Office Actions and Responses (including Declarations) in App. No. 08/330,194

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EXAMINER
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DATE MAILED: 01/30/95

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 01-03-95 ☐ 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. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-28 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-28 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 apppears 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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EXAMINER'S ACTION

Claims 1-28 are pending in this application and considered below.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the invention and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

This objection is based upon inadequate disclosure, regarding the use of the applicants' active agent, astaxanthin, for the treatment of injury to the brain and/or spinal cord (such as stroke, traumatic spinal cord injury and degenerative disease(s) of the central nervous system, as well as the amelioration of neuronal damage.

Note that the prior art recited on pages 10-12 is directed to eye diseases and injuries, per se (note page 10, lines 10-12 of the present specification, with regard to the disclosed and claimed method of treatment).

Further, the recitation of such terminology is not necessarily a basis for claiming same. The specification, therefore, fails to enable administration of astaxanthin for

response being elicited and shown to be due to the effects of astaxanthin, per se. The body of art which is additionally cited, on pages 10-11 of the specification, fails to suggest same. Although the applicants assert that such treatment or amelioration is possible because --- The eye is an extension of the brain, and therefore a part of the central nervous system --- (page 1 of the present specification), contemporary knowledge in this art area cautions against extrapolating to conclusions regarding efficacy or eradication in the CNS based upon therapeutic ophthalmic success, absent a clear and probative correlation between same.

Claims 14-16, 22-26 and 28 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 14-16, 22-26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to methods taught by the present specification. See M.P.E.P. 706.03(n) and 706.03(z).

This rejection is based upon the lack of disclosure regarding the use of astaxanthin to treat any and all injuries to the brain (e.g. stroke, etc.), any and all injuries to the spinal cord or any and all degenerative disease(s) of the CNS, without limitation and all neuronal damage, without limitation.

The applicants must show support for the breadth of the above-stated methods, in that such is presented in the claims without any readily appreciable manner of limitation.

Claims 1-28 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 applicant regards as the invention.

The claims which incorporate the terminology, --- therapeutically-effective amount ---, with regard to the administration of astaxanthin (in which the active ingredient employed for the purposes of treating ameliorating or beneficiating damage or injury to the eye, brain or spinal cord, including stroke, traumatic injury and/or degenerative disease(s) are indefinite since 1) the claims fail to set forth aliment related dosage reference points and 2) the specification fails to set forth any information as to how dosages may differ in obtaining either of the aforestated effects. See **Ex parte Balzarini**, 21 USPQ 2d 1893.

The terminology, --- beneficiating ---, renders the claims which incorporate same indefinite in that such language fails to place any clear limitation upon the intended effect or result of the claimed method, based upon astaxanthin administration. For example, how is the vision of an individual "beneficiated" by said administration? Appropriate clarification is advised.

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