

HECEIVED GROUP 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

FU-KUEN LIN

Serial No: 113,179

Filed: October 23, 1987

(Based on S.N. 675,298, filed November 30, 1984, ) issued as U.S. 4,703,008 ) on October 27, 1987)

"Production of Erythropoietin" Group Art Unit 127 Examiner (Expected): A. Tanenholtz

## APPLICANT'S SECOND PRELIMINARY AMENDMENT

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

Sir:

Consistent with the February 18, 1988 favorable Decision On Petition To Make Special and the provisions of M.P.E.P. \$708.02, please amend the above-identified application as follows:

## IN THE SPECIFICATION

Please delete the entire text of page 1, lines 3-6 as amended October 23, 1987 and insert the following text in / place thereof:

-- This is a continuation of my co-pending U.S. Patent Application Serial No. 675,298, filed November 30, 1984 and issued as U.S. Letters Patent No. 4,703,008 on October 27, 1987, which was a continuation-in-part of my copending U.S. Patent Application Serial No. 561,024, filed December 13, 1983, now abandoned, and a continuation-in-part of Serial No. 582,185, filed February 21, 1984, now aban-

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Page 61, line 25, "hemogeneous" should be --homogeneous--. Page 88, line 36, "lablled" should be --labelled--. Page 91, line 29, please delete "a". Page 92, line 10, "Table VI" should be > --Figure 6--. Page 95, line 10, "membrances" should be > --membranes--.

## IN THE CLAIMS

Please cancel claims 61-64 without prejudice to Applicant to pursue claims of the same or similar scope in a duly-filed continuing application.

Please enter new claims 65-69.

--65. A process for the preparation of an in vivo biologically active glycosylated polypeptide comprising the steps of:

(a) growing a mammalian host cell which is capable of effecting post-translational glycosylation of polypeptides expressed-therein/and which is transformed or transfected with an isolated NA sequence encoding-apolypeptide having-a-primary-structural-conformation sufficiently duplicative of that of naturally occurring human erythropoietin to allow-possession of the in vivobiological property of causing bone-marrow-cells to increase production of reticulocytes and red-blood-cells, or the .progeny thereof, under nutrient conditions suitable to allow, in sequence,

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- (i) transcription within said host /cell of said DNA to mRNA in the sequence of transcription reactions directed by the nucleotide sequence of said DNA;
- (ii) translation within said host cell of said mRNA to a polypeptide in the sequence of translation reactions directed by the nucleotide sequence of said transcribed mRNA;
- (iii) glycosylation within said host cell of said polypeptide in a pattern directed by the amino acid sequence of said translated polypeptide and sufficiently duplicative of the pattern of glycosylation of naturally occurring human erythropoietin to allow possession by/ the translated glycosylated polypeptide product of the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and/red blood cells; and
- (b) isolating/the glycosylated polypeptide so

produced.

66. The process according to claim 65 wherein said host cell is a CHO cell.

67. The process according to claim 65 wherein said host cell is a COS cell.

68. /The process according to claim 65 wherein said DNA is cONA.

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AM670168541 AM-ITC 00953208 with the ruling of the C.A.F.C. in <u>In re Durden</u> because the process herein claimed could not have been expected to provide the valuable product attained.

## CONCLUSION

The foregoing amendments and remarks are believed to establish that claims 65-69 are in condition for allowance and an early notice thereof is solicited.

Respectfully submitted,

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Вv

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