Commissioner=s Decision # 1300
Décision du Commissaire # 1300

TOPIC: F00, B22, O00
SUJET: F00, B22, O00

Application No. : 2,137,815
Demande n^{o}. : 2,137,815

COMMISSIONER'S DECISION SUMMARY

C.D. 1300 Application No. 2,137,815

The subject application relates to intron-containing DNA molecules that encode a human lipase enzyme, termed Bile Salt-Stimulated Lipase (BSSL) or Carboxyl Ester Lipase (CEL), which can advantageously be used in the production of recombinant human BSSL/CEL, in the manufacture of infant formulas or in the manufacture of medicaments for treating pathologies stemming from lipase deficiencies.

In the Final Action the Examiner rejected various claims for lack of novelty, obviousness, lack of support, and lack of clarity. After the Applicant=s response to the Final Action, the Examiner provided a Summary of Reasons for consideration by the Board and the Applicant. The Summary of Reasons indicated that certain claims were still considered to lack novelty. After receiving the Summary of Reasons from the Board, the Applicant (wishing to move the application to allowance) voluntarily sought to remedy the outstanding issue set forth in the Summary of Reasons by proposing the deletion and/or amendment of the offending claims, but, due to the constraints of s. 31 of the *Patent Rules* and the nature of the Final Action review process, was prevented from doing so. The Applicant=s proposed amendments were considered by the Board to be reasonable and, in a Supplementary Summary of Reasons provided to the Board, the Examiner likewise agreed but indicated that another claim was problematic, but for a different reason. Upon being informed by the Board of the conclusions in the Supplementary Summary of Reasons the Applicant proposed that the other problematic claim also be deleted. Recognizing that the proposed amendments would address the outstanding issues, the Board recommended that the Applicant be invited to make the proposed amendments in accordance with ss. 31(c) of the *Patent Rules*.

The Commissioner agreed with the Board=s recommendations and the Applicant was invited to make the proposed amendments, 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 2,137,815 having been rejected under Subsection 30(4) of the *Patent Rules*, the application has been referred to the Patent Appeal Board. The rejection has consequently been considered by the Patent Appeal Board and the Commissioner of Patents.

Agent for the Applicant:

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INTRODUCTION

[1] This decision deals with a review of the Examiner=s Final Action, as well as a review of post-Final Action proposals volunteered by the Applicant, in respect of patent application 2,137,815.

[2] The current application owner is Arexis AB and the inventors are Karl G. Bjursell, Peter N. Carlsson, Curt S. Enerbäck, Stig L. Hansson, Ulf F. Lidberg, Jeanette A. Nilsson and Jan B. F. Törnell.The invention is entitled ADNA SEQUENCES USED IN THE PRODUCTION OF RECOMBINANT HUMAN BSSL/CEL IN TRANSGENIC NON-HUMAN MAMMALS, AND THE PRODUCED BSSL/CEL USED IN INFANT FORMULAS.@

BACKGROUND

[3] The subject application relates to intron-containing DNA molecules that encode a human lipase enzyme, termed Bile Salt-Stimulated Lipase (BSSL) or Carboxyl Ester Lipase (CEL), which can advantageously be used in the production of recombinant human BSSL/CEL in transgenic non-human mammals; the inclusion of the intron sequences, as similarly found in naturally occurring human genomic DNA molecules, seemingly allowing for improved or better regulated gene expression when incorporated into mammalian cells. The disclosed BSSL/CEL products are also said to be useful in the manufacture of infant formulas or in the manufacture of medicaments for treating pathologies stemming from lipase deficiencies.

PROSECUTION HISTORY

[4] The subject application was filed on June 9, 1993 and the Examiner in charge of the application issued a Final Action on December 21, 2007 at which time most of the 40 claims then pending in the application were rejected. Claims 22-24 and 35-40 were rejected for lack of novelty under subsection 28.2(1)(b) of the *Patent Act*; claims 1-3, 5, 6, 8-21 and 25-34 were rejected for obviousness under section 28.3 of the *Patent Act*; and claims 1-3, 5, 6 and claims 8-40 were rejected under subsection 138(2) of the *Patent Rules* for lack of support. Other claims were said to lack clarity due to improper claim dependency or wording.

[5] On May 27, 2008 the Applicant replied to the Final Action and submitted a new claim-set of 41 claims in which former claims 22-24, 27, 28 and 35-40 had been deleted and additional claims had been inserted. The Applicant indicated that the amendments overcame the objections raised in the Final Action and that the application was therefore in condition for allowance.

[6] The Examiner reviewed the response to the Final Action and indicated in a Summary of Reasons that the obviousness, support and clarity issues had been overcome. However, the Examiner noted that the claim dependencies had been changed in the new claim-set, an observation that led her to conclude that the prior art was still applicable and that claims 2, 3, 5, 6 and 8-41 were not allowable since they lacked novelty. In particular, it was noted that claims 2 and 3 now appeared in independent form and omitted certain features (A11 exons interrupted by 10 introns@) previously found in corresponding claims by virtue of their dependency from claims that recited the those features. Claims 5, 6 and 8-41 were considered non-allowable since they depended from either claim 2 or claim 3. The rejection was therefore referred to the Patent Appeal Board for review, the first step of which was to provide the Applicant with a copy of the

Summary of Reasons and inform the Applicant that the application was pending before the Board.

POST- FINAL ACTION MATTERS

[7] After being advised by the Board that the rejection was pending for review, the Applicant, having considered the Summary of Reasons, voluntarily proposed in a letter dated September 10, 2009 that certain claim amendments be made in order to advance the application to allowance. The Applicant proposed cancelling claim 3 and amending claim 2 in order to recite the additional features the Examiner considered critical in order to overcome the prior art.

[8] The Applicant=s proposal was considered by the Board and, after finding the proposed amendments to be reasonable, invited the Examiner to provide a Supplementary Summary of Reasons taking into account the Applicant=s proposal. The Supplemental Summary of Reasons dated November 26, 2009, indicated that:

> It appears that the proposed amendements are acceptable.
>
> However, claim 21, which is directed to the use of a transgenic mammal ... in the obtention of progeny, should be deleted by the applicant because it is related to a natural process according to laws of nature.
>
> If the applicant amends the claims according to the proposed amendements described in the letter of September 10, 2009 and deletes claim 21, then, the application could be accepted.

[9] Upon being informed by the Board that claim 21 may be problematic (presumably under section 2 of the *Patent Act*), the Applicant further proposed, in a letter dated December 4, 2009, that it too be cancelled.

DISPOSITION OF THE PRESENT CASE

[10] After reviewing the amendments proposed by the Applicant in the letters of September 10, 2009 and December 4, 2009, it is understood that all of the issues raised by the Examiner, either in the Final Action or afterwards, would have been overcome if the proposed amendments had been submitted within the time limit to respond to the Final Action.

[11] Under the present circumstances, considering that the proposed amendments would address the outstanding issues, an option for the Commissioner is to inform the Applicant that the proposed amendments are required under subsection 31(c) of the *Patent Rules* (see also *Re Application of SigmaPharm, Inc.* (2008), Commissioner=s Decision no. 1288).

RECOMMENDATIONS

[12] We consider that the present circumstances favour the issuance of an invitation to the Applicant to formally submit the proposed amendments.

[13] 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 address the outstanding issues and would render the application compliant with the *Patent Act* and *Rules*:

$ cancellation of currently pending claims 3 and 21;

$ amendment of claim 2 as proposed in the Applicant=s letter dated September 10, 2009; 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 outstanding issues 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.

Agnès Lajoie	Ed MacLaurin	Mark Couture
Chairperson	Member	Member

COMMISSIONER=S DECISION

[14] I concur with the recommendations of the Patent Appeal Board. Accordingly, I invite the Applicant under subsection 31 (c) of the *Patent Rules* 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 outstanding issues 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 26 day of January ,2010