2854:9-25 (incorrect hexoses/fucose values in U.S. Patents)).

Amgen also asserted that it was inappropriate for the Examiner to consider prior art (the Yokota 4,695,542 patent) in conjunction with the claims of the '008 patent to show that the pending claims were obvious arguing that “as noted in the decisional authorities, [double patenting] must be determined through consideration of the *claims* of the pending application and issued patent -- and not with reference to the prior art.” (AM-ITC 00953700). Amgen presented no authority in support of this proposition, and consequently misstated the law, which provides that consideration of prior art may be necessary to determine whether one of skill in the art would deem the later claim to be merely an obvious variation on the earlier one. *See e.g.* MPEP §804 (“Claim [1] rejected

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Boehringer Mannheim GmbH v. Janssen-Cilag GmbH (4 O 229/91, Landgericht Dusseldorf) (Cilag I), EP 0 205 564 (3) *Boehringer Mannheim GmbH v. Janssen-Cilag GmbH* (4 O 58/92, Landgericht Dusseldorf) (Cilag II), EP 0 411 678; (4) *Boehringer Mannheim GmbH v Kirin-Amgen*, (3 Ni 32/93, Bundespatentgericht (BPG)) and appeals therefrom and (5) *Kirin-Amgen and Ortho Pharmaceuticals v. Boehringer Mannheim GmbH and Boehringer Mannheim UK Ltd.*, The High Court Of Justice Chancery Division, Patents Court (CH 1993-K-No. 937).

Examiner of the '933 patent. (AM-ITC 00092853 (“Where it is possible to compare r-HuEPO and u-HuEPO, the two materials were shown to be identical within the error of the methods.”); “The most relevant findings are the overall similarity of the oligosaccharide structures and the demonstration that all of the carbohydrate structures in r-HuEPO are also found in u-EPO.”); AM-ITC 00092884; AM-ITC 00092981-83). Nor did Amgen explain to the examiner(s) that purported differences in glycosylation and carbohydrate composition were not due to differences between CHO rEPO and urinary EPO, but because of different purification techniques in certain instances and the variability and error in testing techniques. These documents and information were not submitted to the examiners.

Furthermore, after Amgen learned of the error in its reporting of the carbohydrate analysis of CHO rEPO and urinary EPO in example 10 ('933 patent 28:51-67), it did not make that error known to the various examiners or the public by disclosing the mistake in any response or amendment in the file history.

#### **Amgen’s Affirmative Misrepresentations and Omissions Regarding Molecular Weight**

In addition to the information out lined above regarding COS rEPO and CHO rEPO (hereby incorporated), in 1995 Mr. Borun presented for the first time a claim requiring that “said product has a higher molecular weight than human urinary EPO as measured by SDS-PAGE.” (AM-ITC 00941545), and the claim was allowed without a rejection or any amendment. ('933 patent). Relevant literature, as well as Lin’s specification, acknowledged that human urinary erythropoietin is a glycoprotein with a molecular weight of approximately 34,000 daltons (*e.g.* '933, col. 5:48-52 (“Erythropoietin, an acidic glycoprotein of approximately 34,000 dalton molecular weight, may occur in three forms:  $\alpha$ ,  $\beta$  and asialo. The  $\alpha$  and  $\beta$  forms differ slightly in carbohydrate components, but have the same potency, biological activity and molecular

- The June 20, 1989 rejection by Examiner Kushan rejecting, among others, claims 67-73 under 1) the doctrine of obviousness-type double patenting as being unpatentable over the prior invention as set forth in claim 1 to 11 of U.S. Patent No. 4,667,016, 2) 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Sugimoto et al. and 3) 35 U.S.C. 103 as unpatentable over Sugimoto et al. in view of Papayannopoulos et al. Amgen argued for the patentability of claims substantially similar to the rejected claims in the '179, '741, '073 and '197 applications and again failed to disclose the prior rejection by Examiner Kushan. (AM-ITC 00899084; AM-ITC00899123-27; AM-ITC 00899151-54; AM-ITC 0095320709, AM-ITC 00953638-39; AM-ITC 00953205-25; AM-ITC 00953637-48);
- The September 18, 1989 rejection by Examiner Kushan rejecting, among others, claims 67-73 under the doctrine of obviousness-type double patenting as being unpatentable over the prior invention as set forth in claim 1 to 11 of U.S. Patent No. 4,667,016. Amgen argued for the patentability of claims substantially similar to the rejected claims in the '179, '741, '073 and '197 applications and again failed to disclose the prior rejection by Examiner Kushan. (AM-ITC 00899084; AM-ITC00899123-27; AM-ITC 00899151-54; AM-ITC 0095320709, AM-ITC 00953638-39; AM-ITC 00953205-25; AM-ITC 00953637-48).

No individual affiliated with Roche, other than counsel, furnished information or is "most knowledgeable regarding the subject matter of this Interrogatory."

Roche expressly reserves the right to amend and/or supplement its interrogatory response as fact discovery and expert discovery progresses.

DATED: March 14, 2007

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

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/s/ Thomas F. Fleming

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CERTIFICATE OF SERVICE

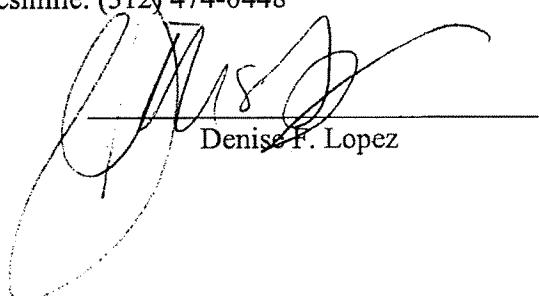
I hereby certify that a copy of DEFENDANTS' RESPONSES AND OBJECTIONS TO PLAINTIFF AMGEN INC.'S THIRD SET OF INTERROGATORIES TO DEFENDANTS (NO. 26) was served upon the attorneys of record for the plaintiff (as listed below) by overnight mail and facsimile on the above date.

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