Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Doc. 623 Att. 8
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Exhibit 8

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Fu-Kuen Lin
Serial No: 08/100,197
Filed: August 2, 1993
For: PRODUCTION OF ERYTHROPOIETIN

Group Art Unit: 1633
Examiner: James Martinell, Ph.D.

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AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Please enter the following amendments.

IN THE SPECIFICATION

At page 22, line 24, please delete [Example] and insert in place thereof --Examples--.

At page 25, following line 5 of the original text and the amendment following this line dated 11/6/90, please delete [Reference is made to FIGURES 1 through 21, wherein: FIGURE 1 is a graphic representation of radioimmunoassay analysis of products of the invention; FIGURES 2 through 4 illustrate vector constructions according to the invention; and, FIGURES 5 through 21 are DNA and polypeptide sequences] and please insert the following:

--Reference is made to FIGURES 1 through 21, wherein: FIGURE 1 is a graphic representation of a radioimmunoassay analysis of products of the invention;
Figure 2 shows vector pDSVL-MkE.

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7 and 10 disclose the production of human erythropoietin in COS-1 and CHO cells respectively. Thus, human erythropoietin is understood to include any polypeptide having the amino acid sequence of EPO isolated from human urine and may be produced in human cells or in other mammalian cells. The application further discloses that the glycosylation of human erythropoietin may differ depending upon the host cell used for production. Claim 64, however, excludes EPO that is isolated from human urine by the phrase "purified from mammalian cells grown in culture." This phrase is intended to include any EPO produced by mammalian cells (human, CHO, COS, etc.) that are grown in culture, which means in vitro.

In contrast to Claim 64, newly added Claim 65 does not limit the source of the EPO but does specify that the EPO is mixed with human serum albumin in the preparation.

As discussed at the interview, Applicant believes that the subject matter of Claims 64 and 65 is novel and non-obvious over the prior art and is fully supported by the disclosure of the application. With respect to Claim 65, the two Goldwasser references reviewed at the interview disclose the use of bovine serum albumin to stabilize partially purified erythropoietin preparations obtained from sheep plasma. These references do not disclose a pharmaceutically acceptable preparation, and there is no indication that BSA or other stabilizing additive would be necessary once the purified EPO was obtained. In fact, the Chapter 10, Erythropoietin, Goldwasser reference states: "It is obvious that, when further purification or protein determinations are being carried out, exogenous protein cannot be added. Loss of activity can then be minimized by keeping solutions as concentrated and as cold as possible."

The present application was the first disclosure to provide a pharmaceutical composition of a therapeutically effective amount of erythropoietin. Applicant reiterates his position that the Sugimoto reference, U.S. 4,377,513, is not repeatable and is non-enabling because no information is provided concerning how to

obtain or select the starting kidney tumor cells or the hybridoma resulting from fusion with a leukemic lymphoblastoid cell. No deposit of any cells is referenced in the Sugimoto patent. Further, the reference does not disclose the isolation or characterization of any EPO product, but only reports that a relatively low level of EPO activity was detected. In any event, Applicant submits that the present claims define patentable subject matter over Sugimoto even if the disclosure is considered to be repeatable. First, there is no disclosure of a pharmaceutical composition in the reference and it cannot be assumed that it was straightforward to purify the EPO from the suspension of disaggregated tumor cells. Second, the purported method of producing EPO disclosed in Sugimoto cannot be viewed as viable for providing sufficient amounts of EPO to prepare a composition having a therapeutically effective amount of EPO. Consequently, it is submitted that both Claims 64 and 65 are novel and non-obvious over the Sugimoto disclosure. It is believed that the other relevant references have been previously distinguished.

Applicant therefore respectfully submits that claims 64 and 65 are in condition for allowance and an early notice thereof is respectfully solicited.

Respectfully Submitted,

Dante J. Pacciano
Attorney for Applicant(s)
Registration No.: 33,543
Phone (570) 668-4774
Date: 4-28-99

Please send all future correspondence to:

BELL, BOYD & LLOYD
P.O. Box 1135
Chicago, IL 60690-1135

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