Amgen Inc. v. F. Hoffmann-LaRoche LTD et alDoc. 744 Att. 3Case 1:05-cv-12237-WGYDocument 744-4Filed 07/16/2007Page 1 of 5

# **EXHIBIT C**

Dockets.Justia.com

#### UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)
	)
Plaintiff,	)
N/	
V.	
F. HOFFMAN-LA ROCHE, LTD.,	)
ROCHE DIAGNOSTICS, GmbH, and	)
HOFFMAN-LA ROCHE, INC.	)
	)
Defendants.	)
	)

Civil Action No. 05-CV-12237 WGY

#### REBUTTAL REPORT OF RALPH A. BRADSHAW, PH.D. TO NEW NON-INFRINGEMENT ARGUMENTS RAISED IN THE REBUTTAL REPORTS OF DEFENDANTS' EXPERTS

Contains Amgen Confidential and Roche Restricted Access Confidential Information BLA/IND Material Subject To Protective Order

# REDACTED

1. I have been retained as an expert in this case by counsel on behalf of Amgen Inc.

("Amgen"). If called to testify at trial, I expect to provide testimony regarding the matters set forth in this Report.

## Qualifications and Compensation

2. I am the same Ralph A. Bradshaw who submitted a Rebuttal Expert Report on

May 11, 2007 in response to Defendants' April 6, 2007 Reports. My qualifications and the

compensation I am receiving as an expert in this matter are set forth in my May 11, 2007 Report

and are incorporated herein by reference.

#### Information Considered

3. In addition to this information identified in my May 11 Report, I have also

considered the following things:

- The May 11, 2007 Non-Infringement Expert Report of Richard A. Flavell, Ph.D. and the references and information cited in ¶¶ 76-85 of that Report;
- The May 11, 2007 Rebuttal Expert Report of Professor Alexander M. Klibanov and references and information cited in ¶¶ 112-122 and 132-133 of that Report;
- The May 11, 2007 Expert Report of Gregory D. Longmore, M.D. and references and information cited in ¶¶ 103-107 of that Report;
- The April 17, 2007 Markman Hearing Transcript, pp. 81-97; and
- The publications, references, and other information cited in this Report.

In forming my opinions, I additionally have relied upon the knowledge, training, and experience

that I have acquired during my over 40 years as a protein chemist.

## Summary of My Opinions

4. I have reviewed the May 11, 2007 Expert Reports of Drs. Richard Flavell,

Alexander Klibanov, and Gregory Longmore. In those reports, Drs. Flavell, Klibanov, and

Longmore offer the opinion that the EPO used to make peg-EPO is materially changed from the

isolated EPO preparation obtained using the processes claimed by Dr. Lin. I have been asked to

consider this opinion.

- 5. Based on my review of the above-referenced documents, it is my opinion that:
- Opinion 1: The human erythropoietin used to make peg-EPO is not materially changed from the human erythropoietin isolated according to the processes claimed in Dr. Lin's '868 and '698 patents.
- Opinion 2: The human erythropoietin used to make peg-EPO is not materially changed from the human erythropoietin claimed in Dr. Lin's '933 and '422 patents.

## **Opinions**

Opinion 1: The human erythropoietin used to make peg-EPO is not materially changed from the human erythropoietin isolated according to the processes claimed in Dr. Lin's '868 and '698 patents.

#### and

Opinion 2: The human erythropoietin used to make peg-EPO is not materially changed from the human erythropoietin isolated according to the EPO claimed in Dr. Lin's '933 and '422 patents.

6. Drs. Flavell, Klibanov, and Longmore's Reports contain the opinion that the

purified EPO used to make peg-EPO is materially changed from the "crude EPO isolate"

obtained using the processes claimed in U.S. Patent Nos. 5,441,868 and 5,618,698 (the '868 and

'698 patents, respectively) and claimed in U.S. Patent Nos. 5,547,933 and 5,955,422 (the '933

and '422 patents, respectively). This opinion is based in part on the premise that one of ordinary

skill in the art, following the teaching in Dr. Lin's specification on how to isolate EPO from cell

with sugar, the presence of contaminants in the crude isolate would not prevent the formation of the pegylated EPO.

27. For all of the reasons set forth above, I disagree with Drs. Flavell, Klibanov, and Longmore's opinion that the human crythropoietin used by Roche to make its peg-EPO is materially changed from the human crythropoietin obtained using the processes taught and claimed by Dr. Lin in his '868 and '698 patents and the human crythropoietin claimed in Dr. Lin's '933 and '422 patents. In my opinion, the human crythropoietin used by Roche, as characterized by Roche's experts, and the human rythropoietin disclosed in Dr. Lin's specification, and included within the scope of Dr. Lin's claims, are not materially different.

13

Dated: June 1, 2007

Ruph A. Bradshaw, Ph.D.

686037\_1