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SERIAL NUMBER 6-113-178	FILING DATE 10-23-87	110 FIRST NAMED APPLICANT	ATTORNEY'S DOCKET NO.
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RUSH-EXAMINER	
ART UNIT 33 PAPER NUMBER	
DATE MAILED: 06.02.88	

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

Doc. 623-Att. 5

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.

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

THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" 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"/> _____ |

SUMMARY OF ACTION

- ☐ Claims 1-13, 16, 39-41, 47-49, 55-57 are pending in the application.
- Of the above, claims _____ are withdrawn from consideration.
- ☐ Claims 14-15, 17, 38, 42-6, 50-9, 58-60 have been cancelled.
- ☐ Claims _____ are allowed.
- ☒ Claims 1-13, 16, 39-41, 47-49, and 55-57 are rejected.
- ☐ Claims _____ are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.
- ☒ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
- ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
- ☐ 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).
- ☐ 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.
- ☐ 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 _____
- ☐ 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.
- ☐ Other

Serial No. 113178

-3-

Art Unit 183

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, 9-13, 16, 40-41 and 47-49 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12 and 25-26 of copending application Serial No. 113178.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-13, 16, 39-41, 47-49 and 55-57 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 use of alternate terms in the claim language renders the cited claims indefinite, and presents questions of enablement and scope. With respect to the actual physical properties, such as amino acid sequence and degree and locations of glycosylation, the actual physical characteristic in question should be presented. The terms "part or all of," "sufficiently duplicative

Serial No. 113178

-4-

Art Unit 183

of," and "average carbohydrate composition which differs from," do not particularly nor adequately point out the distinctions from native erythropoietin (EPO). The actual physical properties which clearly define the protein claimed should be used in the claim language. For example, the "parts" of EPO which are contemplated and supported by the disclosure (in terms of amino acid sequence) and the sites and extent of glycosylation and how they "differ" from native EPO should be pointed out. Note that the glycosylation of EPO is an important aspect of its activity and not every form of EPO is biologically equivalent. With respect to the term having "one or more of the biological properties of naturally occurring" EPO, applicant must point out which biological properties are contemplated. As currently set forth, any protein or peptide showing any biological property of EPO (e.g. "self" recognition of the protein by host) is encompassed. Applicant cannot support this assertion with the current disclosure.

Claims directed toward methods of therapy using the recombinant protein are not enabled. No in vivo results supporting these claims is presented which show the recombinant variant working in an identical manner as the native protein. The slight difference in glycosylation presented in the specification is not sufficiently

Serial No. 113178

-5-

Art Unit 183

discussed with respect to its effect on the in vivo activity of rEPO. For example, does the glycosylation render the human protein antigenic in humans? In vitro assays do not provide clearly relevant support without some type of convincing display to correlate the two. The particular mode of treatment which is contemplated should be set forth. Simply stating administration is not sufficient.

The claims must particularly point out the essential aspects of the disclosed invention. The broadest limitations must also be supported by the disclosure. As currently set forth, the claims are indefinite and to an extent, non-enabled. The particular biological activities and physical properties which can be used to define the rEPO should be reflected in the claim language to adequately define the invention. The particulars concerning the actual method(s) of treatment and support for the claimed effectiveness of said treatment(s) must be shown.

Claims to "synthetic polypeptides" are not enabled by this disclosure. "Synthetic," as opposed to "recombinant," is an art recognized term which indicates a chemically derived rather than genetically engineered protein. No support for chemical synthesis of EPO or EPO fragments is shown by this disclosure. These claims

Serial No. 113178

-10-

Art Unit 183

effects of EPO administration have been shown and explained. Note also that the primary references suggest use of EPO in therapy (Takezawa et al "Background" section).

The claimed method is also considered to be obvious because the recombinant and native derived EPO are biologically equivalent. In other words, both forms show the same in vitro and in vivo activities as asserted by applicant. Use of an agent from a different source which behaves in a manner identical to its known analog would suggest to one skilled in the art that similar results could be obtained using the biologically equivalent analog. The expected result would make obvious the use of the new analog as its activity and effects would be expected (note in re Durden, 226 USPQ 359). In the instant case, use of recombinant EPO, which has been asserted to show the same biological activity as native EPO, in the treatment of an animal to achieve the same known effect of EPO in said animal would be obvious to one skilled in the art.

The art not used above made of record indicates and expands on the nature and utility of EPO.

Any inquiry concerning this communication should be directed to Jeff Kushan at telephone number 703-557-0664.

Kushan:meb
5/18/88:Retype 5/23/88

HOWARD E. SCHAIN
PATENT EXAMINER
GROUP 180 - ART UNIT 183

Howard E. Schain