UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN, INC., Plaintiff, v. F. HOFFMANN-LA ROCHE, LTD., ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE, INC. Defendants.	Civil Action No. 05-CV-12237 WGY

EXPERT REPORT OF DR. ROBERT LANGER

(e) AstraZeneca AB v. Mylan Laboratories, Inc., 265 F. Supp. 2d 213 (S.D.N.Y. 2003)

(f) Shire Laboratories, Inc. v. Barr Laboratories, Inc., 236 F.R.D. 225 (S.D.N.Y. 2006)

(g) Ichor Medical Systems v. Cyto Pulse Sciences (S.D. Cal. 2003)

(h) Novartis v. Teva (ongoing)

IV. MATERIALS CONSIDERED

9. In addition to my review of the patents in suit, I have reviewed the materials listed in Exhibit B, attached to this report. My opinions are based on the materials I have reviewed and cited in this report, as well as on my personal knowledge and experience in the fields of molecular biology, pharmaceutical formulation, and drug delivery. In my report, I am citing to various articles, patents and documents, and if called to testify, I will discuss the dates on the face of these documents. For the purpose of brevity, in this report I may not repeat or discuss the dates on the face of each article, patent and document cited to herein.

V. SUMMARY OF OPINIONS

10. I presently plan to testify and give opinions concerning the validity of Amgen's U.S. Patent Nos. 4,703,008 (the "'008 patent"), 5,411,868 (the "'868 patent"), 5,547,933 (the "'933 patent"), 5,618,698 (the "'698 patent"), 5,621,080 (the "'080 patent"), 5,756,349 (the "'349 patent"), and 5,955,422 (the "'422 patent") (collectively the "Lin patents"). I have also been asked to generate an opinion as to whether these patents would enable a person of skill in the art in 1983-84 to generate analogs of erythropoietin ("EPO") such as a polyethylene glycol ("PEG") modified protein having in vivo erythropoietin-like activity that is therapeutically useful, through routine experimentation. I have also been asked to generate an

opinion as to whether the specification of the Lin patents provide adequate written description of a PEG modified protein having in vivo erythropoietin-like activity that is therapeutically useful.

11. Based on my analysis below, it is my opinion that the Lin patents would not enable a person of ordinary skill in the art in the 1983-84 timeframe to generate a PEG modified protein having in vivo erythropoietin-like activity that is therapeutically useful, through routine experimentation. Roche's counsel has informed me that courts apply certain criteria to ascertain whether a patent claim is enabled. I understand that, among these factors, are the following:

a. the presence or absence of working examples;

b. the state of the prior art;

c. the relative skill of those in the art;

d. the predictability or unpredictability of the art

12. I have been advised that the law does not permit an inventor to claim what was specifically desired but difficult to obtain at the time the application was filed, unless the patent discloses how to make and use it.

13. Roche's counsel has informed me that to satisfy written description a patent must reasonably convey to a person of ordinary skill in the art that the inventor had possession at the time of filling of the claimed subject matter. In my opinion, the Lin patents do not convey to a person of ordinary skill in the art that the inventor was in possession of a PEG modified protein having in vivo erythropoietin-like activity that is therapeutically useful. The bases for my opinions are set forth below, and include the references cited herein.

14. This report is based on information currently available to me. I reserve the right to continue my investigation and study, which may include a review of documents and