

EXHIBIT M-5

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SERIAL NUMBER <u>76</u>	FILED DATE <u>10/23/87</u>	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

MARSHALL O'TOOLE

07/113,178 10/23/87 LHM

18N2/1229

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EXAMINER

ART UNIT

PAPER NUMBER

34

DATE MAILED:

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

Docketed: 2-25-94

☐ This application has been examined ☒ Responsive to communication filed on 11 Jan. 1990 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 2 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. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input checked="" type="checkbox"/> <u>INTERVIEW SUMMARY</u> |

Part II SUMMARY OF ACTION

1. ☒ Claims 76-83 are pending in the application.
 Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☒ Claims 76-83 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

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1. Interference No. 102,334 has been terminated by a decision favorable to Applicant. Ex parte prosecution is resumed.

At the suspension of prosecution (Paper No. 21), claims 76-83, the only claims then pending in the case, stood finally rejected under the doctrine of obviousness-type double patenting as not patentably distinct from claims 1-11 of Lai *et al.* (U.S. 4,667,016). There were no other rejections outstanding, and these were the only claims treated by the Board in the interference.

Claims 84-86 were presented during the course of the interference proceedings. Because they were presented after the final rejection and raise new issues which would require further consideration and/or search, they have not been entered.

2. After further consideration, Applicant's arguments presented in the § 116 amendment filed 11 January 1990 (Paper No. 19) are persuasive, and the obviousness-type double patenting rejection of claims 76-83 over Lai *et al.* is withdrawn.

The present claims delimit an inventive concept which is wholly separate from that of the Lai patent. Even though the methods of Lai can be used to purify the claimed rEPO, the instant specification provides alternative methods of purifying the protein; yet others are known to those of skill in the art. Because the present invention does not require the methods of Lai, it is not believed that the grant of patent for the claimed invention will have the effect of prolonging the term of exclusivity for the method claims of the prior patent.

3. A protest against issuance of a patent upon this application has been filed under 37 C.F.R. § 1.291(a) on 23 July 1993, and a copy has been served on Applicant. Any comments which Applicant desires to file must be submitted within the period for response to this Office action and should be clearly labeled "Comments on § 1.291(a) Protest".

Protestor seeks to establish that he made a contribution to the claimed invention sufficient to merit his proper consideration as a coinventor. It is the Examiner's opinion that the evidence presented in the Protest fails to set forth a *prima facie* case that Applicant Lin is not the sole inventor of the claimed invention.

There are principally two aspects of Protestor's argument: first, that he contributed scientific expertise critical to the realization of the claimed rEPO; and second, that Applicant's level of responsibility for directing Amgen's EPO project has been overstated in related trial proceedings.

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To the first point, the evidence does clearly establish that Protestor was an active participant in the sequencing of uEPO tryptic fragments. What is not clear, however, is whether such participation reflects inventive initiative or whether Protestor's actions were undertaken at Applicant's direction. That Protestor performed the actual manipulations involved in protein sequencing or that he was designated to receive material directly from Dr. Goldwasser's laboratory, for example, neither establishes the former nor contradicts the latter.

At the paragraph bridging pages 1-2 of the Protest, Protestor enumerates five specific contributions to the project which he alleges to define his inventive participation. The evidence presented is insufficient to make the case either that the techniques which Protestor alleges to have pioneered are, in fact, novel and unobvious, or that the selection of particular fragments for sequencing and probe design reflects the exercise of Protestor's critical assessment of the data in a novel and unobvious manner. The evidence cited by Protestor is not inconsistent with his alleged inventive contribution; however, the preponderance of the evidence of record suggests that Applicant is properly the sole inventor of the instant invention.

The second point, that Applicant did not have overall responsibility within Amgen for the EPO project, is not germane to the issue under consideration. Scientific insight and creativity, which are in this instance critical to the inventive process, need not correlate with any inclination or talent for managerial functions. That Amgen may have chosen someone other than Applicant to bear responsibility to the Corporation for the EPO project provides no evidence whatsoever which is relevant to the issue of inventive contribution.

The Amgen annual report which Protestor cites merits some comment. While it is granted that the report does assert that innovative protein microsequencing techniques enabled Amgen to obtain the EPO cDNA, suffice it to say that its representations are not made as part of an oath or declaration, make no reference to Protestor, and are directed to securing the trust of investors rather than to analyzing compliance with 35 U.S.C. § 116. The Examiner has accorded the Amgen publication little probative value relative to Protestor's allegations.

It appears that all of the laboratory notebooks and testimony upon which Protestor relies were available to the District Court and C.A.F.C. (*Amgen v. Chugai*, 18 USPQ2d 1016), which particularly considered whether Applicant Lin was in fact the sole inventor of the isolated EPO cDNA. The definition of inventive contribution for the instantly claimed rEPO protein turns on

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the same issues which were considered by the C.A.F.C. in that case. Protestor has presented no consequential factual evidence which was not available to the Court; the Protest thus fails to clearly and convincingly establish that the Court erred in concluding that Applicant was the sole inventor of an isolated EPO-encoding DNA, and hence of the instantly claimed rEPO. The Examiner therefore relies upon and endorses the Court's conclusions, the present Protest notwithstanding.

4. Claims 76-83 are allowed.

5. This application is in condition for allowance except for the following formal matters.


10 The specification is objected to because of the following informality: the Brief Description of the Drawings must make express reference to each of the Drawings present in the case. Each of the panels of a multi-panel figure (1a, 1b, etc.) must be mentioned. Correction is required. *Failure to insure that the drawings and specification correspond may precipitate a significant delay in issuing a patent.*

15 Note also that formal drawings are required at this time. Applicant's attention is directed to the form PTO-948 annexed to this letter.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

20 A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS ACTION IS SET TO EXPIRE TWO MONTHS FROM THE DATE OF THIS LETTER.

6. Any inquiry concerning this communication or previous communications from the Examiner should be directed to David Fitzgerald (Group Art Unit 1812) at telephone number (703) 308-3934, fax numbers (703) 305-3014 or 308-4227, or through the Group 1800 receptionist at (703) 308-0196. Note also that papers of record may be submitted to Group 1800 by fax at the numbers above; refer to 1096 OG 30.

30 
David L. Fitzgerald
Examiner
24 November 1993


ROBERT J. HILL, JR.
SUPERVISORY PATENT EXAMINER
GROUP 1800