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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/113,179 10/23/87 LIN

F D-8272

EXAMINER HODGES, R

18N2/0811

MARSHALL, O'TOOLE, GERSTEIN, MURRAY AND BORUN 6300 SEARS TOWER 233 SOUTH WACKER DRIVE CHICAGO, IL 60606-6402

ART UNIT PAPER NUMBER

1805

41

DATE MAILED: 08/11/94

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

COPY

[X] 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 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. [X] Interview summary Form PTO-413.

Part II SUMMARY OF ACTION

- 1. [X] Claims 70, 72-75 are pending in the application. Of the above, claims are withdrawn from consideration.
- 2. [] Claims have been cancelled.
- 3. [] Claims are allowed.
- 4. [X] Claims 70, 72-75 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 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.

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At the request of the Director of Group 1800 (see Paper No. 40), this application has been withdrawn from issue and prosecution is hereby reopened.

Claims 70 and 72-75 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 4,703,008 in view of
5 Yokota et al. (U.S. Patent No. 4,695,542). Yokota et al. teach methods of producing a glycosylated protein (GM-CSF) using DNA encoding a mammalian GM-CSF. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to modify the method of Yokota et al. by substituting the instant erythropoietin encoding DNA for the DNA encoding GM-CSF. To
10 do so would be using a known method for its known and expected purpose.

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 timely filed terminal disclaimer in compliance with 37
15 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).

Claims 70 and 72-75 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
20 applicant regards as the invention.

Claim 70 is vague and indefinite in the recitation "an *in vivo* biologically active erythropoietin polypeptide." Applicant has failed to set forth the metes and bounds of the instantly claimed invention because it is not clear what activity or activities the erythropoietin polypeptide is intended to possess. The specification discloses an assay for measuring an *in vivo*

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activity of erythropoietin polypeptides made using the instant method (page 58, example 9).
However, the specification also refers to numerous other types of *in vivo* biological activities contemplated for the erythropoietin polypeptides made with the instantly claimed method (page 86, lines 21-32). It is not clear which of these activities applicant intends the claimed
5 polypeptides to possess. Accordingly, the metes and bounds of the claimed invention are indefinite. It is suggested that applicant may intend to claim a process for the preparation of an erythropoietin polypeptide having the *in vivo* biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells.

Certain papers related to this application may be submitted to Group 1800 by facsimile
10 transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall I (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (October 19, 1988) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Hodges whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays.

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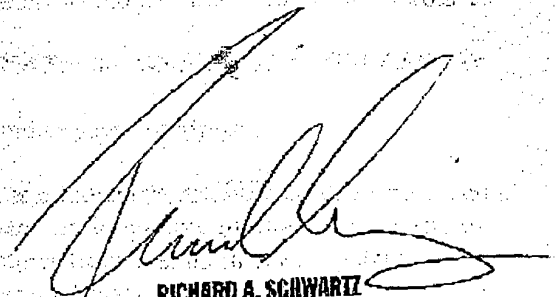
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard A. Schwartz, can be reached at (703) 308-1133. The fax phone number for this Group is (703) 305-3014.

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.

10.

Robert Hodges
August 10, 1994



RICHARD A. SCHWARTZ
SUPERVISORY PATENT EXAMINER
ART UNIT 185

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