Case 1:05-cv-12237-WGY

Document 295-2

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# **EXHIBIT 1**

## KAYE SCHOLER LLP

Patricia Carson 212 836-7466 Fax 212 836-6355 pcarson@kayescholer.com 425 Park Avenue New York, New York 10022-3598 212 836-8000 Fax 212 836-8689

www.kayescholer.com

January 29, 2007

#### BY EMAIL and FAX

Deborah Fishman
Day, Casebeer, Madrid & Batchelder LLP
20300 Stevens Creek Blvd.
Suite 400
Cupertino, CA 95014

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

#### Dear Deborah:

I write in response to your letter to me of January 26 responding to my letter of January 24 regarding reciprocal production of Amgen's cell lines to Roche at the time that Roche produces its cell line to Amgen. Contrary to your baseless assertion that we are trying to stall Roche's production of its cell line, it is Amgen who is delaying the exchange of the cell lines as ordered by the Court. Roche is prepared to make the exchange of cell lines, and it is only Amgen's refusal to produce the reciprocal cell lines to Roche which is serving to delay this exchange.

With respect to your assertion that Amgen has already made reciprocal production to Roche, so that we are clear, Amgen has never produced ANY cell line samples to Roche, and apparently continues to refuse to do so. Your claimed "reciprocal" production is actually certain documents which you claim are sufficient. As you know, Roche attempted to negotiate an exchange of information that might meet the parties' needs without exchanging actual cell lines. Amgen rejected this approach, and moved the Court for production of samples of Roche's cell line. The Court in turn ordered the production of Roche's cell line and reciprocal discovery from Amgen, which are the relevant Amgen cell lines. Your citation to certain documents does not comply with the Court's order.

Furthermore, the documents to which you cite do not provide the information that Roche needs with respect to Amgen's requested cell lines described in my January 24 letter, and are completely inadequate even if the Court ordered exchange of documents rather than cell line samples.

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You do not contest on grounds of relevance Roche's request for the cell lines used by Amgen in the production of its commercial products, or the cell lines disclosed or covered by Amgen's EPO Patents. Therefore, I only address your incorrect assertion that "Amgen has produced regulatory filings and laboratory notebooks that demonstrate that its EPO-producing cell lines meet the production level requirements of its '349 Patent claims'.

Amgen's '349 Patent claim 1 recites an element of "producing erythropoietin in the medium of their growth in excess of 100 U of erythropoietin per 10<sup>6</sup> cells in 48 hours." The documents cited in your letter are insufficient to show Amgen's cells satisfy this requirement. At best the documents that you have pointed to in your letter (AM-ITC 00603050 - 52; 3057-58) disclose the production rate for a "period of approximately seven days" and for "a second sevenday cycle." In addition, the yield for each harvest is reported in "units/ml determined by radioimmunoassay". Even if the reported results could be authenticated and converted into the terms Amgen chose to use in drafting its claims in the '349 Patent, under the Court's order, Roche is entitled to directly measure and evaluate the production level of Amgen's cells. Moreover, the documents cited in your letter provide no information to confirm that the RIA reported therein would correlate with results obtainable with materials and techniques available at the time the patent was filed. The laboratory notebooks you identified are equally insufficient to establish if and when Amgen possessed EPO-producing cell lines that meet the production level claimed in the '349 Patent. In addition, the documents you have cited provide no information about the cell lines used to produce Aranesp.

The documents you have cited do not in any way obviate the need for samples of Amgen's cell lines identified in my January 24 letter. As you point out in your letters, expert discovery is coming very quickly, and there is no way that exchange of these cell lines can be delayed any longer due to the need to have an expert perform necessary tests on the cell lines and report his results in a timely fashion. Amgen must produce the cell lines now. The parties should decide on a date certain for exchange to acceptable experts.

To this end, although Dr. McLawhon himself has not been subpoenaed in this litigation, he is affiliated with a party that has been - the University of Chicago. It is inappropriate to have an expert witness employed by a potential third party who may be a witness and almost certainly will be an entity about whom testimony will be elucidated at trial. At the very least, since the credentials and credibility of experts are significant factors, it is improper to have an expert whose credibility may be impacted by the credibility of a third party to the lawsuit, and *vice versa*. We maintain our objection to producing Roche's cell line to Dr. McLawhon or anyone affiliated with the University of Chicago.

With regard to the protections to be afforded each sides' cell lines, Judge Young did not endorse the Protective Order as providing ample protection. He ordered the cell lines exchanged and to be covered by the Protective Order, which means that the cell lines, if marked highly confidential for example, cannot be accessed by in-house counsel, and can only be accessed by outside counsel and their retained expert. As you know, the Protective Order is silent on any provisions regarding how cell lines are to be maintained, how much can be grown, how the cell lines are to be treated, etc. These cell lines are unique and very valuable assets of Roche and

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Amgen. We proposed certain conditions that would be significant steps toward assuring that each sides' cell lines are properly protected, and issues such as the threat of theft by outside parties, for example, is minimized. We are willing to negotiate these terms in good faith if you believe certain of them do not accomplish the goal of protection, and instead propose alternatives. Of course, we will abide by the same conditions to protect Amgen's cell lines produced to Roche as we expect Amgen to follow to protect Roche's cell line. We are available to discuss these issues, and believe that a telephone conference will be productive toward resolving the remaining issues regarding the exchange of each parties' cell lines. Please let me know your availability.

Very truly yours,

Patricia Carson

cc: Michele E. Moreland, Esq. (via fax w/out encl.)
Mark Izraelewicz, Esq. (via fax w/out encl.)
Julia Huston, Esq. (via fax w/out encl.)
Leora Ben-Ami, Esq. (via fax w/out encl.)

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