EXHIBIT H

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VIA FACSIMILE

Deborah Fishman, Esq.
DAY CASEBEER MADRID & BATCHELDER LLP
20300 Stevens Creek Blvd., Suite 400
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Re: *In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin*

Dear Deborah:

I write in response to your letter of June 30 regarding the deposition of Dr. Cynthia Dinella. This letter is yet another in an endless series of attempts by Amgen to create the appearance that discovery on the 271(e)(1) issue was somehow incomplete, while in reality Amgen has been provided with all the discovery relevant to Respondents' motion for summary determination based on 271(e)(1) and then some. You now complain, over two weeks after the deposition of Dr. Dinella, that she was not adequately prepared on the topic for which she was designated. Once again, you fail to identify any specific information that is relevant to the 271(e)(1) motion that Amgen has been denied. In particular, in support of your claim that Dr. Dinella was not prepared you quote extensively from a section of her deposition where she says that within her department for different periods of time, two of her subordinates were the persons in her group most knowledgeable about CERA. The passage doesn't say these people were even the most knowledgeable about the FDA submissions for CERA, just about CERA in general. Furthermore, the quoted passage is completely irrelevant to whether Dr. Dinella was prepared on Topic 8 - it is not surprising that a couple of Ms. Dinella's subordinates are the most knowledgeable people about CERA in her group - that doesn't mean Dr. Dinella isn't knowledgeable about CERA and prepared to provide information related to Topic 8.

In fact, Dr. Dinella is very knowledgeable about Topic 8 - facts and circumstances regarding regulatory submissions to the FDA including the IND and BLA for CERA. You conveniently ignore Dr. Dinella's testimony, located shortly after your long quote, that Dr. Dinella "is the person ultimately responsible on behalf of Roche relative to the FDA for all regulatory filings concerning CERA." Dinella Tr. 59:19 - 60:2. Dr. Dinella is a Vice President at Roche Nutley in

charge of Drug Regulatory Affairs, managing about 130 people including people who do submissions to the FDA, archiving, medical writers, a labeling group, a chemistry manufacturing control group, and program management staff. Dinella Tr. 16:9-19 and 23:11-21. In addition to heading the drug regulatory affairs group in Nutley, Dr. Dinella sits on several Roche boards relating to regulatory affairs such as the Roche Global Regulatory Operating Committee, the Nutley Leadership Team, and the North American Operating Committee. Dinella Tr. 43:17 - 44:2. Clearly, Dr. Dinella is an appropriate person to testify as to the regulatory filings of Roche regarding CERA.

I would also note that the few details you cite in your letter that Ms. Dinella supposedly could not provide, such as the amino acid sequence of the protein portion of CERA, the category of filing for the BLA, and other "biophysical characteristics" of CERA are contained in Roche's IND and BLA filings, 10 text-searchable copies of which have been produced to Amgen in this action as discussed more fully below. Amgen's complaints that it could not obtain this information rings hollow. Amgen has had full discovery on Topic 8, and a designation of a further witness on this topic is unnecessary.

Your complaints regarding electronically searchable versions of the BLA are also unfounded. Roche has gone to extraordinary lengths to produce both a hard copy of the BLA (which took over 48 hours to print and then to deliver to your office in California), and 10 electronically searchable versions of the BLA. Amgen requested production of documents in this matter in TIFFS, contrary to your statements in the letter, and when it requested searchable versions, Roche agreed to produce the BLA as OCR versions bates numbered and with the confidentiality legends of this case and the side letter agreement attached. Due to the highly confidential nature of this document, a representative of Roche personally flew the copies of the BLA to California for delivery to your firm. We have also worked closely with you to address your complaints that there were problems with the OCR data so that you have 10 fully-searchable copies as requested. You claim that you are unable to find in the hard copy version provided certain "hyperlinked documents in the electronic version submitted to the FDA." To our knowledge, there are no documents submitted to the FDA with the BLA that are not included in the copies that Amgen has received. It is notable that you do not claim you cannot find these documents in the electronic versions provided, nor do you identify any particular document. In sum, Amgen has received full copies of the BLA for CERA in the form in which it was requested and agreed that Roche would provide it. Your request for any further versions that would not be bates-numbered or stamped with the applicable confidentiality legends is simply a request to get the same information you already have, but in a form that does not protect Roche's confidentiality of this very sensitive document. Again, Amgen complains it wants something beyond what was agreed to, and beyond what is needed.

Finally, you request a plethora of documents that you characterize as being mentioned at Dr. Dinella's deposition. First, some of the documents requested have in fact already been produced, for example, you ask for "records concerning the disposition of unused clinical supplies of 50-3821." Assuming you mean CERA or Ro50-3821, please see as examples the following documents: Site Close-Down forms confirming either destruction or return of unused product to Roche Nutley at ITC-R-00028032-36; ITC-R-00028097-98; ITC-R-00028220-26; ITC-R-

00028907-08; ITC-R-00029640-43; ITC-R-00029959-62; ITC-R-00030110-112; ITC-R-00030163-64; ITC-R-53040-42; ITC-R-00053151-53; ITC-R-00086758-60; ITC-R-000694434-36; ITC-R-00069247-48; ITC-R-00066798-800; ITC-R-00066167-170; ITC-R-00059939-943; "Drug Return" records at ITC-R-00027626; ITC-R-00027649; ITC-R-00027672; ITC-R-00027673; ITC-R-00027674 (a list of these Drug Return records is attached as Ex. 1 to Respondents' Supplemental Response to Amgen Inc.'s Interrogatory No. 5, filed June 22, 2006); and documents confirming destruction of expired or returned CERA at Roche Nutley at ITC-R-00005707-723. Second, the vast majority of these documents are not relevant to Respondents' Motion for Summary Determination, and will be produced in the normal course of discovery, to the extent they exist, are relevant, and have not yet been produced.

Amgen has received full discovery of all documents, and witnesses for 30(b)(6) depositions, related to the Respondents' motion for summary determination. To the extent you request document not relevant to this motion, and they exist, have not been produced and are otherwise relevant, they will be produced in the normal course. In all other respects, your letter is nothing more than an attempt to gain information you already have, or to make it appear, with no basis, that you have not already received all relevant evidence for the summary determination motion.

Sincerely,

Peter Fratangelo

cc: Anne Goalwin, Esq.
Cecelia Gonzalez, Esq.
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Leora Ben-Ami, Esq.

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