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March 1, 2007

William G. Gaede III
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Re: ***Amgen, Inc. v. F. Hoffman-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-LaRoche Inc., Civ. No. 05-CV-12237WGY, D. Mass***

VIA FAX AND EMAIL

Dear Bill:

I write regarding the continued deficiencies in Amgen's supplemental interrogatory responses. Over one month ago, I sent you a letter regarding the numerous shortcomings in Amgen's Responses to Roche's First Set of Interrogatories. (See 1/24/07 H. Heckel letter to W. Gaede). In that letter, I included a chart laying out in bullet-point detail deficiencies in Amgen's responses. Amgen's supplemental responses address just a pittance of those deficiencies; it even omits completely Roche's Interrogatory No. 13, a request you assured would be supplemented. (See 1/24/07 W. Gaede letter to H. Heckel).

The attached chart again sets forth Roche's interrogatories and some of the most notable deficiencies in Amgen's responses to each. Though not an exhaustive list, this chart enumerates the issues we've identified thus far while taking into account the little supplementation you've

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provided. Please notify us immediately whether Amgen will supplement its interrogatory responses further to finally correct these deficiencies.

Very truly yours,

Hank Heckel

Hank Heckel

cc: Deborah Fishman
Mark Izraelewicz
Julia Huston
Thomas Fleming

Roche's Interrogatories	Deficiencies in Amgen's Response
INTERROGATORY NO. 1 Separately for each claim of each of the patents-in-suit, identify whether Amgen alleges that Roche makes, uses, offers to sell or sells a product that Amgen contends infringes that claim and explain whether the claim is contended to be infringed literally, by the doctrine of equivalents, directly, contributorily, or by inducement; and explain in claim chart form, the particular element or elements of each claim that Amgen contends are present in Roche's accused product or processes for making the Roche product and the construction of each claim element; and identify the person or persons likely to have discoverable information regarding this interrogatory; and all documents and things that support or otherwise refute Amgen's response to this interrogatory.	• Fails to identify all bases for Amgen's infringement contentions, and by Amgen's own admission does not disclose all documents and things of which Amgen is aware that supports or refutes Amgen's infringement contentions on a limitation by limitation basis. • As to terms which Amgen contends still must be construed, this response fails to set forth claim construction for each claim on a limitation by limitation basis. • Fails to identify each document and thing that supports or otherwise refutes Amgen's proposed claim construction for such terms, including all intrinsic and extrinsic evidence. • Fails to identify which claims Amgen believes are infringed directly and which claims Amgen believes are infringed indirectly; and then offers no explanation or description of the alleged acts of indirect infringement. • Fails to describe how Roche would be liable for inducement of the persons or entities listed, and fails to adequately identify the persons or entities Amgen claims are or would be induced to directly infringe, including failing to identify "entities involved in Defendants' current 'seeding' and other pre-marketing studies." • Fails to identify all the evidence that supports or otherwise refutes Amgen's contentions regarding inducement to infringe. • Fails to identify which, if any, claims of the '080 patent Amgen contends are infringed by the doctrine of equivalents or at least when Amgen will provide this information.

Roche's Interrogatories	Deficiencies in Amgen's Response
INTERROGATORY NO. 2 Identify all current and former employees of Amgen likely to have knowledge of facts in connection to Amgen's assertions within its Amended Complaint in this action, dated April 25, 2006, including but not limited to Amgen's assertions regarding "Dr. Lin's Pioneering Inventions," "Roche's Infringing Process and Product," and "First Cause of Action."	• Fails to state whether it has responded with a comprehensive list of all current and former employees of Amgen likely to have knowledge of facts in connection with Amgen's assertions within its Amended Complaint. • Points generally to "produced documents" for responsive information where the burden is greater on Roche to glean this information from the documents than Amgen pursuant to FRCP 33(d) and does not identify specifically the documents to which it refers.
INTERROGATORY NO. 3 For each of the claims of Amgen's EPO patents, describe Dr. Fu-Kuen Lin's contribution to the claimed subject matter therein, including his conception and reduction to practice of each claimed element, including without limitation the date of any such conception or reduction to practice, and identify all documents and things that support or otherwise refute Amgen's response to this interrogatory.	• Fails to provide when each limitation on the claims of Amgen's EPO patents were conceived or reduced to practice. • Amgen lists a few example documents to evidence dates of conception and reduction to practice; however, if Amgen contends that further documents are responsive to this interrogatory, please identify in a further supplement. • Fails to describe Dr. Lin's purported inventive contribution to the claimed subject matter of Amgen's EPO patents on a limitation by limitation basis. • Fails to provide all evidence corroborating Dr. Lin's purported conception and reduction to practice of the subject matter of Amgen's EPO patents on even a claim by claim basis for the asserted claims.

Roche's Interrogatories	Deficiencies in Amgen's Response
INTERROGATORY NO. 4 Describe Dr. Fu-Kuen Lin's role in developing any method for expressing DNA encoding human EPO in mammalian host cells, including without limitation his role in identifying and developing any vectors, host cells, and/or protocols or procedures for transforming host cells, culturing host cells, glycosylating the EPO protein so expressed and/or isolating the resulting EPO protein to make a product having biological activity *in vivo*, and identify all documents and things that support or otherwise refute Amgen's response to this interrogatory.	• Answer is completely conclusory; a detailed response is required. • Fails to describe Dr. Lin's role in developing any method for expressing DNA encoding EPO in mammalian host cells. • Fails to describe what methods were worked on by Dr. Lin other than those in the patents in suit; and fails to identify any documents relating to same. • Amgen offers certain example documents to corroborate Dr. Lin's role in developing any method for expressing DNA encoding EPO in mammalian host cells; however, if Amgen contends that further documents are responsive to this interrogatory, please identify in a further supplement. • Citing generally to cases without specific evidence adduced in those cases is inadequate.

Roche's Interrogatories	Deficiencies in Amgen's Response
INTERROGATORY NO. 5 Describe any basis and/or evidence that Amgen contends demonstrates that by September 1984, once one of skill in the art of the patents-in-suit had possession of the DNA sequence encoding human EPO, why the claimed subject matter would not have been obvious, including without limitation any basis and/or evidence for why it would not have been routine and/or obvious for that person to express the DNA sequence encoding human EPO in mammalian host cells to produce a glycosylated protein and to isolate the resulting EPO protein to make an *in vivo* biologically active product, and identify all documents and things that support or otherwise refute Amgen's response to this interrogatory.	• Answer is completely conclusory; a detailed response is required. • Fails to describe any particularized basis and/or evidence that Amgen contends demonstrates that by September 1984, once one of skill in the art of the patents-in-suit had possession of the DNA sequence encoding human EPO, it would not have been routine and/or obvious for that person to express the DNA sequence encoding human EPO in mammalian host cells to produce a glycosylated protein and to isolate the resulting EPO protein to make an *in vivo* biologically active product. • Fails to define the skill level of one of ordinary skill in the art that would be relevant to this interrogatory. • Fails to identify each document and thing in Amgen's possession and knowledge that supports or otherwise refutes Amgen's response. All Amgen does is cite broad categories of documents; this is not sufficiently detailed or responsive.
INTERROGATORY NO. 6 Describe whether Amgen contends that in the event that Roche sells MIRCERA™ in the U.S. during the pendency of this lawsuit, Amgen will be seeking monetary damages in this case, and the nature and extent of these monetary damages.	• Fails to state whether Amgen will be seeking monetary damages in this case and if so what type of monetary damages and the extent of such damages. • Fails to state whether Amgen contends there are any current acts of infringement that would currently warrant the seeking of monetary damages. Does state that Amgen "is not seeking monetary damages for any past acts [of infringement]" contending that there have been such acts without identifying or describing them in detail.

Roche's Interrogatories	Deficiencies in Amgen's Response
INTERROGATORY NO. 7 Describe any attempts by Amgen to modify EPO or G-CSF proteins, including attempts successful or otherwise to create pegylated compounds using EPO or G-CSF such that the chemical, physical, pharmacological and/or pharmacokinetic properties of the chemically modified compound differs from the EPO or G-CSF starting material and identify all documents and things that support Amgen's response to this interrogatory.	• Fails to describe any attempts by Amgen to modify EPO or G-CSF proteins, including attempts to create pegylated compounds using such proteins. • Fails to describe all attempts at pegylation of EPO, does not identify,all documents in Amgen's possession or knowledge on this subject even though admittedly in existence.
INTERROGATORY NO. 8 Separately for each claim of the patents-in-suit, identify whether Amgen contends that the making, using, offering to sell or selling of ARANESP® is covered by any or all of the claims of the patents-in-suit, explain whether the making, using, offering to sell or sale is contended to be covered literally or by the doctrine of equivalents, and identify all documents and things that support or otherwise refute Amgen's response to this interrogatory.	• Fails to identify specifically by patent and claim numbers which, if any, claims, other than claim 1 of the '698 patent, of the patents-in-suit cover the making, using, offering to sell or selling of ARANESP and for each claim which Amgen contends covers the making, using, offering to sell or selling of ARANESP, how that claim is covered: please identify whether these claims and claim 1 of the '698 patent are literally covered or whether they are covered under the doctrine of equivalents. • Fails to specifically identify each document and thing that supports or otherwise refutes Amgen's response to this interrogatory.
INTERROGATORY NO. 9 Describe whether Amgen contends that CERA is not materially changed pursuant to 35 U.S.C. § 271(g) from "human erythropoietin," as that term is used in the asserted claims of the patents-in-suit, any basis and/or evidence, and the identity of all documents and things that support or otherwise refute Amgen's response to this interrogatory.	• Fails to specifically identify each document and thing that supports or otherwise refutes Amgen's response. • Fails to identify any evidence specifically supporting the statement "the addition of one or more peg molecules to the EPO does not alter the molecule in any relevant manner."

Roche's Interrogatories	Deficiencies in Amgen's Response
INTERROGATORY NO. 10 As to each asserted claim of the patents-in-suit identified in response to Interrogatory No. 1, describe the reasons why each claim is not rendered invalid under the claims of U.S. Patent No. 4,703,008 pursuant to obviousness-type double patenting, the reasons for this contention, including whether 35 U.S.C. § 121 applies as a defense to obviousness-type double patenting, and the identity of all documents and things that support or otherwise refute Amgen's response to this interrogatory.	• Answer is completely conclusory; a detailed response is required. • Fails to provide any explanation or supporting evidence for the statement "[t]he Asserted Claims are each patentably distinct from the claims of U.S. Patent No. 4,703,008." • Amgen lists certain patents as being exempt by action of 35 U.S.C. section 121; please confirm that all claims within the patents listed are exempt for the reasons stated in your supplement to this Interrogatory; if not all claims are being asserted as exempt, please identify which ones are. • Fails to provide any explanation or supporting evidence for the statement "the later issued claims are consonant with the examiner's restriction requirement." • Fails to provide all reasons for why Amgen contends double patenting does not apply to the asserted patents. • Fails to identify each document and thing that supports or otherwise refutes Amgen's response to this interrogatory.
INTERROGATORY NO. 11 Describe whether Amgen contends that claim 1 of U.S. Patent No. 5,955,422 is not a "product by process claim"[1] and any basis and/or evidence for that contention.	• Fails to state whether Amgen contends that claim 1 of U.S. Patent No. 5,955,422 is not a "product by process claim." • Fails to provide any basis and/or evidence to support Amgen's contention as to whether or not claim 1 of U.S. Patent No. 5,955, 422 is a "product by process claim."

[1] For "product by process claims," reference should be made to M.P.E.P. Section 2113.

Roche's Interrogatories	Deficiencies in Amgen's Response
INTERROGATORY NO. 12 Describe whether Amgen contends that the work of Goldwasser[2] demonstrated a "therapeutically effective amount of human erythropoietin" as these terms were construed in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, Appeal No. 05-1157 (Fed. Cir. August 3, 2006), any basis and/or evidence for that contention, and the identity of all documents and things that support or otherwise refute Amgen's response to this interrogatory.	• Amgen offers one example explanation for how "[t]he 'Goldwasser work' did not demonstrate a 'therapeutically effective amount of human erythropoietin' as its results were at best inconclusive." If Amgen contends there are other reasons, please identify them as well as any further supporting documents responsive to this interrogatory. • Fails to identify each document and thing that supports or otherwise refutes Amgen's response.
INTERROGATORY NO. 13 Identify each customer, or potential customer, with which Amgen has discussed or proposed a sole source contract, requirements contract, or any form of exclusive dealing arrangement or similar arrangement, for the sale of EPOGEN® and/or ARANESP®, and identify any person, including third parties, with knowledge of any such discussion or proposal.	• Fails to state whether there are any other customers or potential customers responsive to this interrogatory besides the one identified in Amgen's response.

[2] This refers to Goldwasser's work relating to the Clinical Study of Purified Human Erythropoietin (H-EPO), as described in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, Appeal No. 05-1157 (Fed. Cir. August 3, 2006)