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**Datasheet for the decision  
of 10 February 2010**

**Case Number:** T 0692/08 - 3.3.08

**Application Number:** 96921391.7

**Publication Number:** 0843818

**IPC:** G01N 33/554

**Language of the proceedings:** EN

**Title of invention:**

Lawsonia intracellularis cultivation, anti-Lawsonia  
intracellularis vaccines and diagnostic agents

**Patentee:**

BOEHRINGER INGELHEIM VETMEDICA, INC.

**Opponents:**

Akzo Novel N.V.  
Wyeth

**Headword:**

Lawsonia intracellularis/BOEHRINGER

**Relevant legal provisions:**

EPC Art. 123(2)(3), 84, 111

**Keyword:**

"Main request filed at oral proceedings: admissibility (yes),  
added subject-matter (no), clarity (yes)"  
"Remittal (yes)"

**Decisions cited:**

T 0190/99

**Catchword:**

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Case Number: T 0692/08 - 3.3.08

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.08  
of 10 February 2010

**Appellant I:** Akzo Nobel N.V.  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 11 February 2008  
rejecting the opposition filed against European  
Patent No. 0843818 pursuant to Article 101(2)  
EPC.

**Composition of the Board:**

**Chairman:** L. Galligani  
**Members:** F. Davison-Brunel  
J. Geschwind

## Summary of Facts and Submissions

- I. European patent No. 0 843 818 with the title "Lawsonia intracellularis cultivation, anti-Lawsonia intracellularis vaccines and diagnostic agents" was granted with 23 claims on the basis of European patent application No. 96 921 391.7.

Claims 1, 15 and 16 read as follows:

"1. A method for cultivating *L.intracellularis* bacteria comprising obtaining culture cells infected with *L.intracellularis*, incubating said infected cells at an oxygen concentration of less than about 18 percent while maintaining said infected cells in suspension.

15. A method for cultivating *L.intracellularis* bacteria comprising the steps of:

(1) inoculating culture cells with an inoculum comprising *L.intracellularis* bacteria so as to infect said cells with said bacteria; and

(2) incubating said infected cells at a temperature of from about 36°C to about 38°C in an oxygen concentration of 0% to about 8% while agitating said infected cells so as to cultivate the *L.intracellularis* while maintaining said infected cells in suspension.

16. A method for producing an attenuated *L.intracellularis* strain comprising obtaining culture cells infected with *L.intracellularis* bacteria, incubating said infected cells at an oxygen concentration of 0 percent to about 18 percent, agitating said infected cells so as to cultivate said

bacteria while maintaining said infected cells in suspension, passaging at least a portion of said cultivated bacteria, harvesting at least a portion of said cultivating bacteria, and selecting for an attenuated strain to provide an attenuated *L.intracellularis* bacteria."

Dependent claims 2 to 13 related to further features of the method of claim 1. Claim 14 was directed to specific deposited *L.intracellularis* strains. Dependent claims 17 to 23 related to further features of the method of claim 16.

- II. Two oppositions were filed under Article 100 (a) to (c) EPC for lack of novelty and inventive step (Articles 54 and 56 EPC), lack of sufficient disclosure (Article 83 EPC) and added subject-matter (Article 123(2) EPC). The opposition division rejected the oppositions under Article 101(2) EPC.
- III. Appellants I and II (opponents 01 and 02) filed appeals and submitted statements of grounds of appeal on 2 June 2008 and 16 June 2008, respectively. Both appellants contested only the finding on inventive step in the decision of the opposition division.
- IV. The respondent (patentee) filed a reply to the statements of grounds of appeal on 30 October 2008 maintaining the granted claim request as its main request. This, in turn, prompted an answer by appellant I on 30 January 2009.
- V. The board sent a communication pursuant Article 15(1) of the Rules of Procedure of the Boards of Appeal

(RPBA), giving its preliminary, non-binding opinion on 10 July 2009.

VI. All parties replied to this communication. Appellant's I submissions dated 2 December 2009 were accompanied by experimental evidence. The respondent's submissions dated 8 January 2010 were accompanied by four auxiliary requests, new documents and additional data.

Claims 1 and 14 of the auxiliary request I read as follows:

"1. A method for cultivating *L.intracellularis* bacteria comprising obtaining culture cells infected with *L.intracellularis*, incubating said infected cells at an oxygen concentration of less than about 18 percent while maintaining said infected cells in suspension, **wherein harvesting is done when greater than about 70% of the cells as determined by the TCID<sub>50</sub> method are infected.**" (emphasis added by the board)

14. A method for cultivating *L.intracellularis* bacteria comprising the steps of:

(1) inoculating culture cells with an inoculum comprising *L.intracellularis* bacteria so as to infect said cells with said bacteria; and

(2) incubating said infected cells at a temperature of from about 36°C to about 38°C in an oxygen concentration of 0% to about 8% while agitating said infected cells so as to cultivate the *L.intracellularis* while maintaining said infected cells in suspension; **wherein harvesting is done when greater than about 70% of the cells as determined by the TCID<sub>50</sub> method are infected.**" (emphasis added by the board)

Claims 2 to 13, 15 to 22 respectively corresponded to granted claims 2, 4 to 14, 16 to 23. Granted claim 3 was deleted.

VII. Further submissions were received from the appellants on 29 January 2010 (appellants I and II) and on 5 February 2010 (appellant II). The submissions by appellant I included also an addendum to the previously filed experimental evidence.

VIII. Oral proceedings took place on 10 February 2010. The parties addressed the board on the issue of inventive step with respect to claim 1 of the main request (granted claim 1). After discussion, the board indicated that it considered said claim to lack an inventive step and thus invited the respondent to state whether it wished to proceed on the basis of the auxiliary request I which had been filed on 8 January 2010 (cf Section VI, *supra*).

After a short intermission, the respondent confirmed that it wished to proceed on the basis of said auxiliary request I. During the discussion, *inter alia* objections under Article 84 EPC were raised against claim 1 of this request and reference was made to the experimental evidence on file. The admissibility into the proceedings of said experimental evidence was then debated. Having heard the parties, the board indicated that the experimental data filed by appellant I on 2 December 2009 as well as the further addendum to said data filed with the submissions of 29 January 2010, and the experimental data filed by the respondent on 8 January 2010 were not admitted into the proceedings.

At this point, the respondent filed an amended auxiliary request I in replacement of the one on file. The newly filed request was discussed under the point of view of its admissibility into the proceedings and of Articles 84 and 123(2)(3) EPC. The request was admitted and found to be in compliance with the said provisions of the EPC.

The board indicated its intention to remit the case to the first instance for further prosecution. At this point, the respondent withdrew the request that the appeal be dismissed and made the auxiliary request I filed during the oral proceedings its main request.

IX. Claims 1 and 14 of the new main request read as follows:

"1. A method for cultivating *L.intracellularis* bacteria comprising obtaining culture cells infected with *L.intracellularis*, incubating said infected cells at an oxygen concentration of less than about 18 percent while maintaining said infected cells in suspension, wherein harvesting is done when greater than about 70% of the cells **as determined by the IFA method** are infected."(emphasis added by the board)

14. A method for cultivating *L.intracellularis* bacteria comprising the steps of:

(1) inoculating culture cells with an inoculum comprising *L.intracellularis* bacteria so as to infect said cells with said bacteria; and

(2) incubating said infected cells at a temperature of from about 36°C to about 38°C in an oxygen concentration of 0% to about 8% while agitating said infected cells so as to cultivate the *L.intracellularis* while maintaining said infected cells

in suspension; wherein harvesting is done when greater than about 70% of the cells **as determined by the IFA method** are infected." (emphasis added by the board)

The other claims remained as in the auxiliary request I filed on 8 January 2010.

- X. Appellants I and II 's arguments may be summarized as follows:

*Main request (request filed as auxiliary request I during oral proceedings)*

*Admissibility*

The new main request was only filed at oral proceedings ie. too late to be admissible. In fact, its filing was an attempt to reintroduce in the proceedings the auxiliary request I filed on 8 January 2010 for which the board had indicated during the course of oral proceedings that the reference to TCID<sub>50</sub> in claim 1 - as a way to determine the number of infected cells - may render the claim unclear. The respondent should not be allowed to improve its position at such a late stage.

*Formal requirements*

- The passage on page 14 lines 1 to 6 of the application as filed could not serve as the basis for acknowledging that the method of claim 1 had been disclosed therein (Article 123(2) EPC). Indeed, this passage contained the extra information that the harvest should be done "after sufficient growth of the culture cells" and, furthermore, the reference to "... subsequent



infection by *L.intracellularis* at greater than about 70% cell infectivity..." was a reference to the amount of infected cells before they were put in suspension rather than a reference to the amount of infected cells in suspension before harvesting. Thus, the teaching in the application as filed was different from the subject-matter of claim 1.

- Claim 1 was also unclear (Article 84 EPC) because in the expression "wherein harvesting is done when greater than about 70% of the cells as determined by the IFA method are infected", the term "about" introduced an ambiguity as regards the number of cells that needed to be infected before harvest.

XI. The respondent's arguments may be summarized as follows:

*Main request (request filed as auxiliary request I during oral proceedings)*

*Admissibility*

The main request differed from the earlier main request (granted claims) in that in claim 1, a further characteristic had been added to define the claimed method of cultivating *L.intracellularis*, namely that the harvesting should be done "when greater than about 70% of the cells as determined by the IFA method are infected". The introduction of this feature was a simple attempt at restoring inventive step after the board had indicated that it considered obvious the subject-matter of granted claim 1.

The filing of this request was not too late. Indeed, the request corresponded to the auxiliary request I

filed on 8 January 2010 - more than one month before the oral proceedings -, the difference between them being that the number of infected cells was said to be measured by the IFA rather than by the TCID<sub>50</sub> method, both methods being unambiguously identified in the patent-in-suit as being equally suited for the given purpose.

For these reasons, the request was admissible.

*Formal requirements*

A basis for the subject-matter of claim 1 was found on page 14, lines 1 to 6 of the application as filed (Article 123(2) EPC).

The IFA method would have been well known by the skilled person at the relevant date and, in addition, the way to put it into practice was explained in detail in paragraph [56] of the granted patent. The claimed subject-matter was, thus, clear, concise and supported by the description (Article 84 EPC).

- XII. Appellants I and II requested that the decision under appeal be set aside and the patent be revoked.

The respondent requested that the decision under appeal be set aside and that the patent be maintained on the basis of either auxiliary request I filed during the oral proceedings (main request) or of any of auxiliary requests II to IV filed on 8 January 2010.

## **Reasons for the decision**

*Main request - filed as auxiliary request I during the oral proceedings*

### *Admissibility*

1. The main request was filed during oral proceedings, initially as a new auxiliary request I replacing the auxiliary request I submitted on 8 January 2010. This earlier auxiliary request I had been filed more than one month before the oral proceedings, in answer to the board's preliminary, non-binding opinion under Article 15(2) RPBA and as a precautionary measure against any subsequent findings by the board that the subject-matter of claim 1 of the main request then on file (granted claim 1) may be obvious.
  
2. At oral proceedings, appellant I challenged the admissibility of the new auxiliary request I on the basis that in claim 1 of this request, reference was made to the IFA method as a means to determine the number of infected cells whereas in claim 1 of auxiliary request I filed on 8 January 2010, it was the TCID<sub>50</sub> method which was mentioned in this respect (compare Sections VI and IX, supra). It was argued that this change was introduced to avoid any possible findings of lack of clarity attached to the TCID<sub>50</sub> method and, accordingly to ward off a possible rejection of auxiliary request I filed on 8 January 2010. Thus, according to the appellant, accepting the new auxiliary request I in the proceedings would amount to giving an opportunity to the respondent to improve its position at a late stage.

3. The board is not convinced by this argument. The critical feature for the analysis of inventive step is not whether the IFA or the TCID<sub>50</sub> method is used to measure the amount of infected cells before harvesting. Indeed, both methods are mentioned (rightly or wrongly) in the patent in suit as being comparable (page 14, lines 1 to 6). It is rather that the percentage of infected cells before harvesting must be about 70%. This feature was present in claim 1 of the auxiliary request I of 8 January 2010 and it is also present in claim 1 of the new auxiliary request I filed at oral proceedings - now the main request. Thus, accepting the amended request in the proceedings does not amount to allowing the respondent to improve its position at a late stage. For this reason, the main request is admissible.

*Formal requirements*

4. The subject-matter of claim 1 is of a narrower scope than the subject-matter of the corresponding granted claim 1 since the harvesting step in the claimed method is only to be taken when the number of infected cells has reached 70%, whereas in granted claim 1, no limitation has been put as to the time of harvest. The protection conferred has not been extended (Article 123(3) EPC).
5. The respondent pointed out to the passage on page 14, lines 1 to 6 of the application as filed as a disclosure of the now claimed method. This passage reads as follows:

*"After sufficient growth of the culture cells and subsequent infection by L.intracellularis at greater than about 70% cell infectivity, as determined by IFA, TCID<sub>50</sub> or other comparable method, at least a portion of the cultivated L.intracellularis bacteria is then harvested."*

Appellant I argued that the feature *"After sufficient growth of the culture cells..."* amounts to meaningful information missing from the present claim. The board cannot agree. It is implicit that one will wait until the culture cells are sufficiently grown before harvesting them. To do otherwise would be counter-productive.

6. In addition, appellant I saw the feature *"... subsequent infection by L.intracellularis at greater than about 70% cell infectivity"* as defining the early step of infection which took place on solid medium rather than the last step in the cultivation process when the cells are in suspension - as is now claimed. Yet again, the board cannot follow the argument because the passage on page 14, lines 1 to 6 must be read in its context and the sentence immediately below mentions that:

*"The harvesting step may be performed by separating the bacteria **from the suspension** by various techniques known to those skilled in the art, given the teachings herein." (emphasis added by the board)*

For these reasons, the board concludes that the now claimed method has a basis in the application as filed (Article 123(2) EPC).

7. An objection for lack of clarity was raised against the term "about" in the expression "wherein harvesting is done when greater than about 70% of the cells as determined by the IFA method are infected". In accordance with the case law (eg. T 190/99 of 6 March 2001), a patent must be construed by a mind willing to understand, not a mind desirous of misunderstanding. Here, the skilled person would be fully aware that, because of the number of parameters which may influence cell growth, it will not be possible exactly to predict when the number of cells will reach a defined mathematical value (70%). Yet, he/she would have no problem in evaluating when the cell culture has reached an essentially equivalent stage (here "about 70%"). For this reason, there is no lack of clarity in claim 1.
  
8. A last observation is that the findings as regards claim 1 equally apply to the subject-matter of claim 14 which is also directed to a method for cultivating *L.intracellularis* comprising the feature "wherein harvesting is done when greater than about 70% of the cells as determined by the IFA method are infected". The fact that the indirect fluorescent antibody (IFA) method is adequate for determining the percentage of infection of the cells was not contested by the appellants.
  
9. The requirements of Articles 123(2)(3) and 84 EPC are fulfilled by the main request.

*Further course of action*

10. The feature "wherein harvesting is done when greater than about 70% of the cells as determined by the IFA method are infected" in present claims 1 and 14 is an essential feature which was taken from the description. It is critical in the assessment of inventive step of the claimed subject-matter since, at oral proceedings, a claimed method which does not contain it has been found obvious by the board (see Section VIII, supra). It is possible that additional documents/experimental data may be needed for a proper assessment of its relevance. Finally, the opposition division has not had the opportunity to consider the request. For these reasons, the board finds it appropriate to remit the case to the first instance for further prosecution under Article 111 EPC.

**Order:**

**For these reasons, it is decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution.

The Registrar

The Chairman

A. Wolinski

L. Galligani