Case 1:05-cv-12237-WGY

Filed 07/03/2007

Page 1 of Exhibit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: LIN, Fu-Kuer.

Serial No.: 08/202,874

Filed: February 28, 1994

For:

PRODUCTION OF ERYTHROPOIETIN

Group Art Unit: 1812

Examiner: D. Fitzgerald

) I hereby certify that this paper is being transmitted via facsimile to: Hon. Commissioner of Patents and Trademarks, Washington, D.C. 20231 on this date:

June 13, 1994

Greta E. Noland

) Registration No. 35,302 ) Agent for Applicant

PRELIMINARY AMENDMENT

Hon. Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

Please enter the following amendments.

In the Claims

Cancel claims 76-83 without prejudice.

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Add the following claims 84-94 An erythropoietin glycoprotein product having in vivo

biological activity and having glycosylation which differs from that of human urinary erythropoietin.

A glycoprotein product of the expression in a eucaryotic host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin said product possessing the in vivo biological property of causing human bone marrow cells to increase production of reticulocytes and red blood cells.

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The in vivo biologically active human erythropoietin glycoprotein product of the process comprising the steps of:

- (a) growing, under suitable nutrient conditions, mammalian host cells transformed on transfected with an isolated DNA sequence encoding the human erythropoietin amino acid sequence set out in FIG 6 or a fragment thereof; and
- (b) isolating a glycosylated erythropoietin polypeptide therefrom.

The in vivo olologically active human erythropoletin glycoprotein product of the process comprising the steps of:

- (a) growing, under spitable retrient conditions, mammalian host cells transformed of transfected with an isolated DNA sequence comprising a sequence encoding the signal sequence of human erythropoietin set out in RIG 6; and
- (b) isolating a glycosylated erythropoietin polypeptide therefrom.

9| 88. A glycoprotein product according to claim 86 wherein the exogenous DNA sequence is a CDNA sequence.

A glycoprotein product according to claim so wherein the exogenous DNA sequence is a genomic DNA sequence.

A glycoprotein product according to claim wherein the host cell is a non-human mammatian cell.

A glycoprotein product according to claim of human mammalian cell is a CHO cell

A pharmaceurical composition comprising an effective amount of a glycoprotein product according to claim 24, 35, 50 or 27 pharmaceutically acceptable diluent, adjuvant or carrier.

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A method for providing erythropoietin therapy to mammal comprising administering an effective amount of a pharmaceutical composition of claim 92.5

A method according to claim 93 wherein the therapy comprises enhancing hematocrit levels

Respectfully submitted,

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By:

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