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MARTINELLI, J EXAMINER

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ART UNIT PAPER NUMBER

1805

38

DATE MAILED: 08/16/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 04/08/94 + 06/13/94 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 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 of Draftsman's Patent Drawing Review, PTO-948.
- 3. Notice of Art Cited by Applicant, PTO-1449.
- 4. Notice of Informal Patent Application, PTO-152.
- 5. Information on How to Effect Drawing Changes, PTO-1474.
- 6. Copy of p. 62
Methods in Yeast Genetics

Part II SUMMARY OF ACTION

- 1. Claims 87-97 are pending in the application.
Of the above, claims are withdrawn from consideration.
- 2. Claims 1-83 have been cancelled.
- 3. Claims are allowed.
- 4. Claims 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 of Draftsman's Patent Drawing Review, 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 has been approved; disapproved (see explanation).
- 12. Acknowledgement is made of the claim for priority under 35 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 Claims 84-86 (Filed 03/16/90) were not entered.

EXAMINER'S ACTION

Serial No. 08/202,874

Art Unit 1805

(In re Brown, 173 USPQ 685, CCPA 1972). Finally, the term "exogenous" in claim 84 means only that the gene has an origin outside of the host cell. It does not mean that the host cell has to be non-human in this claim. Thus, the claim reads on human EPO produced in human cells.

Claims 95-97 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Sugimoto et al. Sugimoto et al discloses pharmaceutical preparations of EPO for the administration of EPO to animals. These preparations are embraced by the claims. The discussion in the previous rejection is incorporated here.

Claims 89-94 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over either one of Espada et al (Fed. Proc. 41: 1159 (1982)) or Miyake et al (J. Biol. Chem. 252: 5558 (1977)). Each of the references discloses the purification of human EPO. Absent evidence to the contrary, the EPO of the references is the same or essentially the same as the EPO of the claims. It is not evident that the process of production defines the product. Since the PTO has no laboratories, the burden is on applicant to show a difference between a claimed product and a product of the prior art (see In re Brown, 173 USPQ 685, CCPA 1972).

Claim 95 is rejected under 35 U.S.C. § 103 as being unpatentable over either one of Sugimoto et al or Chiba et al as applied to claims 87-94 above, and further in view of applicant's admitted state of the prior art (page 87, line 29 through page 88, line 28). Applicant acknowledges pharmaceutically acceptable carriers, adjuvants, and diluents to be standard. It would be obvious for one of ordinary skill in the art to prepare a pharmaceutically acceptable composition containing the EPO of either one of the primary

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Serial No. 08/202,874

Art Unit 1805

teaches the administration of compositions containing EPO to animals including mammals. The reference further discloses higher hematocrits in animals receiving EPO. It would be obvious for one of ordinary skill in the art to administer the compositions of either one of Espada et al or Miyake et al to animals in the manner of Papayannopoulou et al in order to increase hematocrits in animals as disclosed by Papayannopoulou et al..

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1805.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 at (703) 305-3014. The faxing of such papers must conform with the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication should be directed to J. Martinell at telephone number (703) 308-0296.


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SENIOR LEVEL EXAMINER
GROUP 1800