Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Case 1:05-cv-12237-WGY

Document 567-4

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EXHIBIT C

Baxley Decl. in Support of Amgen's Opposition To Roche's Motion for Summary Judgment that Claim 1 Of '422 Patent is Invalid Under 35 USC S. 112

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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AMGEN INC.,

Plaintiff,

VS.

HOECHST MARION ROUSSEL, INC. and TRANSKARYOTIC THERAPIES, INC.,

Defendants.

Civil Action No.: 97-10814-WGY

CONFIDENTIAL SUBJECT TO **PROTECTIVE ORDER**

FILED UNDER SEAL

DECLARATION OF JEFFREY K. BROWNE, Ph.D.

Trial Exhibit AVE 97-10814-WGY

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DECLARATION OF JEFFREY K. BROWNE Ph.D.

l, Jeffrey K. Browne, declare under penalty of perjury under the laws of the United States of America that all statements made herein of my own knowledge, are true and correct, and that all statements made on information or belief are believed to be true and correct:

- 1. I received my B.A. degree in Biology from the University of California at San Diego in the United States of America in 1974. After working a year at the Salk Institute as a Laboratory technician doing various types of general molecular biology work such as isolating DNA and RNA and restriction mapping, I entered the Ph.D. program at the Molecular Biology Institute at the University of California, Los Angeles in 1975. I completed my thesis work in October 1981 and my Ph.D. degree in Molecular Biology was awarded in early 1982. Annexed hereto and marked **Exhibit JKB-1** is my curriculum vitae which includes a list of the publications that I have authored or coauthored, many of which relate to recombinant erythropoietin.
- 2. I joined Amgen on October 12, 1981 as a Research Scientist and was continuously employed by Amgen until I retired in January 1998. At that time, I held the position of Senior Director of Product Development after serving for some time as Laboratory Head of Molecular Cell Biology, Manager of Product Development, and Director of Product Development. From 1983 through July 1997, I worked on and had been involved with the development and production of human erythropoietin at Amgen through use of recombinant DNA technology. Specifically, I was responsible for the expression and production of erythropoietin from mammalian cells. In November 1984, I became the leader for the erythropoietin product development team at Amgen and continued in that capacity until July of 1997. In that role, I was involved in all aspects of the development of Amgen's erythropoietin products including laboratory research, clinical research, manufacturing process development, and preparation of regulatory license applications.
- 3. I am familiar with the content of United States Patent No. 5,621,080 ("the `080 patent"). Example 10 of the `080 patent describes methods of producing human erythropoietin by recombinant expression of the DNA sequence set forth in Figure 6 of the patent. As the

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former erythropoietin team leader, I am also familiar with the production of human erythropoietin at Amgen since Amgen began its large scale production in 1985. The erythropoietin made and sold by Amgen and its licensees world-wide is, and always has been, produced according to Example 10 of the '080 patent, using a CHO cell line selected from the original population of cells created and described in that Example. This erythropoietin product is a glycoprotein with a 165 amino acid sequence polypeptide backbone. The amino acid sequence of this erythropoietin product is the amino acid sequence set forth as +1 to 165 in Figure 6 of the '080 patent.

Executed on September 28, 1999 in Ventura County, California.

Jeffrey K. Browne, Ph.D.

browne hmrdeci.US.001

Exhibit JKB-1

CURRICULUM VITAE

Jeffrey King Browne

Address: 1244 Calle Aurora Camarillo, CA 93010 . (805) 484-8320

Biographical:

Birthplace:	Los Angeles, California
Birthday:	January 29, 1952
Marital Status:	Married, three children
Citizenship:	United States

Education:

Ph.D. 1981Molecular Biology, Molecular Biology Institute, University of California at Los Angeles, Los Angeles, California.

Ph.D. Thesis Title, "Sequences of Cloned Mammalian Genes and Their Study by DNA-Medicated Gene Transfer into Living Animals."

B.A. 1974 Biology, University of California at San Diego, La Jolla, California, "With High Honors".

Scholarships:

N.I.H. Genetics Training Grant, 1977-1980 N.I.H. Molecular Biology Training Grant, 1975-1977

Professional Experience:

10/1981-1986:	Research Scientist; Amgen Inc.
1986-12/87:	Department Head, Molecular Cell Biology; Amgen Inc.
12/87-1/89:	Manager, Product Development; Amgen Inc.
2/89-11/95:	Director, Product Development; Amgen Inc.
11/95-1/98:	Senior Director, Product Development, Amgen Inc.
1/98 - present:	Independent Consultant: Pharmaceutical Product Development

PUBLICATIONS:

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