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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/22/94 02/22/85

EXAMINER

MARTINELLI, J

ART UNIT PAPER NUMBER

43

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1804  
DATE MAILED:

05/17/95

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 02/22/85  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.

Part II SUMMARY OF ACTION

- 1.  Claims 87-90, 93-96, and 98 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
- 2.  Claims 1-86, 91, 92, and 97 have been cancelled.
- 3.  Claims \_\_\_\_\_ are allowed.
- 4.  Claims 87-90, 93-96, and 98 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

EXAMINER'S ACTION

PTO-326 (Rev. 2/83)

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The disclosure is objected to because of the following informalities.

- (a) In claim 96, "to mammal" should be changed to "to a mammal" (see Office action mailed August 16, 1994, page 2).
- (b) At page 9, line 20, "(Citations omitted)" is not understood (see Office action mailed August 16, 1994, page 2).
- (c) In the amendment filed February 22, 1995, in the description to Figure 5, "hov" should be changed to "shov".

Appropriate correction is required.

The amendment filed February 22, 1995 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows.

- (a) The description to Figure 6 is new matter because applicant does not point to basis in the specification as filed for the amendment.
- (b) The description to Figure 14 is new matter because applicant does not point to basis in the specification as filed for the amendment.
- (c) There is no basis in the specification as filed for "SpCEPO" in the description to Figure 17.

Applicant is required to cancel the new matter in the response to this Office action.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed. The recitation of "fragment thereof" in claim 89 is new matter. This objection and the following rejection are repeated for reasons already of record (e.g., Office action mailed August 16, 1994, page 3). Applicant's arguments (paper no. 42, page 8) are not convincing because pages 91-92 of the application discuss fragments of mature EPO, while Figure 6 (referred to in claim 89) discloses unprocessed EPO.

Claims 89, 93-95, and 98 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 87, 89, 90, 93-96, and 98 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.

- (a) The recitation of "having glycosylation which differs from that of human urinary erythropoietin" (claim 87) is vague and indefinite because there is no glycosylated standard for human urinary EPO. This rejection is repeated for reasons already of record (e.g., Office action mailed August 16, 1994, pages 4-5, item (b)). Applicant's arguments (paper no. 42, pages 8-9) and the copy of the statement by Dr. Cummings are not persuasive because neither

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points out how one of skill in the art would know whether a given sample of EPO had a glycosylation that differed from that of human urinary EPO in the absence of a standard.

- (b) The recitation of "fragment thereof" (claim 89) is vague and indefinite because no lower limit of fragment size is mentioned. This rejection is repeated for reasons already of record (e.g., Office action mailed August 16, 1994, page 5, item (c)). Applicant's argument (paper no. 42, page 9, item 4) is not convincing because applicant fails to address the issue of an absence to recite a lower limit for the fragment size.
- (c) Claim 90 is vague, indefinite, and incomplete because there is no antecedent basis for "the signal sequence of human erythropoietin set out in FIG 6". There is no signal sequence identified as such in FIG 6. Applicant's statement (paper no. 42, page 9, item 5) confirms the basis of the rejection. Accordingly, this rejection is repeated for reasons already of record (e.g., Office action mailed August 16, 1994, page 5, item (d)).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 87-90, 93, and 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 Sugimoto et al (U.S. 4,377,513) or Chiba et al. This rejection is repeated for reasons already of record (e.g., Office action mailed August 16, 1994, paragraph running from page 7 to page 9). Applicant's arguments (paper no. 42, pages 10-11) are not convincing because applicant merely

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asserts that neither reference discloses or enables the production of human EPD. No evidence of any difference between the products of the references and the products embraced by the claims is presented. This is not an invitation to present such evidence subsequent to a final Office action.

Claims 95, 96, and 98 are rejected under 35 U.S.C. § 103 as being unpatentable over Sugimoto et al. This rejection is repeated for reasons already of record (e.g., Office action mailed August 16, 1994, first full paragraph on page 9). Applicant's argument is not convincing for the reasons given in the preceding rejection. Applicant did not argue this rejection separately from the rejection over Sugimoto et al as outlined above.

Claims 89, 90, 93, and 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)). This rejection is repeated for reasons already of record (e.g., Office action mailed August 16, 1994, page 9, second full paragraph). Applicant's argument (paper no. 42, page 11) and the copy of the statement of Dr. Cummings are not convincing. Neither the argument nor the statement of Dr. Cummings identifies either of the references. This is not an invitation to submit further evidence subsequent to a final Office action.

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 87-90, 93, and 94 above, and further in view of applicant's admitted state of the prior art (page 87, line 29 through page 88, line 28). This rejection is repeated for reasons already of record (e.g., Office action mailed August 16, 1994, paragraph bridging pages 9-10). Applicant argues that the primary reference

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fails. The discussion in connection with Sugimoto et al and Chiba et al hereinabove is incorporated here.

Claim 95 is rejected under 35 U.S.C. § 103 as being unpatentable over either one of Espada et al (Fed. proc. 41: 1159 (1982)) or Miyake et al (J. Biol. Chem. 252: 5558 (1977)) as applied to claims 89, 90, 93, and 94 above, and further in view of applicant's admitted state of the prior art (page 87, line 29 through page 88, line 28). This rejection is repeated for reasons already of record (e.g., Office action mailed August 16, 1994, first full paragraph on page 10). Applicant argues that the primary reference fails. The discussion in connection with Espada et al and Miyake et al hereinabove is incorporated here.

Claims 96 and 98 are 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 87-90, 93, and 94 above, and further in view of Papayannopoulou et al. This rejection is repeated for reasons already of record (e.g., Office action mailed August 16, 1994, second full paragraph on page 10). Applicant argues that the primary reference fails. The discussion in connection with Sugimoto et al and Chiba et al hereinabove is incorporated here.

Claims 96 and 98 are rejected under 35 U.S.C. § 103 as being unpatentable over either one of Espada et al (Fed. proc. 41: 1159 (1982)) or Miyake et al (J. Biol. Chem. 252: 5558 (1977)) as applied to claims 89, 90, 93, and 94 above, and further in view of Papayannopoulou et al. This rejection is repeated for reasons already of record (e.g., Office action mailed August 16, 1994, paragraph bridging pages 10-11). Applicant argues

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that the primary reference fails. The discussion in connection with Espada et al and Miyake et al hereinabove is incorporated here.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Art Unit 1804 at (703) 308-4312. 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.

  
JAMES MARTINELL, PH.D.  
SENIOR LEVEL EXAMINER  
GROUP 1800

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