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STANTON, B EXAMINER

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1904 20

DATE MAILED: 08/01/94

U.S. PATENT AND TRADEMARK OFFICE

This application has been examined Responsive to communication filed on 1/10/94 This action is made final.

A shortened statutory period for response to this action is set to expire 1 (THREE) month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- 1. Notice of References Cited by Examiner, PTO-892. 2. Notice re Patent Drawing, PTO-948. 3. Notice of Art Cited by Applicant, PTO-1449. 4. Notice of Informal Patent Application, Form PTO-152. 5. Information on How to Effect Drawing Changes, PTO-1474. 6.

Part II SUMMARY OF ACTION

- 1. Claims 61-63 are pending in the application. Of the above, claims are withdrawn from consideration. 2. Claims have been cancelled. 3. Claims are allowed. 4. Claims 61-63 are rejected. 5. Claims are objected to. 6. Claims are subject to restriction or election requirement. 7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. 9. The corrected or substitute drawings have been received on Under 37 C.F.R. 1.84 these drawings are acceptable. not acceptable (see explanation or Notice re Patent Drawing, PTO-948). 10. The proposed additional or substitute sheet(s) of drawings, filed on has (have) been approved by the examiner. disapproved by the examiner (see explanation). 11. The proposed drawing correction, filed on has been approved. disapproved (see explanation). 12. Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. ; filed on. 13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. 14. Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

A 42411

250-B

Serial No. 08/100,197 -2-
Art Unit 1804

This Application is a Continuation of Application No. 07/957,073, filed 10/6/92, now abandoned, which is a Continuation of Application No. 07/609,741, filed 11/6/90, now abandoned, which is a Divisional of Application No. 07/113,179, filed 10/23/87, now pending, which is a Continuation of Application No. 06/675,298, filed 11/30/84, now U.S. Patent No. 4,703,008, which was a Continuation-in-Part of Application No. 06/561,024, filed 12/13/83, now abandoned, and a Continuation-in-Part of Application No. 06/582,185, filed 2/21/84, now abandoned, and a Continuation-in-Part of Application No. 06/655,841, filed 9/28/84, now abandoned.

The amendment after final filed 1/10/94 (Paper No. 18) has been entered. Claims 61-63 remain pending in the instant Application.

Applicant is hereby informed that the FINALITY of the previous Office Action mailed 10/5/93 (Paper No. 16) is WITHDRAWN. Prosecution on the merits of the instantly claimed invention is herein reopened and the following new grounds of rejection are advanced.

Claims 62 and 63 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 62 is vague and indefinite because it is unclear what the claimed composition is required to be "effective" for.

Claim 63 is vague and indefinite because it is unclear as to how the recitation that the claimed erythropoietin is "recombinant" modifies the physical erythropoietin composition. It is noted that in the body of the paragraph bridging pages 18 and 19, the specification indicates that a "recombinant" erythropoietin molecule may be prepared in eukaryotic cells and be fully glycosylated. Therefore, while the claimed erythropoietin may be prepared using recombinant techniques, the product would not necessarily distinguish over that found in nature.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A 42412

250-C

Serial No. 08/100,197
Art Unit 1804

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It should be noted that the instant specification in general and claim 63 in particular is addressed towards the use of erythropoietin that is prepared using recombinant DNA technology. Within the paragraph bridging pages 18 and 19 of the specification, applicant states that:

The present invention provides...isolated polypeptide products having part or all of the primary structural conformation...and one or more of the biological properties (e.g. immunological properties and in vivo and in vitro biological activity) of naturally occurring erythropoietin...These polypeptides are also uniquely characterized by being the product of procaryotic or eucaryotic host expression...of exogenous DNA sequences obtained by genomic or cDNA cloning or by gene synthesis...Depending upon the host employed, polypeptides of the invention may be glycosylated with mammalian or other eucaryotic carbohydrates or may be non-glycosylated

From this quotation, it is apparent that the claimed erythropoietin (EPO) compositions read on any erythropoietin molecule regardless of its source. In particular, the specification indicates that glycosylated erythropoietin that exhibits the characteristic amino acid sequence and biological properties of naturally occurring erythropoietin is envisioned. Therefore, the EPO recited in the claims reads directly upon natural isolates and the basis of the instant rejection as explained above properly establishes that the claimed invention would have been *prima facie* obvious

This Application contains claims which conflict with the claims of U.S. Patent No. 4,806,524. Although the instant Application has an effective U.S. filing date earlier than that of the conflicting patent, the instant Application may not issue if it would result in two patents being directed toward the same patentable invention, (see MPEP 2308.03).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Stanton telephone number is (703) 308-2801.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Brian R. Stanton, Ph.D.
May 26, 1994

Elizabeth C. Weimar
ELIZABETH C. WEIMAR
SUPERVISORY PATENT EXAMINER
ART UNIT 184

A 42414

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