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March 13, 2007

## VIA FACSIMILE AND E-MAIL

Vladimir Drozdoff, Esq.  
Kaye Scholer LLP  
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**Re: *Amgen Inc. v. F. Hoffmann-La Roche Ltd., et al.*  
Case No. 05 Civ. 12237 WGY**

Dear Vladimir:

I write to follow up on your letter of Thursday, March 8, 2007, on Amgen's designation of witnesses on Topics 1-10 under Roche's Rule 30(b)(6) deposition notice. You state that Amgen is not willing to provide witnesses on liability topics. That is not the case, as was previously communicated to Roche in my letter of March 7, 2007. As discussed below, with respect to Roche Topics 1-10 that your letter focuses on, we are providing testimony and/or have provided information on at least nine of the Topics. (Moreover, we are providing testimony and/or further interrogatory responses on sixteen of the remaining nineteen Roche Topics, many of which further touch on liability issues.) The illusion your letter seeks to create that Amgen is not providing discovery on liability is simply untrue.

The problem lies not in Amgen's willingness to produce witnesses, as the above shows. Rather, the problem lies in Roche's insistence of attempting to enforce requests that are overbroad, unduly burdensome, irrelevant, and lack reasonable particularity. For example, as discussed in further detail below, Roche is demanding that Amgen prepare a witness to testify on the contents of over 120,000 pages of material that have been produced, while refusing to agree to Amgen's common sense solution that Roche identify specifically the documents in that group it is interested in so Amgen can prepare a witness. With this background in mind, we turn to the Topics your letter addresses:

### • Topic 1

Roche stated that this topic requires a witness on all characterizations relied upon (even if not expressly referred to), discussed, or referred to in the Amgen EPO prosecution histories or opposition proceedings in Europe. As I told Roche in my March 7 letter, Amgen cannot prepare a witness to testify on characterizations that are not stated or referred to anywhere in the prosecution histories or oppositions. Moreover, given that the volume of materials exceeds over 120,000 pages of material, the issue as framed is lacking reasonable particularity.

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Your letter acknowledges this burden and breadth, but does little to address it, demanding that Amgen simply designate someone. Your letter failed to address our good faith efforts to reach a meaningful compromise on this point. First, we designated Dr. Strickland and he appeared as a Rule 30(b)(6) witness on the characterization of any human erythropoietin relied on, discussed or referred to in his experiments and his declaration that were submitted in the U.S. prosecution or opposition proceedings. Second, we asked Roche to identify any other specific documents from the 120,000 pages at issue addressing specific characterizations, and, assuming reasonable designations and particularity as could be performed with Dr. Strickland, we may be in a position to designate a witness(es). Please reconsider the unreasonableness of your position of refusing to identify the documents that you wish testimony upon, particularly where you acknowledge the volume of material at issue.

• **Topic 2**

This topic relates to the role of any Amgen employee in the prosecution of the EPO patents in the United States, in Europe, and foreign oppositions in Europe. The request is so broad that it even asks for Amgen to prepare a witness on any "statements" by any such individual(s) regarding the characterization of human EPO.

Your letter did not dispute Ms. Carson's earlier representation that Roche would reserve on the issue pending Mr. Borun's deposition. Thus, the first time Roche is raising an issue on this Topic is in your letter of March 8. The delay here is on Roche, not on Amgen. Moreover, the volume of material at issue exceeds over 120,000 pages of materials, and this represents a volume and breadth of material that fails to satisfy the reasonable particularity requirement.

On Friday, Roche requested the deposition of Stuart Watt for March 29, 2007. Per my letter of yesterday, we confirmed this date. We will designate Mr. Watt to further testify on this Topic in that he will be prepared to discuss the identity and general role (subject to privilege) of individuals involved in the relevant patent proceedings. Given Roche's failure to identify specific documents at issue (*See* Topic 1), it is not possible to prepare Mr. Watt, or any other witness, on subsection d, which, as drafted, relates to any representation or "statements" by an Amgen Employee or Agent on the characterization of EPO absent Roche identifying specific and a limited set of documents.

• **Topic 3**

Roche stated that it wants testimony on this topic on all successful and failed attempts, or alternative strategies, to express human EPO in any cell line with any construct up to 1995, excluding production of EPO, and attempts to identify a source for EPO.

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As stated in my letter of March 7, we do not understand the relevance up to 1995 to the issues in the case. Your letter does nothing to address the issue as to why the timeframe up to 1995 is relevant given that the patent applications at issue relate back to the 1983-1984 filings. Amgen proposed as a reasonable compromise that we provide testimony on those examples in the specification as it reflects specific work done prior to the Asserted Patents' priority date. Nonetheless, Thomas Boone will testify as a Rule 30(b)(6) witness on post-1984 expression in cell lines other than Amgen's cell line developed for production purposes.

As to pre-1985, we are prepared to designate Dr. Lin on the examples in the Specification of the Asserted Patents as well as efforts to identify cells or tissue expressing or secreting erythropoietin. We note that if your intent is to question Dr. Lin on the very specifics performed by Amgen scientists that is set forth in the voluminous quantity of notebooks we have produced, then you should depose any such individual because preparing a witness on this quantity of material is unreasonably burdensome and lacks particularity.

• **Topic 4**

With this Topic Roche is seeking testimony on efforts by Amgen to express glycoproteins prior to January 1, 1985. Our letter of March 7 stated that we were prepared to provide a deponent on the examples described in the specification of the Asserted Patents that relate to the recombinant expression of EPO as a glycoprotein as Amgen can then prepare a witness to testify on that subject. Your letter proposes that the deposition topic be limited to "obligate glycoproteins." Mr. Boone will be the Rule 30(b)(6) witness on the recombinant expression of glycoproteins other than EPO prior to 1985. Dr. Lin will testify as a 30(b)(6) witness on the specific examples disclosed in the Asserted Patents that relate to the recombinant expression of EPO as a glycoprotein as discussed in Topics 3 and 6

• **Topic 5**

Your letter fails to respond in any meaningful fashion to the points made in my letter of March 7. Thus, we understand it is confirmed that Roche agreed that the subject matter of Amgen's non-ESA pegylated proteins are not at issue under Judge Young's January 3, 2007 Order, and that Roche is not seeking testimony on peg-Aranesp.

We understand that you failed to question Dr. Strickland on this subject during his deposition. Accordingly, we withdraw Dr. Strickland. Pursuant to my letter of March 9, 2007, Mr. Boone will be providing testimony on peg-EPO under this Topic.

• **Topic 6**

Though not addressed in your letter, we are still confirming that Dr. Lin will be Amgen's deponent on the work disclosed in the specification of the Asserted Patents. We note that if your intent is to question Dr. Lin on the very specifics performed by Amgen scientists that is set forth

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in the voluminous quantity of notebooks we have produced, then you should depose any such individual because preparing a witness on this quantity of material is unreasonably burdensome and lacks particularity.

• **Topic 7**

This topic seeks testimony on the earliest effective filing date of each of the asserted claims in Amgen's EPO patents, and surrounding facts and circumstances. Roche acknowledged that this is a contention deposition. Roche earlier stated that it wants testimony on whether Amgen is going to deviate from the positions taken in the interferences and the bases therefore.

Your letter changes that position, and states that you are seeking a deposition on the underlying subject matter that was included in the Lin Application "that Amgen may use as support for various possible filing dates." Again, if you want to understand further the facts underlying the examples disclosed in the Specification in addition to those set forth in Amgen's detailed Supplemental Response to Roche Interrogatory No. 3, consistent with the scope of Mr. Lin's anticipated deposition on Topic 6, we are prepared to have him testify, assuming we can confirm on this point. If you still seek contentions, as the quoted language from your letter indicates you may still be seeking, then we will object at the deposition and instruct not to answer as such questioning will be beyond our agreed scope. Please confirm.

• **Topic 8**

This topic addresses the relationship between Eugene Goldwasser and Amgen, including communications and the transfer, exchange, provision or supply of information, know-how, or things between them, concerning erythropoietin in several forms, erythropoietin radioimmunoassays, purification methods, and antibodies. Roche stated that it will limit the time frame of this topic to prior to 1996.

Dr. Strickland has testified on this Topic for Amgen. Beyond what Dr. Strickland testified to, Amgen is unable to identify a current employee of Amgen who has knowledge beyond that provided by Dr. Strickland and otherwise recorded in the documents produced and prior testimony of Amgen employees. Accordingly, Amgen's production of witnesses on this Topic is complete.

• **Topic 9**

Your letter does not dispute our understanding from our February 27, 2007, meet and confer set forth in my March 7 letter that (a) "Roche acknowledged that Amgen has provided the characterization information sought by this topic for EPOGEN®, but still seeks characterization information for Aranesp®" and (b) "Roche indicated that it will reconsider this topic since it is getting Amgen cell lines."

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The first communication from Roche on this Topic that it believed that receipt of the cell lines was insufficient was in your March 8, 2007 letter. Again, any delay is due to Roche, not Amgen, on this Topic.

Now that you are raising the issue, we still fail to see the relevance of sub-topics j-o to the issues in the litigation. These sub-topics request Amgen's knowledge on Aranesp's interaction with the Epo receptor, pharmacodynamics, pharmacokinetics, immunogenicity and/or antigenicity, internalization and recycling by cells, and manner of clearance.

Aranesp is not an accused product. Any attempt to compare products, and justify discovery thereon, rests on an improper infringement analysis. An infringement liability analysis requires the application of the Asserted Claims to the accused Roche product and methods. Your letter does not explain the relevance of the information sought, and we do not see how such subject matter on Aranesp generally comports with the Court's previous Order.

• **Topic 10**

Topic 10 concerns any comparisons performed by or for Amgen on the active drug product in Aranesp® to any recombinant human erythropoietin. Your letter failed to articulate the liability issue that such comparisons are relevant to. Further, as discussed on Topic No. 9, any such comparison rests on an improper infringement analysis. To the extent Roche may contend that some of such subtopics are potentially relevant to an injunction, Amgen's witnesses will be testifying on facts relevant to an injunction in response to Topic 13. We understand from your letter that Roche intends to seek Court assistance on this Topic, and see no basis to justify such a request.

I look forward to resolving the above remaining issues as soon as possible.

Very truly yours,



William G. Gaede, III

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