

EXHIBIT M-3

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MARSHALL O'TOOLE

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/113,178	10/23/87	LIN	F D-3278

MICHAEL F. BORUN, ESQ.
MARSHALL, O'TOOLE, GERSTEIN, MURRAY &
BECKNELL
TWO FIRST NATIONAL PLAZA
CHICAGO, IL 60603

EXAMINER	
KUSHAN, J	
ART UNIT	PAPER NUMBER
186	16

DATE MAILED: 09/18/89 *rechecked*

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 _____ 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 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 67-75 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- 2. Claims 1-66 have been cancelled.
- 3. Claims _____ are allowed.
- 4. Claims 67-75 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 which are acceptable for examination purposes until such time as allowable subject matter is indicated.
- 8. Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
- 9. The corrected or substitute drawings have been received on _____. These drawings are acceptable; not acceptable (see explanation).
- 10. The proposed drawing correction and/or 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). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
- 12. Acknowledgment 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

AM 27 033478

Rev. 7-82)

EXAMINER'S ACTION

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

16. Claims 67 to 75 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable
5 over claims 1 to 11 of U.S. patent no. 4,667,016.

As set forth in the last office action, the recombinantly produced erythropoietin as instantly claimed, would have been a prima facie obvious modification of the claimed process of producing recombinant EPO recited in previously patented claims of Lai et al.
10 Of particular relevance here is the fact that the identical cell lines used in the instant disclosure by applicant were used by Lai et al to produce the impure recombinant EPO, which was then processed according to the process of purification recited in the claims. It is not likely that use of identical mammalian COS or CHO
15 cell lines to produce a recombinant species of EPO will give rise to a species of recombinant EPO that differs in a material fashion from the instantly claimed EPO product of applicant. Furthermore, this rejection is not simply a rejection of the EPO as being recombinantly produced, and therefore being equivalent to the unique
20 recombinant product as claimed instantly. Rather the rejection is based upon the fact that identical source material of the recombinant species of EPO purified by the procedure of Lai et al will be indistinguishable from the instantly claimed product.

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This is not an identical patenting situation. The claims of the Lai et al patent are clearly directed to a process of producing the species of EPO instantly claimed. Thus, no rejection over 35 USC 101, for identical type double patenting has been made.

5 16. The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A
10 timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

17. Claims 67 to 75 are rejected under 35 U.S.C. 112, first and
15 second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 As pointed out in the discussions between applicant's representative Mr. Odre on 6/22/89, the claims as set forth continue to be deficient under 35 USC 101. Applicant must recite that the measure of EPO activity is based upon the ability of the recombinant

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EPO to cause human bone marrow cells to increase production of reticulocytes and red blood cells. This is an essential and critical feature of applicant's invention, and is not presented in the claims. Failure to recite accurately the means of discerning the invention which is disclosed and claimed renders said claims deficient for failing to particularly point out and define that which applicant considers his invention.

Applicant's representative acknowledged that this modification of the claim would be appropriate and forthcoming. No response has been received as of the date of this action, however.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

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 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY

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ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE
LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

19. Applicant's arguments regarding points 1,2, and 4 of the
rejection over 35 USC 112 presented in the last office action are
5 persuasive, in view of the amendments to the claim 67.

19. The amendment to claims 67 also obviates the basis for the
rejection over the prior art of Sugimoto et al. The claims, now are
limited to species of recombinant EPO produced by non-human host
cells and this obviates the basis for rejection as set forth in the
10 last office action.

20. Any consideration of applicant's concern over the joining of
this application to the interferences declared would be premature.
This consideration and a determination therefrom will be appropriate
when this application is in condition for allowance.

15 21. Any inquiry concerning this communication or earlier
communications from the examiner should be directed to Examiner
Kushan whose telephone number is (703) 557-7627. 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
20 (703) 557-0664.

jpk

September 14, 1989.

MM
MARGARET MOSKOWITZ
SUPERVISORY
PATENT EXAMINER
ART UNIT 186

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