Langer, Robert S. (Restricted Access - BLA/IND Material) 6/18/2007 8:15:00 AM

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EXHS. 1 - 8

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

* * * * * * * * * * * * * * * *

Amgen, Inc., *

Plaintiff *

*

v. * Civil Action

* No. 05-CV-12237 WGY

F. Hoffmann-LaRoche, Ltd., *

Roche Diagnostics GmbH, and *

Hoffmann-LaRoche, Inc., *

Defendants *

* * * * * * * * * * * * * * * *

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BLA/IND Information

Video Deposition of Robert S. Langer, Sc.D.

Monday, June 18, 2007

McDermott Will & Emery LLP

28 State Street - 34th Floor

Boston, Massachusetts 02109

---------- J. Edward Varallo, RMR, CRR ----------

Registered Professional Reporter

Farmer Arsenault Brock LLC, Boston, Mass.

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Q. I am trying to determine whether -- Well, I think I've established it, actually, but let me just ask a clarifying question. So in forming your opinion, you did not consider whether the patents enable production of erythropoietin, did you?

A. Well, what I considered, I considered everything, but what I'm trying to say is -- So I considered everything that's in the patent production, everything that they talked about. The question, though, that I am specifically addressing is whether the patents gave sufficient information to enable a person of ordinary skill in the art in the '83-84 time frame, information that was sufficient to generate a PEG-modified protein having erythropoietinlike activity that is therapeutically useful with routine experimentation.

Q. Then you do not have an opinion on whether the patents in suit enable production of erythropoietin itself?

MR. SAPHIA: Recombinant erythropoietin? Recombinant?

MS. DENNETT: Recombinant. I'm sorry. Recombinant erythropoietin.

A. I didn't look at that issue, no.

Q. Did you look at the issue of whether any

of the patents in suit enable a process for preparing human erythropoietin?

A. Again, I think I've tried to say what I did consider. In other words, if we're talking about did they give information sufficient to generate PEG-modified protein having in vivo erythropoietinlike activity that is therapeutically useful, that's what I looked at.

Q. Was the scope of your analysis determined by the attorneys for Roche?

A. That's what they asked me to look at. That was the question that they asked me to address.

Q. If we could turn to paragraph 28 of your report.

A. 28?

Q. 28. And there you say that PEGylation typically refers to the covalent modification of proteins. We kind of established this before, I think. But when you talk about covalent modification, do you consider that chemical modification of the protein?

A. I'm not sure I understand the question.

Q. Well, if you covalently bond PEG to a protein, do you alter the amino acid sequence of the protein?