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Title of invention:
Methods and compositions for modulating the immune system of animals

Applicant:
The Lauridsen Group Incorporated

Headword:
Immunoglobulin concentrate/LAURIDSEN

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EPC Art. 56, 83, 84, 111(1), 123(2)

Keyword:
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G 0005/83

Catchword:

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Case Number: T 1494/11 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 8 April 2016

Appellant: (Applicant)	The Lauridsen Group Incorporated 2325 North Loop Drive, P.O. Box 645 Ames, IA 50010 (US)
Representative:	Webber, Philip Michael Dehns St Bride's House 10 Salisbury Square London EC4Y 8JD (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 8 December 2010 refusing European patent application No. 02736484.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	G. Alt
Members:	A. Chakravarty
	M.-B. Tardo-Dino

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division refusing European patent application No.02736484 entitled "*Methods and compositions for modulating the immune system of animals*".

II. The examining division considered a main request and five auxiliary requests.

Claims 1 to 6, 14 and 15 of the **main request** read:

"1. An immunoglobulin concentrate derived from animal plasma for reducing a systemic inflammatory reaction in an animal, wherein said immunoglobulin concentrate is for oral administration.

2. Use of an immunoglobulin concentrate derived from animal plasma in the manufacture of a medicament for oral administration for reducing a systemic inflammatory reaction in an animal.

3. An immunoglobulin concentrate as claimed in claim 1 or the use of claim 2, wherein the systemic inflammatory reaction is caused by a vaccine protocol and wherein the immunoglobulin concentrate or medicament is administered prior to, simultaneously with, or immediately following vaccination.

4. An immunoglobulin concentrate as claimed in claim 1 or the use of claim 2, wherein the systemic inflammatory reaction is caused by a respiratory disease challenge.

5. An immunoglobulin concentrate derived from animal plasma for improving survival in a disease-challenged

animal, wherein the concentrate is administered orally and wherein the disease is a respiratory disease.

6. Use of an immunoglobulin concentrate derived from animal plasma in the manufacture of a medicament for improving survival in a disease challenged animal, wherein the medicament is administered orally and wherein the disease is a respiratory disease.

14. An immunoglobulin concentrate or a use as claimed in claim 3, wherein the vaccine is a Rotavirus vaccine or a PRRS vaccine.

15. An immunoglobulin concentrate or a use as claimed in any one of claims 4 to 6, wherein the respiratory disease state is selected from the group consisting of avian influenza, chronic respiratory disease, infectious sinusitis, pneumonia, fowl cholera, and infectious synovitis".

Claim 11 of **auxiliary request 1** read:

"11. An immunoglobulin concentrate as claimed in any one of claims 1 to 9, wherein the immunoglobulin is obtained from bovine, pig or poultry blood".

Claim 1 of **auxiliary request 5** read:

"1. An immunoglobulin concentrate derived from animal plasma for preventing and treating respiratory diseases, wherein the immunoglobulin concentrate is administered orally".

III. In the decision under appeal the examining division held that the main request included subject-matter which extended beyond the content of the application as filed,

contrary to Article 123(2) EPC. In particular, claim 3 combined features which were not disclosed in combination in the application as filed, while claim 4 related to an undisclosed generalisation of a specific example. The examining division held that "[C]*laims 5 and 6* [were] *allegedly based on previous claim 7*" which however related only to "*non-antibody specific immunoglobulin*". Furthermore, claims 5 and 6 no longer mentioned "[...] *feed efficiency and the aspect relating to the modulation of the immune system*".

IV. Furthermore, the entire set of claims of the main request was held to lack clarity and support in the description (Article 84 EPC) because "*[t]he division [did] not understand how, under the general heading of claim 1 referring to "a systemic inflammatory reaction", the applicants consider that a vaccine protocol (claim 3), a respiratory disease (challenge) (claims 4-6), a rotavirus vaccine or a PRRS vaccine (claim 14) or finally the disease states of claim 15 can all fall within this general heading*".

V. Claims 1 to 12 of auxiliary requests 1 to 4 were held to lack clarity (Article 84 EPC) due to incorrect dependency of claim 11. The objection was held to apply *mutatis mutandis* to auxiliary requests 2 to 5.

VI. The subject-matter of each of claims 1 to 3 of the main request and claims 1 and 2 of auxiliary requests 1 to 4 lacked inventive step (Article 56 EPC) because "*figures* [1 and 2 of the application showed that], *the effect obtained* [was] *clearly a reduction of the immune response towards the rotavirus, respectively PRRS vaccine*". An optimized, improved vaccine was generally accepted as one that elicited a higher immune response and hence invoked an improved protection, however the

claimed immunoglobulin concentrate was "*characterized by a reduction of the immune response*". It followed that "*the problem that claim 1 is aiming to solve, namely an optimization of the response to antigens has not been obtained when giving the animal plasma* [...]".

VII. Finally claim 1 of auxiliary request 5 lacked inventive step *inter alia* because "[r]*espiratory diseases can be for instance of allergic nature*" and "[t]*he application does not show that the problem* [of the provision of an effective treatment or preventive treatment against respiratory diseases] *has been solved over the whole scope of the claim.*" I

VIII. With the statement setting out the grounds of appeal, the appellant submitted amended main and auxiliary claim requests 1 to 6.

Claims 1 to 4, 14 and 17 of the main request read:

"1. An immunoglobulin concentrate derived from animal plasma for reducing a systemic inflammatory reaction in an animal, wherein said immunoglobulin concentrate is for oral administration.

2. Use of an immunoglobulin concentrate derived from animal plasma in the manufacture of a medicament for oral administration for reducing a systemic inflammatory reaction in an animal.

3. An immunoglobulin concentrate derived from animal plasma for modulating the immune system and improving feed efficiency and survival in a disease-challenged animal, wherein the concentrate is administered orally and wherein the disease is a respiratory disease.

4. Use of an immunoglobulin concentrate derived from animal plasma in the manufacture of a medicament for modulating the immune system and improving feed efficiency and survival in a disease-challenged animal, wherein the medicament is administered orally and wherein the disease is a respiratory disease.

14. An immunoglobulin concentrate derived from animal plasma for optimizing the response to antigens presented during vaccination of an animal, wherein the immunoglobulin concentrate is administered orally.

17. An immunoglobulin concentrate derived from animal plasma for preventing and treating respiratory diseases, wherein the immunoglobulin concentrate is administered orally".

IX. The board appointed oral proceedings and in a communication pursuant to Article 15(1) RPBA, noted that in the case of claims to medical uses, the achievement of the therapeutic effect was a technical feature of the claim. Thus, issues dealt with in the decision under appeal under the heading of inventive step and based on the reason that "*problem has not been solved*", should instead have been dealt with by considering whether or not the application disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, i.e. under the heading of Article 83 EPC (see point 7 of the communication).

X. The board further indicated that, since the examining division had given no opinion on whether the invention was sufficiently disclosed (Article 83 EPC) or obvious over the prior art (Article 56 EPC) a considerable part of the examination of the application had yet to be carried out. It thus informed the appellant of its

intention to set aside the decision of the examining division and to remit the case to the first instance for further prosecution.

XI. With a letter dated 18 November 2015, the appellant withdrew the request for oral proceedings, on the condition that the decision of the board would be issued in the terms set out in the communication of the board.

XII. The board cancelled the oral proceedings.

XIII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution. In the event that the board of appeal was not able to comply with this request, it was requested that oral proceedings before the board be held (Article 116 EPC).

Reasons for the Decision

Main request

1. In the decision under appeal, objections were raised under Article 123(2) EPC - amendments, Article 84 EPC - clarity and support and Article 56 EPC - inventive step (see Sections II to VII, above).

2. In relation to amendments, the long established case law of the Boards of Appeal is that an amendment should be regarded as introducing subject-matter which extends beyond the content of the application as filed if it results in the skilled person being presented with a disclosure which is not directly and unambiguously derivable from that previously presented by the application, even when account is taken of matter which is implicit to a person skilled in the art (see Case Law

of the Boards of Appeal of the European Patent Office, 7th edition, 2013, II.E.1).

3. The objections of the examining division raised under Article 123(2) EPC to claims 3 and 4 of the main request before it, have been overcome by the deletion of the subject-matter of these claims.

4. The subject-matter of claims 5 and 6 of the main request considered by the examining division is found, in slightly amended form, in claims 3 and 4 of the pending main request. The sole reasoning of the examining division in finding claims 5 and 6 not allowable was that "*previous claim 7 did contain the wording non-antibody specific*" (see Section II, above). Thus, there is no analysis in the decision under appeal of whether the subject-matter of the claims is directly unambiguously derivable from the disclosure presented by the application as filed or not. Hence, the board considers that the examining division's assessment of whether or not the amendments comply with the requirements of Article 123(2) EPC, is not complete enough to be persuasive.

5. The claims of the main request now comprise four separate independent claims (see Section VIII). The indications "modulating the immune system and improving feed efficiency and survival in a disease-challenged animal", mentioned in independent claims 3 and 4 of the main request, are no longer presented as a sub-category of "reducing a systemic inflammatory reaction", as they were in the claims of the main request considered by the examining division. Thus, the inconsistency considered unclear by the examining division has been removed.

6. With regard to the objection of lack of support in the description, raised by the examining division against the subject-matter of the claims of the main request (see Section IV), the board notes that, beyond a statement that the examining division "*does not understand on the basis of which technical contribution disclosed in the application as originally filed, the applicants consider that the claims are technically supported over the whole of their scope*", the decision contains no explanation of how this conclusion was reached or any evidence in its support. It follows that the board cannot find the objection persuasive.

7. On the topic of inventive step (Article 56 EPC), the examining division held that claim 1 of each of the main and auxiliary requests 1 to 5 lacked an inventive step essentially because it was not persuaded that the problem addressed by the claimed subject-matter had been solved (see Sections VI and VII).

8. According to long standing case law of the Boards of Appeal, the "problem and solution approach" is applied in the course of deciding whether or not claimed subject-matter fulfils the requirements of Article 56 EPC (see Case Law of the Boards of Appeal of the European Patent Office, 7th edition, 2013, I.D.1). In cases where attainment of a technical effect required to solve the problem is not a feature of the claim, it is generally determined whether the problem described in the application has been solved by the invention as claimed. If it is determined that this is not the case, the problem is then adapted ("reformulated") to reflect the actual technical success achieved by the claimed subject-matter (*Id.*, I.D.4.3.2). A simple determination that the problem has not been solved, as made in the

decision under appeal, therefore does not constitute a complete assessment of inventive step.

9. Moreover, the claims regarded as obvious by the examining division in the decision under appeal, were for a medical use of an immunoglobulin concentrate and were drafted following the provisions in Article 54(5) EPC or in the Swiss-type format as instituted by decision G 5/83 (OJ EPO 1985, 64). For all such claims, attaining the claimed therapeutic effect is considered to be a functional technical feature of the claim. Thus, the assessment of whether this therapeutic effect is attainable must be made in the context of Article 83 EPC, i.e. it is evaluated, unless this is already known to the skilled person at the priority date, whether or not the application discloses the suitability of the product to be manufactured for the claimed therapeutic effect (*Id.* II.C.6.2).

10. Consequently, the issues dealt with in the decision under appeal under the heading of inventive step should properly have been dealt with under the heading of disclosure of the invention.

11. The decision under appeal (even under the heading of inventive step) does not address the question of whether the application in fact discloses the suitability of the products to be manufactured for the claimed therapeutic applications, i.e. "*reducing a systemic inflammatory reaction in an animal*" (claims 1 and 2), "*modulating the immune system and improving feed efficiency and survival in a disease-challenged animal, wherein the concentrate is administered orally and wherein the disease is a respiratory disease*" (claims 3 and 4), "*optimizing the response to antigens presented during vaccination of an*

animal" (claim 14) and "*preventing and treating respiratory diseases*".

12. In summary, the main request and the subject-matter to which it relates, either overcomes the reasons for refusal of the application (Points 3 and 5, above) or the reasons given for refusal in the decision under appeal do not persuade the board (Points 4 and 6 to 11, above). Hence the decision under appeal is set aside.

Remittal - Article 111(1) EPC

13. In its decision, the examining division gave no opinion on whether the invention was sufficiently disclosed or obvious over the prior art. Moreover, the amendments made require that the topic of clarity of the claims is revisited.

14. Since a considerable part of the examination of the application has yet to be carried out, the board deems it appropriate to exercise its power under Article 111(1) EPC to remit the case to the examining division for further examination of whether the amended claims comply with the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution.

The Registrar: The Chairwoman:

D. Hampe G. Alt

Decision electronically authenticated