

DAY CASEBEER
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June 4, 2006

VIA FACSIMILE & U.S. MAIL

CONFIDENTIAL
SUBJECT TO PROTECTIVE ORDER

Howard Suh, Esq.
Kaye Scholer LLP
425 Park Avenue
New York, NY 10022-3598

Re: *Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin*, ITC Investigation No. 337-TA-568

Dear Howard:

In the Side Letter Agreement of June 1, 2006, Roche agreed to produce one paper copy and ten electronically searchable CD copies of its BLA. We received the paper copy (51 boxes) on June 2 and the CD copies on June 3. Roche's BLA production appears to total approximately 152,000 pages.

After only a single day's review of the June 2 and 3 production sets, we have identified multiple significant irregularities. These irregularities (1) render many pages indecipherable; and (2) obscure the overall organization and content of Roche's BLA. If not remedied, these production problems will materially hinder our ability to prepare for the upcoming depositions, which begin in three days.

Notably, these problems are a direct result of Roche's decision to convert the BLA from its original highly organized, user-friendly electronic format into unlinked images. The most practical and effective solution to the problems identified below would be to reproduce the BLA to Amgen in the same electronic format as it was provided to the FDA.

Because Amgen has had just a day to review this enormous document, we are in no position to know whether we have identified all of its irregularities. Accordingly, Amgen reserves the right to make further objections after it has had a reasonable opportunity to review the document in depth.

To comply with the Side Letter Agreement, Roche must immediately remedy each of the following issues:

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A. Missing Bates Ranges (Paper and CD)

REDACTED

B. Non-Sequential Page Order (Paper and CD)

REDACTED

C. Non-Sequential Bates Numbering Order (Paper)

REDACTED

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REDACTED

D. Illegible Pages (Paper)

REDACTED

REDACTED

REDACTED

E. Non-OCR'ed Pages (CD)

REDACTED

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As you know, Administrative Law Judge Luckern extended the due date for Amgen's response to Roche's motion for summary determination to June 26, 2006, for the express purpose of "develop[ing] a complete record relating to [Roche's motion]." In order to adequately prepare for the depositions beginning as early as next week, we require responsive documents and, in particular, Roche's BLA submission to FDA.

Roche presumably submitted its BLA to the FDA in legible and orderly form. There should have been no difficulty in providing the same electronic format of the BLA to Amgen counsel for our review and analysis. Instead, you chose to go out of your way to make that production unintelligible and to construct road blocks impeding our ability to review and understand the material in a timely manner. We are troubled by your apparent attempt to seem cooperative by producing the BLA, while at the same time going to unusual lengths to hinder our preparation for the upcoming depositions.

Please confirm that you will take immediate steps to rectify your production by 12:00 p.m. PST on Monday, June 5. In particular, Roche should produce 10 electronically searchable copies of the BLA in the same electronic format it provided to the FDA, and:

- paper replacements with legible bates numbers and substantive text for the bates ranges listed in section D above, as well as all other pages of Roche's paper BLA production that bear illegible bates numbers and/or substantive text; and
- the missing ranges listed in section A above, as well as all other missing ranges, according to the Side Letter Agreement.

If Roche is unwilling to provide accurate electronic copies of the BLA, it should at the very least provide searchable text for all 152,000 pages and a listing (in paper and electronic format) of each page of the BLA ordered in the order that the FDA received the same from you, and each page's corresponding bates number.

REDACTED

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Very truly yours,

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Victoria Smith /rlp
Victoria Q. Smith

VQS:rlp

cc: Anne Goalwin, Esq.
Tony Pezzano, Esq.
Kent R. Stevens, Esq.
Leora Ben-Ami, Esq.