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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

I hereby certify that this paper is Application of: being deposited with the United States Postal Service as first class mail, Fu-kuen Lin postage prepaid, in an envelope addressed to: Serial No: 08/202,874 Commissioner of Patents and Filed: February 28, 1994 Trademarks, Washington, DC 20231, For: PRODUCTION OF on this date: **ERYTHROPOIETIN** Dated: February 16, 1995 Group Art Unit: 1805)UP 1800 Examiner: J. Martinell Michael F. Borun Reg. No. 25,447 Attorney for Applicant(s)

APPLICANT'S AMENDMENT AND REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. §§1.111 AND 1.115

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

Dear Sir:

This is in response to the Office Action dated August 16, 1994 in the above-identified application wherein, of pending claims 87-97, all but claims 88, 93 and 94 were rejected under 35 U.S.C. §112, first or second paragraph, and all claims were variously rejected under 35 U.S.C. §102(b) and/or 103. Reconsideration and allowance is respectfully requested in view of the foregoing amendments and remarks.

isolation of any actual protein product to which the activity can be attributed, there is simply no factual basis whatever for maintaining that the presently claimed human erythropoietin glycoproteins, pharmaceutical compositions and treatment methods are rendered obvious by, much less anticipated by, the cited references.

3. The rejection of claims 89-94 under 35 U.S.C. §102(b) and/or §103 based on the disclosures of human urinary EPO in Espada et al. and Miyake et al. should also be withdrawn inasmuch as it is based on the assumption that the recombinant erythropoietin glycoprotein products recited therein are the same as human urinary EPO. This assumption, of course, is directly contradicted by the publications made of record as attachments to the Exhibit B expert opinion of Dr. Cummings. These publications establish that it is in fact "evident that the process of production defines the product" as alluded to by the Examiner at page 9 of the Office Action.

Most simply put, no human urinary EPO product as describe in Miyake et al. or Espada et al. is embraced by the claims, nor does any such human urinary EPO product render the claimed glycoproteins, pharmaceutical compositions and methods of claims 89 through 94 obvious.

Because the "primary" references of record (Sugimoto et al., Chiba et al., Espada et al. and Miyake et al.) fail to disclose or suggest the products of claims 87, 88, 89 and 90, no basis exists for maintaining that the claim 95 pharmaceutical compositions incorporating these products are rendered obvious by these references, standing alone, or in combination with Papayannopoulou et al. The same is true of the therapeutic methods of claims 96 and 98 involving use of the claim 95 pharmaceutical compositions.

CONCLUSION

The foregoing and amendments and remarks are believed to establish that claims 87-90, 93-96 and 98 are in condition for allowance and an early notice thereof is solicited.

Respectfully submitted,

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By:

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