

DAY CASEBEER
MADRID & BATCHELDER LLP

20300 Stevens Creek Blvd., Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

Deborah E. Fishman
(408) 342-4587
dfishman@daycasebeer.com

June 6, 2006

VIA FACSIMILE & U.S. MAIL

CONFIDENTIAL

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:

I write to follow up on our prior correspondence and discussions regarding the problems we have encountered with Roche's production of its BLA, as well as its failure to produce responsive information from Roche's corporate networks, databases, and enterprise resource systems. In accordance with Judge Luckern's direction yesterday, I also wish to meet and confer with you today to see if we can resolve these issues with no further need for motions to compel.

Electronically Searchable Copies of the BLA and INDs

Pursuant to the Side Agreement of June 1, 2006, Roche agreed to produce one paper copy and 10 electronically searchable CD copies of its BLA and INDs. During the negotiations culminating in the Agreement, Rusty Day specifically stated that TIFF images of the BLA and IND were unacceptable because they were not electronically searchable, and insisted that Roche produce its BLA in a readily searchable electronic format, such as OCR. Roche agreed to do so. Although "electronic" in nature, the CDs produced to date are either not searchable, or obviously omit information that was contained in the electronic copies that were apparently provided to the FDA. As Linda Baxley advised Tom Fleming and you yesterday following a telephone conference with your IT specialist, we had identified approximately 44,000 pages of documents that could not be searched via OCR, even following the procedures outlined by your IT specialist. In addition, we were continuing to review the remaining CDs to give you a full count of non-searchable pages.

REDACTED

DAY CASEBEER
MADRID & BATCHELDER LLP

Howard Suh, Esq.
June 6, 2006
Page 2

Because each OCR file contains OCR-text of pages ranging in number from a single page to hundreds of pages, determination of which pages of your BLA production are searchable required us to review every one of the 348 OCR files. As of now, we have identified over 58,000 pages from disks 1 and 2 of the BLA production that are non-searchable pages.

Recognizing the problems created by Roche's need to include a confidentiality legend and Bates number on each page of the documents to be produced, we have proposed alternative means by which Roche may comply with our side Agreement and produce searchable electronic copies of its BLA and INDs. One proposal we have made is for Roche to produce the BLA and INDs in their native, electronic format with the understanding that Amgen will print copies of the documents for use in depositions or hearings only from the paper copy bearing the correct legend and Bates number(s). Another proposal we have made is for you to produce to us the same electronic copies that were provided to FDA.

In addition to the non-searchable nature of many of the electronic files you have produced, it appears that the electronic files we received omit highly relevant hyperlinks contained in the electronic files provided to the FDA. Based on our review of the documents you have produced, it appears that the electronic copy of the BLA provided to the FDA was submitted in an electronically searchable format that included hyperlinks. These hyperlinks would enable the reader to easily access supporting data/documents referenced in the text of the BLA. Please confirm whether this is correct.

By way of contrast, Roche has produced to Amgen an "electronic" picture of the document filed with the FDA. The hyperlinks in the FDA's copy appear in the copy provided to Amgen as inactive static text in a different size and font from the surrounding text. Amgen has no way of determining the content of these hyperlinks or the documents to which they refer because they merely appear as static file names in Amgen's copy. Presumably, the linked documents are somewhere in the production, but Amgen is left guessing as to their identity and specific location.

REDACTED

Corporate Databases and Systems

REDACTED

DAY CASEBEER
MADRID & BATCHELDER LLP

Howard Suh, Esq.
June 6, 2006
Page 3

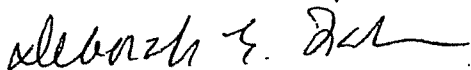
REDACTED

Meet and Confer

We wish to meet and confer with you today in an effort to resolve both of these issues. While we have a conference already scheduled today to discuss Roche's corporate databases and systems, we'd like to use that meeting also to resolve the outstanding problems with your BLA production

Very truly yours,

DAY CASEBEER
MADRID & BATCHELDER LLP



Deborah E. Fishman

DEF:sr

cc: Anne Goalwin
Thomas Fleming
Cecilia Gonzalez
Kevin Flowers
James Adduci