Commissioner=s Decision #1288

Décision de la Commissaire #1288

TOPICS: F01, B22, B00

SUJETS: F01, B22, B00

Application No : 2,422,871

Demande no : 2,422,871

COMMISSIONER'S DECISION SUMMARY

C.D. 1288 App'n No. 2,422,871

The application relates generally to stable pharmaceutical formulations in dry dosage forms comprising amino acids (e.g. gabapentin) and methods of making the same. In particular the application relates to formulations comprising amino acids and methods of forming the same wherein the formation of undesirable lactam impurities is inhibited.

Of the 57 claims pending at the time of the Final Action, the Examiner rejected claims 1-17, 20, 22-39, 42, and 44-57 for reasons including novelty, lack of support, indefiniteness, and improper claiming in dependent form. After the applicant=s response to the Final Action, which included 54 claims, the Examiner, in a Summary of Reasons, maintained objections to claims 1-16, 21-37, and 42-54 based on lack of novelty and indefiniteness. In an attempted voluntary amendment after the deadline to respond to the Final Action, but before they were aware of the contents of the Summary of Reasons, the Applicant sought to comply with the objections made by the Examiner by deleting and/or amending the offending claims, but due to the constraints of s. 31 of the *Patent Rules*, was prevented from doing so. In recognition of the Applicant=s attempt to comply, the Board recommeded that the Applicant be invited to delete claims 1-16, 21-37, and 42-54 in accordance with ss. 31(c) of the *Patent Rules.*

The Commissioner agreed with the Board=s recommendations and the Applicant was invited to delete claims 1-16, 21-37, and 42-54, failing which further review of the application would take place in due course.

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,422,871 having been rejected under Subsection 30(4) of the Patent Rules, the application has been reviewed. The rejection has been considered by the Patent Appeal Board and by the Commissioner of Patents. The findings of the Board and the decision of the Commissioner are as follows:

Agent for the Applicant

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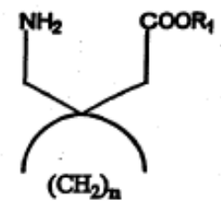



I

**INTRODUCTION**

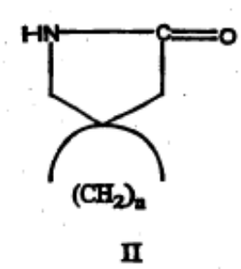
[1] This decision deals with a review by the Commissioner of Patents of the Examiner=s Final Action on patent application no. 2,422,871 entitled ASTABLE SOLID DOSAGE FORMS OF AMINO ACIDS AND PROCESSES FOR PRODUCING SAME@. The Applicant is SIGMAPHARM, INC. The inventor is Spiridon Spireas.

[2] The application relates generally to stable pharmaceutical formulations in dry dosage forms comprising amino acids (e.g. gabapentin) and methods of making the same. In particular the application relates to formulations comprising amino acids and methods of forming the same wherein the formation of undesirable lactam impurities is inhibited.

[3] As disclosed by the Applicant, cyclic amino acids of general Formula I:

wherein $R_1$ is H or a lower alkyl radical and n is 4, 5, or 6, are known to be useful in the treatment of certain cerebral and neurodegenerative diseases. One such cyclic amino acid,

gabapentin, has been shown to be useful as an anticonvulsant agent. A problem with the use of such cyclic amino acids is that they can easily degrade during storage. As Applicant has pointed out the degradation is believed to be due, at least in part, to conversion of the cyclic amino acid to its lactam of Formula II:




II

Applicant=s disclosed process produces formulations wherein the formation of such lactams is inhibited.

**BACKGROUND**

[4] This application originated as a PCT application and accordingly maintains its international filing date of September 26, 2001. It is based on two US priority applications, 60/235,349 (September 26, 2000) and 09/928,467 (August 13, 2001). It is also noted that the present application is under Special Order. It was rejected on July 19, 2007 in a Final Action in which the Examiner found claims 1-17, 22-39, and 44-57 to lack novelty and to contain formality issues, claims 20 and 42 to be unpatentable due to formality issues, and claims 18-19, 21, 40-41, and 43 (directed to methods of preparation of the pharmaceutical formulations) to be allowable. The specific issue with respect to claims 20 and 42 was that there was no factual support in the description for the stabilizer to be used in the formulation being a Aliquid surface active agent@ or an Aaldehyde@, therefore contravening section 84 of the *Patent Rules*.

[5] In response to the Final Action the Applicant cancelled claims 16, 38, and 45 and amended claim 27, leaving 54 claims pending. The Applicant presented arguments in favor of the novelty of the claims and to counter the Examiner=s objections as to lack of support and indefiniteness.

[6] In a Summary of Reasons submitted to the Patent Appeal Board by the Examiner the objections as to lack of novelty and indefiniteness were maintained against the remaining 54 claims, however the objection as to lack of support was dropped. As a result of this concession by the Examiner, it was indicated in the Summary of Reasons that claims 17-20 and 38-41 were in allowable form and that the impasse could be resolved by removal of

claims 1-16, 21-37, and 42-54.

[7] Before the Board could offer the Applicant an opportunity for an oral hearing and before the Applicant was provided with a copy of the Summary of Reasons, the Applicant submitted a letter on May 15, 2008 in which a AVOLUNTARY AMENDMENT@ was made in order to cancel claims 1-16, 21-37, and 42-54 and amend other claims to place the application in condition for allowance. The presently proposed claims correspond to claims 17-20 and 38-41 indicated as being allowable by the Examiner in the Summary of Reasons, with minor amendments having been effected to claims 19 and 40 (corresponding to former claims 20 and 42 at the time of the Final Action), as previously required by the Examiner. The Applicant has since been provided with a copy of the Examiner=s Summary of Reasons.

[8] It is noted that the abovementioned voluntary amendment was submitted more than six months after the date of the Final Action. Unfortunately, after the expiration of the time for reply to the Final Action, no amendments may be made to an application except under the specific circumstances outlined in section 31 of the *Patent Rules*. Section 31 of the *Patent Rules* states:

> 31. An application that has been rejected by an examiner shall not be amended after the expiry of the time for responding to the examiner=s requisition, made pursuant to subsection 30(4), except,
> (a) where the rejection is withdrawn in accordance with subsection 30(5);
> (b) where the Commissioner is satisfied after review that the rejection is not justified and the applicant has been so informed;
> (c) where the Commissioner has informed the applicant that the amendment is necessary for compliance with the Act and these Rules; or
> (d) by order of the Federal Court or the Supreme Court of Canada.

[9] Paragraph (a) would not apply since the rejection has not been withdrawn by the Examiner, paragraph (b) would not apply because the Applicant, in the letter of May 15, 2008, acquiesced to the objections of the Examiner, and obviously paragraph (d) is not at issue. Therefore the only option is for the Commissioner, under s. 31(c) to inform the Applicant that amendments are required for compliance with the *Patent Act* and *Rules*.

**DISPOSITION OF THE PRESENT CASE**

[10] It is clear from the Summary of Reasons that amendments to the claims to satisfy section 84 of the *Patent Rules* are no longer necessary. After reviewing the amendments recently proposed by the Applicant, it is clear that by their attempted amendments, all of the objections in the Final Action would have been overcome if the amendments had been

submitted within the time to respond to the Final Action. Further, since the Applicant could not technically make such amendments at that point, the Board sees no reason to bind the Applicant to the changes which were proposed in the letter of May 15, 2008, some of which are, as previously noted, no longer necessary.

**RECOMMENDATIONS**

[11] Accordingly, the Board recommends that the Commissioner:

(1) inform the Applicant, in accordance with paragraph 31(c) of the *Patent Rules*, that the following amendments to the application would overcome the Examiner=s objections and would therefore appear necessary for compliance with the *Patent Act* and *Rules*:

- deletion of currently pending claims 1-16, 21-37, and 42-54, and
- adjustment of claim numbering and dependencies accordingly;

(2) invite the applicant to make the above amendments within three months from the date of the Commissioner=s decision; and

(3) advise the Applicant i) that, if the above amendments and only the above amendments are made within the specified time, the examiner=s rejection will be considered to have been overcome, and ii) that, if the above amendments and only the above amendments are not made within the specified time, further review of the examiner=s rejection will take place in due course.

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| Agnès Lajoie | Ed MacLaurin | Stephen MacNeil |
| Chairperson | Member | Member |

[12] I concur with the findings and recommendations of the Patent Appeal Board. Accordingly,

I invite the Applicant to make the above amendments, and only the above amendments, within three months from the date of this decision, and advise the Applicant i) that, if the above amendments and only the above amendments are made within the specified time, the examiner=s rejection will be considered to have been overcome, and ii) that, if the above amendments and only the above amendments are not made within the specified time, further review of the examiner=s rejection will take place in due course.

Mary Carman
Commissioner of Patents

Dated at Gatineau, Quebec,
this 28 day of November, 2008