



**UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
077113,178	10/23/87	LIN	F D-8273

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EXAMINER	
KUSHAN, J	
ART UNIT	PAPER NUMBER
186	13

DATE MAILED:

06/20/89

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

Amgen Inc. v. F. Hoffmann-LaRoche LTD et al

Doc. 623 Att. 3

This application has been examined Responsive to communication filed on 6/5/89 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. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474 | 6. <input type="checkbox"/> _____ |

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Of the above, claims _____ are withdrawn from consideration.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

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shown to be commonly owned with this application. See 37 CFR 1.78(d).

17. Claims 67 to 75 are rejected under 35 U.S.C. 112, first and 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.

The claims as presented remain deficient under 35 USC 112 first and second paragraphs. The following modifications are suggested to overcome this rejection.

1. In claim 67, line 3, the phrase "a primary structural conformation" should be changed to "a primary structure and conformation...". This modification makes it clear that the recombinant protein possess the primary structure (e.g. the amino acid sequence of naturally occurring human EPO) and the tertiary or spatial conformation of human EPO to the extent that the recombinant EPO retains the biological activity of the human EPO in vivo.

2. The claim must be limited to recombinant human erythropoietin. As presented, a non human analog which possesses enough similarity to native human erythropoietin is encompassed by the claims. This breadth is not supported by the disclosure. Applicant may recite that the exogenous DNA sequence codes for human erythropoietin.

3. At lines 5 to 7 of claim 67, applicant presents a general description of the biological activity of the recombinantly

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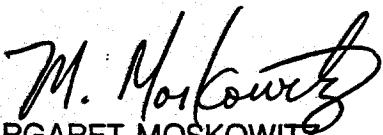
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Kushan whose telephone number is (703) 557-7627. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 557-0664.

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jpk

June 14, 1989.


MARGARET MOSKOWITZ
SUPERVISORY
PATENT EXAMINER
ART UNIT 186