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January 24, 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 your letter of January 18, 2007 and the January 19, 2007 meet and confer regarding the numerous shortcomings in Amgen's Responses to Roche's First Set of Interrogatories. We asked you to address these issues and notify us whether Amgen would supplement its interrogatory responses by Monday, January 22 on which date you asked for another day to reply. Yesterday morning you said you would reply by last night. We still have heard nothing. Your continued delay prejudices Roche's ability to prepare its case, especially given the tight discovery schedule. For example, you have not yet identified the person at Amgen who verified the interrogatory responses; clearly this is information that you can obtain without any difficulty.

The attached chart sets forth Roche's interrogatories and some of the most notable deficiencies in Amgen's response to each. Though not an exhaustive list, this chart enumerates the issues we were able to address in the limited amount of time you allowed for the meet and confer. Please notify us immediately whether Amgen will supplement its interrogatory responses to rectify these deficiencies. In addition, we asked you at the meet and confer to explain why Amgen has two different claim constructions for the claim term "a pharmaceutical composition." Please also provide a response to this question.

Very truly yours,


Hank Heckel

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NEW YORK CHICAGO LOS ANGELES WASHINGTON, D.C. WEST PALM BEACH FRANKFURT LONDON SHANGHAI

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cc: Deborah Fishman
Mark Izraelewicz
Julia Huston
Thomas Fleming

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Roche's Interrogatories	Deficiencies in Amgen's Response
<p><u>INTERROGATORY NO. 1</u></p> <p>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.</p>	<ul style="list-style-type: none"> • 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 provide sufficient information regarding Amgen's contentions regarding inducement of infringement including the identities of persons and/or entities that Amgen contends are induced to directly infringe. • 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.
<p><u>INTERROGATORY NO. 2</u></p> <p>Identify all current and former employees of Amgen likely to have knowledge</p>	<ul style="list-style-type: none"> • 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

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Roche's Interrogatories	Deficiencies in Amgen's Response
<p><u>INTERROGATORY NO. 2</u></p> <p>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."</p>	<ul style="list-style-type: none"> • 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.
<p><u>INTERROGATORY NO. 3</u></p> <p>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.</p>	<ul style="list-style-type: none"> • Answer is completely conclusory; a detailed response is required. Says only that Dr. Lin invented the subject matter of asserted claims but no details. • Even though Amgen admits that this information is known to those in Amgen, the responses, fail to provide specific dates for the asserted claims setting for the dates for Dr. Lin's purported conception and reduction to practice of the subject matter of Amgen's EPO patents on a limitation by limitation basis. • Fails to produce all documents that evidence each of these dates of conception and reduction to practice even though known to Amgen. The applications for the patents-in-suit purportedly go back over 20 years, and have been the subject of litigation in the past; thus Amgen cannot credibly claim that it cannot yet provide this information. • 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 a limitation by limitation basis for the asserted

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Roche's Interrogatories	Deficiencies in Amgen's Response
<p><u>INTERROGATORY NO. 3</u></p> <p>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.</p>	<ul style="list-style-type: none"> • Answer is completely conclusory; a detailed response is required. Says only that Dr. Lin invented the subject matter of asserted claims but no details. • Even though Amgen admits that this information is known to those in Amgen, the responses, fail to provide specific dates for the asserted claims setting for the dates for Dr. Lin's purported conception and reduction to practice of the subject matter of Amgen's EPO patents on a limitation by limitation basis. • Fails to produce all documents that evidence each of these dates of conception and reduction to practice even though known to Amgen. The applications for the patents-in-suit purportedly go back over 20 years, and have been the subject of litigation in the past; thus Amgen cannot credibly claim that it cannot yet provide this information. • 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 a limitation by limitation basis for the asserted claims.
<p><u>INTERROGATORY NO. 4</u></p> <p>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 <i>in</i></p>	<ul style="list-style-type: none"> • Answer is completely conclusory; a detailed response is required. • Fails to describe Dr. Lin's role in developing <u>any</u> 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. • Fails to provide all evidence corroborating

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Roche's Interrogatories	Deficiencies in Amgen's Response
<p><u>INTERROGATORY NO. 4</u></p> <p>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 <i>in vivo</i>, and identify all documents and things that support or otherwise refute Amgen's response to this interrogatory.</p>	<ul style="list-style-type: none"> • Answer is completely conclusory; a detailed response is required. • Fails to describe Dr. Lin's role in developing <u>any</u> 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. • Fails to provide all evidence corroborating Dr. Lin's role in developing any method for expressing DNA encoding EPO in mammalian host cells. Even though request is broader than No. 3 only cites the same materials as No. 3. • Citing generally to cases without specific evidence adduced in those cases is inadequate.
<p><u>INTERROGATORY NO. 5</u></p> <p>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 <i>in vivo</i> biologically active product, and identify all documents and things that support or otherwise refute Amgen's response to this interrogatory.</p>	<ul style="list-style-type: none"> • 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 <i>in vivo</i> 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

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Roche's Interrogatories	Deficiencies in Amgen's Response
<p><u>INTERROGATORY NO. 5</u></p> <p>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 <i>in vivo</i> biologically active product, and identify all documents and things that support or otherwise refute Amgen's response to this interrogatory.</p>	<ul style="list-style-type: none"> • 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 <i>in vivo</i> 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.
<p><u>INTERROGATORY NO. 6</u></p> <p>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.</p>	<ul style="list-style-type: none"> • 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.
<p><u>INTERROGATORY NO. 7</u></p> <p>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</p>	<ul style="list-style-type: none"> • 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

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Roche's Interrogatories	Deficiencies in Amgen's Response
<p><u>INTERROGATORY NO. 7</u></p> <p>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.</p>	<ul style="list-style-type: none"> • 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.
<p><u>INTERROGATORY NO. 8</u></p> <p>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.</p>	<ul style="list-style-type: none"> • Fails to identify specifically by patent and claim numbers which, if any, claims 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® whether it is covered literally or under the doctrine of equivalents. • Fails to specifically identify each document and thing that supports or otherwise refutes Amgen's response to this interrogatory.
<p><u>INTERROGATORY NO. 9</u></p> <p>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.</p>	<ul style="list-style-type: none"> • 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."
<p><u>INTERROGATORY NO. 10</u></p> <p>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.</p>	<ul style="list-style-type: none"> • 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.

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Roche's Interrogatories	Deficiencies in Amgen's Response
<p><u>INTERROGATORY NO. 10</u></p> <p>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.</p>	<ul style="list-style-type: none"> • 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." • Fails to identify which claims of the patents-in-suit are "exempt by action of 35 U.S.C. § 121." • 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.
<p><u>INTERROGATORY NO. 11</u></p> <p>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.</p>	<ul style="list-style-type: none"> • 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."
<p><u>INTERROGATORY NO. 12</u></p> <p>Describe whether Amgen contends that the work of Goldwasser² demonstrated a "therapeutically effective amount of human erythropoietin" as these terms were construed in</p>	<ul style="list-style-type: none"> • Fails to provide any explanation or supporting evidence for the statement "[t]he 'Goldwasser work' did not demonstrate a 'therapeutically effective amount of human erythropoietin' as its results were at best inconclusive." A

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

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)

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Roche's Interrogatories	Deficiencies in Amgen's Response
<p><u>INTERROGATORY NO. 12</u></p> <p>Describe whether Amgen contends that the work of Goldwasser² demonstrated a "therapeutically effective amount of human erythropoietin" as these terms were construed in <i>Amgen, Inc. v. Hoechst Marion Roussel, Inc.</i>, 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.</p>	<ul style="list-style-type: none"> • Fails to provide any explanation or supporting evidence for the statement "[t]he 'Goldwasser work' did not demonstrate a 'therapeutically effective amount of human erythropoietin' as its results were at best inconclusive." A detailed response is required. • Fails to identify each document and thing that supports or otherwise refutes Amgen's response.
<p><u>INTERROGATORY NO. 13</u></p> <p>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.</p>	<ul style="list-style-type: none"> • Fails to state whether there are any other customers or potential customers responsive to this interrogatory besides the one identified in Amgen's response.

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