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March 6, 2007

VIA FACSIMILE AND E-MAIL

Hank Heckel, Esq.
Kaye Scholer LLP
425 Park Avenue
New York, NY 10022-3598

Re: *Amgen Inc. v. F. Hoffmann-La Roche Ltd., et al.*
Case No. 05 Civ. 12237 WGY

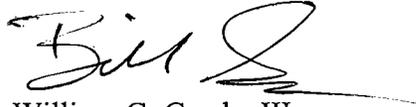
Dear Hank:

This letter is in response to your letter of March 1, 2007 regarding alleged deficiencies in Amgen's Supplemental Response to Defendants' First Set of Interrogatories (Nos. 1-13). I address each of your complaints in turn in the attached chart.

As you will see, in many instances, Roche's complaints that Amgen did not provide certain information are based on Roche's failure to provide the facts and circumstances relating to Roche's assertions that the patents-in-suit are invalid. Roche must come forward and make its prima facie case of invalidity before Amgen has any obligation (or ability) to counter such claims.

In other instances, Roche's complaints relate to interrogatories that did not request the information in the first place. And elsewhere, Amgen has provided the information that Roche claims is lacking. Please let me know if you wish to discuss further.

Very truly yours,



William G. Gaede, III

cc: Mike Gottfried, Esq.
Krista Carter, Esq.
Sandip H. Patel, Esq.

▫ Identification

DEFENDANTS' 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.

Roche's claimed deficiencies in Amgen's response

- 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,

Amgen's response to claimed deficiencies

- Identification of "all bases for Amgen's infringement contentions" not required by this interrogatory, and given the large volume of documents Roche has produced, requiring Amgen at this point to state "all facts" is premature.
- This statement is incorrect. Amgen previously provided claim construction for each term that is contended requires construction and has addressed the issues in its claim construction brief.
- A request that Amgen "identify each document and thing that supports or otherwise refutes Amgen's proposed claim construction for such terms, including all intrinsic and extrinsic evidence" is overbroad and unduly burdensome and not called for in the interrogatory.
- This statement is incorrect; Amgen identified the claims that Roche infringes directly or via inducement or contributory infringement. Explanation/description of alleged acts of indirect infringement is not requested by this interrogatory.
- This statement is incorrect; Amgen identified entities by name or relationship to Roche. Roche is in a far better position to know the persons or entities Roche has induced to

<p>including failing to identify "entities involved in Defendants' current 'seeding' and other pre-marketing studies."</p> <ul style="list-style-type: none"> • 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>infringe by making, using, selling, offering to sell, or importing Roche's peg-EPO, including "entities involved in Defendants' current 'seeding' and other pre-marketing studies."</p> <ul style="list-style-type: none"> ▫ A request that Amgen "identify all the evidence that supports or otherwise refutes" Amgen's contentions regarding inducement is overbroad and unduly burdensome. ▫ This statement is incorrect. Amgen stated that it would prove that each limitation of the asserted claims is infringed under the doctrine of equivalents, if necessary.
<p><u>DEFENDANTS' INTERROGATORY NO. 2</u> 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>	<p>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>
<p>Roche's claimed deficiencies in Amgen's response</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>Amgen's response to claimed deficiencies</p> <ul style="list-style-type: none"> ▫ This interrogatory does not require Amgen to affirmatively state that is has provided "a comprehensive list." Furthermore, Amgen's response clearly states that this interrogatory is unduly burdensome and lacks relevance in that it requires Amgen to inquire of tens of thousand of current and former employees regarding their knowledge on this topic. ▫ Amgen specifically identified eight individuals with relevant knowledge. The burden for obtaining additional information from documents is substantially the same for Roche and Amgen.

DEFENDANTS' 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.

Roche's claimed deficiencies in Amgen's response

- 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.

Amgen's response to claimed deficiencies

- Roche has burden to adequate identify prior art, which it has not done, before conception and reduction to practice of patents presumed valid become discoverable. Amgen will supplement this interrogatory response after Roche provides complete responses to Amgen's Interrogatory Nos. 9, 10, and 11.
- Amgen identified thousands of pages of relevant documents. Amgen will supplement if when and if additional information becomes available.
- Roche has the burden to prove invalidity of the patents-in-suit. In attempting to require Amgen to "describe Dr. Lin's purported inventive contribution ... on a limitation by limitation basis," Roche is improperly shifting the burden of proof to Amgen. Amgen has already provided extensive, detailed information on Dr. Lin's work.
- Roche has the burden to prove invalidity of the patents-in-suit. In attempting to require Amgen to "provide all evidence corroborating Dr. Lin's purported conception and reduction to practice," Roche is improperly shifting the burden of proof to Amgen. Furthermore, this requirement is overbroad and unduly burdensome.

DEFENDANTS' INTERROGATORY NO. 4

Describe Dr. Fu-Kuen Lin's role in developing any method for expressing 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.

Roche's claimed deficiencies in Amgen's response

- 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.

Amgen's response to claimed deficiencies

- Amgen disagrees that its answer is conclusory.
- Amgen identified documents from which this information can be obtained.
- This interrogatory does not call for this information.
- Amgen identified thousands of relevant pages, substantially more than Roche's characterization of "certain example documents."
- This comment is unclear.

DEFENDANTS' 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.

Roche's claimed deficiencies in Amgen's response

- 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.

Amgen's response to claimed deficiencies

- Amgen disagrees that its answer is conclusory.
- Roche has the burden to prove invalidity of the patents-in-suit. In attempting to require Amgen to "describe any basis and/or evidence ... [demonstrating] why the claimed subject matter would not have been obvious," Roche is improperly shifting the burden of proof to Amgen. Amgen will supplement this interrogatory response after Roche provides complete responses to Amgen's Interrogatory Nos. 9, 10, and 11.
- This interrogatory does not require Amgen to make such a definition.
- Roche has the burden to prove invalidity of the patents-in-suit. In attempting to require Amgen to "identify all documents and things that support or otherwise refute" Amgen's response, Roche is improperly shifting the burden of proof to Amgen. Furthermore, this requirement is overbroad and unduly burdensome.

<p><u>DEFENDANTS' INTERROGATORY NO. 6</u> 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>	
<p>Roche's claimed deficiencies in Amgen's response</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>Amgen's response to claimed deficiencies</p> <ul style="list-style-type: none"> ▫ Amgen's response is clear and unambiguous. ▫ This interrogatory does not seek information on "whether Amgen contends there are any current acts of infringement that would currently warrant the seeking of monetary damages." Moreover, Roche's statement incorrectly characterizes Amgen's response.
<p><u>DEFENDANTS' INTERROGATORY NO. 7</u> 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>	
<p>Roche's claimed deficiencies in Amgen's response</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>Amgen's response to claimed deficiencies</p> <ul style="list-style-type: none"> ▫ As stated in Amgen's response to this interrogatory, information on relating to modification of G-CSF proteins is irrelevant to any issue in this case and has been rejected by Judge Young in his January 3 Order. Amgen has adequately responded to this interrogatory with respect to pegylated EPO. ▫ Amgen has provided hundreds of pages of documents showing its knowledge.

<p><u>DEFENDANTS' INTERROGATORY NO. 8</u> 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>	<p>Roche's claimed deficiencies in Amgen's response</p> <ul style="list-style-type: none"> • 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. 	<p>Amgen's response to claimed deficiencies</p> <ul style="list-style-type: none"> ▫ The Court's January 3, 2007 Order excluded the discovery sought by this interrogatory from this case. ▫ Roche has failed to support the relevant of this request.
<p><u>DEFENDANTS' INTERROGATORY NO. 9</u> 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> <p>Roche's claimed deficiencies in Amgen's response</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>Amgen's response to claimed deficiencies</p> <ul style="list-style-type: none"> ▫ This interrogatory does not request Amgen to "specifically identify each documents and thing that supports or otherwise refute Amgen's response." Amgen has provided a good faith response and is continuing to review Roche documents. ▫ This interrogatory does not request that Amgen identify "evidence specifically supporting the statement 'the addition of one or more peg molecules to the EPO does not alter the 	

<p>molecule in any relevant manner.”</p>	<p>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>
<p>DEFENDANTS' 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.</p>	<p>Roche's claimed deficiencies in Amgen's response</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." • 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.
<p>Amgen's response to claimed deficiencies</p> <ul style="list-style-type: none"> ▫ Amgen disagrees with this statement. ▫ Roche has the burden to prove invalidity of the patents-in-suit. In attempting to require Amgen to prove non-obvious before Roche has even attempted to make a prima facie case of obviousness, Roche is improperly shifting the burden of proof to Amgen. Furthermore, this requirement is overbroad and unduly burdensome. 	<p>DEFENDANTS' 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" and any basis and/or evidence for that contention.</p> <p>Roche's claimed deficiencies in Amgen's response</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."
<p>Amgen 5,955,422 is not a "product by process claim" and any basis and/or evidence for that contention.</p>	<p>Amgen's response to claimed deficiencies</p> <ul style="list-style-type: none"> ▫ Amgen's response to this interrogatory is sufficient.

<ul style="list-style-type: none"> • 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>DEFENDANTS' INTERROGATORY NO. 12</u> Describe whether Amgen contends that the work of Goldwasser [] 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>	<p>Amgen 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>
<p>Roche's claimed deficiencies in Amgen's response</p> <ul style="list-style-type: none"> • 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. 	<p>Amgen's response to claimed deficiencies</p> <ul style="list-style-type: none"> ▫ Amgen will supplement its response to this interrogatory to the extent it identifies additional relevant information. ▫ Amgen identified numerous documents in response to this interrogatory. To the extent required, Amgen will supplement this interrogatory response after Roche provides complete responses to Amgen's Interrogatory Nos. 9, 10, and 11.
<p><u>DEFENDANTS' INTERROGATORY NO. 13</u> 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>	<p>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>
<p>Roche's claimed deficiencies in Amgen's response</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. 	<p>Amgen's response to claimed deficiencies</p> <ul style="list-style-type: none"> ▫ This statement is incorrect. Please see Plaintiff's Supplemental Response to Defendants' First Set of Interrogatories (No. 13), served February 9, 2007.