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Datasheet for the decision of 23 February 2016

Case Number: T 2542/12 - 3.3.08

Application Number: 06819369.7

Publication Number: 1948783

IPC: C12N1/20, A61K39/02, C12Q1/68, C12R1/68

Language of the proceedings: EN

Title of invention:
NOVEL BACTERIUM AND VACCINE

Applicant:
Intervet International BV

Headword:
Cod's syndrome, Francisella/INTERVET INTERNATIONAL BV

Relevant legal provisions:
EPC 1973 Art. 83
EPC 1973 R. 28(1)(d), 28(2)

Keyword:
Main and sole request - sufficiency of disclosure (no)

Decisions cited:
T 2068/11

Catchword:

Europäisches Patentamt
European Patent Office
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Case Number: T 2542/12 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 23 February 2016

Appellant: (Applicant)	Intervet International BV Wim De Körverstraat 35 P.O. Box 31 5830 AA Boxmeer (NL)
Representative:	Keus, J.A.R. Intervet International B.V. Hertford Road Hoddesdon, Hertfordshire EN11 9BU (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 6 July 2012 refusing European patent application No. 06819369.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Wieser
Members:	B. Stolz
	C. Heath

Summary of Facts and Submissions

I. The applicant (appellant) filed an appeal against the decision of the examining division whereby European patent application No. 06819369.7 was refused. The examining division decided that the subject matter of claims 1 to 22 filed with letter of 10 August 2009 was insufficiently disclosed (Article 83 EPC).

II. The appellant was summoned to oral proceedings. A communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to the summons, informed it of the preliminary non-binding opinion of the board on some of the issues of the appeal proceedings.

III. In reply to this communication, the appellant submitted two declarations, D7 and D8, from the inventor.

IV. Oral proceedings were held on 23 February 2016.

V. Claims 1 to 22 of the sole request before the board of appeal are identical with the claims underlying the decision under appeal. Independent claims 1 to 5 read:

"1. Novel rod-shaped pleiomorphic non-motile Gram-negative bacterium causing Cod's Syndrome in cod characterized in that the nucleotide sequence of the region of the 16S rRNA gene corresponding to the 16S rRNA gene as depicted in SEQ ID NO 1 has a level of identity of at least 99.1 %, preferably 99.2 %, more preferably 99.3 %, 99.4 %, 99.5 %, 99.6 %, 99.7 %, 99.8 %, 99.9 % in increasing order of preference and most preferably 100 % to the nucleotide sequence as depicted in SEQ ID NO 1.

2. Novel rod-shaped pleiomorphic non-motile Gram-negative bacterium causing Cods Syndrome in fish, characterized in that the nucleotide sequence of the region of the 23S rRNA gene corresponding to the 23S rRNA gene as depicted in SEQ ID NO 3 has a level of identity of at least 96.0 %, preferably 96.5 %, more preferably 97.0 %, 97.5 %, 98.0 %, 98.5 %, 99.0 %, 99.2%, 99.4 %, 99.6 %, 99.8 %, 99.9 % in increasing order of preference and most preferably 100 % to the nucleotide sequence as depicted in SEQ ID NO 3.

3. Novel rod-shaped pleiomorphic non-motile Gram-negative bacterium causing Cod's Syndrome in cod characterized in that its 16S rRNA gene reacts in a PCR reaction with a primer as depicted in SEQ ID NO 4 or 5, and with a primer as depicted in SEQ ID NO 6 or 7 to give a PCR product of 567 +/- 10 base pairs (CSF1 + CSR1), 523 +/- 10 base pairs (CSF2 + CSR1), 283 +/- 10 base pairs (CSF1 + CSR2) or 239 +/- 10 base pairs (CSF2 + CSR2).

4. Novel rod-shaped pleiomorphic non-motile Gram-negative bacterium causing Cod's Syndrome in fish, characterized in that the nucleotide sequence of the region of the 16S rRNA gene corresponding to the 16S rRNA gene as depicted in SEQ ID NO 1 has a level of identity of at least 99.1 %, preferably 99.2 %, more preferably 99.3 %, 99.4 %, 99.5 %, 99.6 %, 99.7 %, 99.8 %, 99.9 % in increasing order of preference and most preferably 100 % to the nucleotide sequence as depicted in SEQ ID NO 1 and the nucleotide sequence of the region of the 23S rRNA gene corresponding to the 23S rRNA gene as depicted in SEQ ID NO 3 has a level of identity of at least 96.0 %, preferably 96.5 %, more

preferably 97.0 %, 97.5 %, 98.0 %, 98.5 %, 99.0 %, 99.2%, 99.4 %, 99.6 %, 99.8 %, 99.9 % in increasing order of preference and most preferably 100 % to the nucleotide sequence as depicted in SEQ ID NO 3.

5. Novel rod-shaped pleiomorphic non-motile Gram-negative bacterium causing Cod's Syndrome in fish, characterized in that the nucleotide sequence of the region of the 16S rRNA gene corresponding to the 16S rRNA gene as depicted in SEQ ID NO 1 has a level of identity of at least 99.1 %, preferably 99.2 %, more preferably 99.3 %, 99.4 %, 99.5 %, 99.6 %, 99.7 %, 99.8 %, 99.9 % in increasing order of preference and most preferably 100 % to the nucleotide sequence as depicted in SEQ ID NO 1 and in that the nucleotide sequence of the region of the 23S rRNA gene corresponding to the 23S rRNA gene as depicted in SEQ ID NO 3 has a level of identity of at least 96.0 %. preferably 96.5 %, more preferably 97.0 %, 97.5 %, 98.0%, 98.5 %, 99.0 %. 99.2%, 99.4 %, 99.6 %, 99.8 %, 99.9 % in increasing order of preference and most preferably 100 % to the nucleotide sequence as depicted in SEQ ID NO 3 and in that the 16S rRNA gene reacts in a PCR reaction with a primer as depicted in SEQ ID NO 4 or 5, and with a primer as depicted in SEQ ID NO 6 or 7 to give a PCR product of 567 +/- 10 base pairs (CSF1 + CSR1), 523 +/- 10 base pairs (CSF2 + CSR1), 283 +/- 10 base pairs (CSF1 + CSR2) or 239 +/- 10 base pairs (CSF2 + CSR2)."

Claims 6 to 22 refer to specific embodiments and to therapeutic and diagnostic uses of the bacterium according to claims 1 to 5.

VI. The following documents are referred to in this decision:

D3: NYLUND A ET AL: "Francisella sp. (Family Francisellaceae) causing mortality in Norwegian cod (Gadus morhua) farming", ARCHIVES OF MICROBIOLOGY, vol. 185, June 2006 (2006-06) , pages 383-392;

D4: OLSEN A B ET AL: "A novel systemic granulomatous inflammatory disease in farmed Atlantic cod, Gadus morhua L., associated with a bacterium belonging to the genus Francisella", JOURNAL OF FISH DISEASES, vol. 29, May 2006 (2006-05) , pages 307-311;

D5: OTTEM K F ET AL: "Occurrence of Francisella piscicida in farmed and wild Atlantic cod, Gadus morhua L., in Norway", JOURNAL OF FISH DISEASES , vol. 31, 2008, pages 525-534;

D6: ALFJORDEN A ET AL: "A systemic granulomatous inflammatory disease in wild Atlantic cod, *Gadus morhua* associated with a bacterium of the genus Francisella", DipNet Newsletter 44, 2006;

D7: Declaration by Prof. Dr. ARE NYLUND in connection with the public availability of cod suffering from cod's syndrome;

D8: Declaration by Prof. Dr. ARE NYLUND in connection with the deposit of Francisella n.sp. GM 2212.

VII. Appellant's arguments as far as relevant for this decision can be summarized as follows:

Infected cod could be obtained freely from cod farms in Norway. The disease was known and spreading from 2004 onwards. According to Document D3, the first major disease in larger cod caused by the bacterium occurred at different production sites in Western Norway during the spring and summer of 2004. Affected fish were collected from 4 different farms in western Norway. According to Document D4, elevated mortalities were recorded at a cod farm on the West coast of Norway at the beginning of July 2005 and peaked towards the end of August. Figure 5 of document D5 showed how widespread the disease in Norway was. Document D5 also showed that 25% of fish from fish farms were affected. As shown by document D6, during the summer of 2004, fisherman reported an increased occurrence, up to 20%, of trapped cod with skin ulcers from southern Skagerrak. The disease was therefore widely known. As could also be seen from document D4, several institutes received affected fish from cod farms. As stated by Professor Nylund in its declaration, D7, affected fish were obtained unconditionally. The disease was therefore known to the public and diseased fish were abundantly available already in 2004.

Regarding the deposit of the microorganism the following had to be considered. The applicant's premier depot, patent application EP 05110602.9, fulfilled the requirements for getting a filing date according to Rule 40(1) EPC. The omission to provide the information required under Rule 28(1)(d) EPC was a formal deficiency that could be remedied under Rule 28(2)(a) EPC within 16 months after the filing date. This formal deficiency had no effect on the filing requirements of the EPC according to Article 87 or on the material presence of the invention in the application. Consequently, the priority application EP 05110602.9

was duly filed, according to Art 87 EPC and gave rise to the right to validly claim priority. In a letter dated 29.12.2009, the Examiner stated on page 2, fifth paragraph, that the patent application (Application number EP 06819369.7) contained the name and the address of the depositor (on form PCT ROl01), and that the depositor was co-Applicant for one of the PCT-contracting states, which could be considered as a statement of consent for the use of the deposit. Therefore, the priority right could be validly claimed.

VIII. The appellant requested that the decision under appeal be set aside and the case be remitted to the examining division for further examination.

Reasons for the Decision

1. The subject matter of independent claims 1 to 5 of the sole request before the board is a rod-shaped pleiomorphic non-motile Gram-negative bacterium causing Cod' syndrome in cod (claims 1 and 3) or in fish (claims 2, 4 and 5).

2. This decision refers exclusively to the examination of the requirements of Article 83 EPC.

3. The claims make no mention of the deposited strain (cf. item V, above). Therefore, as long as the patent application provides sufficient guidance as to how to re-isolate the claimed microorganism, it is irrelevant whether the deposit was made in accordance with the respective legal requirements. Only if biological material is not available to the public and cannot be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, a deposit with a

recognized depositary institution is required (see decision T 2068/11 of 17 March 2015, point 3.1 of the reasons).

Is the claimed microorganism sufficiently disclosed without a deposit?

4. There is no prior art on file disclosing the occurrence of the disease, let alone any symptoms thereof, before the claimed priority date. The first documents describing the disease (D3, D4 and D6) were published in the priority year. The skilled person trying to reproduce the invention at the priority date had therefore to rely entirely on the disclosure of the patent application.

5. The priority application contains very little information about suitable sources for obtaining the bacterium. On page 2 of the description it is stated that the microorganism was found in Atlantic cod. The disease is described as follows: "*Atlantic cod suffering from this new disease show loss of appetite, reduced swimming performance, and dark pigmentation. There are few other external signs of disease, but white spots may be found on gills and in the mouth cavity. It has been observed that the disease spreads within cod farms.*" (lines 7 to 10). The bacterium is described as rod-shaped pleiomorphic non-motile Gram-negative bacterium furthermore characterized by its 16S and 23S rRNA sequences (claims 1 to 5). The application also discloses PCR primers for the amplification of fragments of the rRNA genes (Seq ID NOs: 4 to 9, page 11).

6. Based on documents D3 to D6, the appellant argues that the disease was widely known among fishermen and

breeders in Norway and Sweden in the year 2004 and that re-isolation of the microorganism was therefore readily possible by obtaining an infected fish from a fish farm or a fisherman.

7. The board is not convinced by these arguments.

8. At the priority date, unless the skilled person had personal knowledge of Swedish fisherman or Norwegian cod farms, he had no indication where to start looking for infected fish.

9. As far as farmed cod is concerned, there is no information in the priority document whether the disease was present in all cod farms along the Atlantic ocean. The statement that it spreads within cod farms can be interpreted as meaning that it spreads within a cod farm once some fish are infected.

10. A more important point is however that cod farms are commercial entities which are not freely accessible and under no obligation to share their diseased fish with anybody asking for a sample. They may do so, they may however also refuse to do so. This is one of the reasons why the patent legislator, in order to provide unrestricted and continued access, foresaw the deposit of a claimed microorganism under the provisions of Rule 28 EPC 1973.

11. Based on document D4 and a declaration by the inventor (document D7), the appellant argued that diseased fish was sent to several public veterinary institutes in Norway and Sweden without any restrictions.

12. This may well be the case, it does however not demonstrate a guaranteed access to suitable samples either.

13. As far as wild cod as a source of the microorganism is concerned, the priority application provides no guidance where infected fish could be found. Even within Norway, only wild cod south of Sogn og Fjordane was infected with the claimed microorganism, while wild cod north of that region appeared to be unaffected (Document D5 (abstract). Document D5, which was only published in 2008, gives no indication how widespread the disease was at the priority date. Moreover, the document reports that clinical signs of francisellosis were seen in only a few of the wild cod positive for F. piscicida (document D5, page 531, left column). Document D6 reports an increased occurrence of Atlantic cod with skin ulcers in 2004 in Sweden. Skin ulcers are however not among the disease symptoms listed on page 2 of the priority application.

14. The disease symptoms, loss of appetite and reduced swimming performance, are of little help when trying to obtain an infected fish from fishermen along the Atlantic shore. Dark pigmentation is an external symptom according to page 2 of the description and white spots "***may be*** *found on gills and in the mouth cavity*" (emphasis added).

15. The board concludes that the skilled person, based on the information available from the priority document was not in position to reliably and without undue burden re-isolate the claimed microorganism from wild or farmed cod. The priority application does therefore not describe the claimed microorganism in a manner

sufficiently clear and complete for it to be re-isolated by the skilled person without undue burden.

16. The technical content of the patent application is literally identical with the content of the priority application. In contrast to the situation at the priority date, the skilled person, trying to reproduce the claimed invention at the filing date, could also consult documents D3, D4 and D6. The technical information derivable from documents D3 and D4 is basically the same as the information derivable from the patent application. As an additional piece of information, both documents state that the microorganism was isolated from cod farmed in Western Norway. As stated above, commercial fish farms do not constitute a reliable source of infected fish because they are under no obligation to share any of their diseased fish. Swedish fisherman as described in document D6 are also not a source for reliably obtaining infected fish. They are a possible source, there is however no guarantee that by contacting any of them one could reliably and continuously obtain a fish infected with the claimed microorganism.

17. Under these circumstances, the invention can only be regarded as sufficiently disclosed if a sample has been deposited according to the relevant legal requirements.

Does the deposit of the microorganism comply with the legal requirements?

18. On 13 December 2007, the EPC 2000 entered into force. According to the transitional provisions on the applicability of the EPC 2000, Article 83 EPC shall not apply to European patent applications pending at the date of entry into force of the EPC 2000. Thus, Article

83 EPC 1973 together with Rule 28 EPC 1973 apply to the present case.

19. In its communication dated 29 December 2009, the examining division correctly argued that according to the *"Notice of the European Patent Office dated 18 July 1986 concerning European patent applications and European patents in which reference is made to microorganisms"* (OJ EPO 8/1986, 269) (points 7, 8), a deposit in conformity with the legal requirements of Rule 28(1)(d) EPC 1973 was required *(see decision T 2068/11, point 5.14 of the reasons).*

20. Point 8 of this Notice of the EPO reads:

"Where a European patent application claims the priority of a previous application in accordance with Articles 87 to 89 EPC, the general conditions covering disclosure of the invention in the previous application apply to the microorganism.

In particular, if an invention, in order to be sufficiently disclosed, requires the deposit of a micro-organism culture to supplement the written description, the culture must have been deposited not later than the date of filing of the previous application. The depositary institution and ***the legal statute under which the micro-organism is deposited must comply with the requirements of the country in which the previous application has been filed.***

The previous application must also refer to this deposit in a manner enabling it to be identified.

Where the micro-organism deposit referred to in the European patent application is not the same as the

deposit referred to in the previous application, it is up to the applicant, if the EPO considers it necessary to provide evidence that the two micro-organisms themselves are identical." (emphasis added by the board).

21. The Board thus notes that, to the extent that the priority application was a European patent application, and the international application designated the European Patent Office, both applications need to comply with Rule 28 EPC 1973.

22. Regarding the deposit of the claimed microorganism, the following facts appear from the file:

(a) On 3 November 2005 (seven days before the filing date of the priority document), a microorganism has been deposited under the provisions of the Budapest treaty under accession number CNCM I-3511 at the CNCM (Institut Pasteur, Paris). The depositor was ARE NYLUND of Bønes, Norway.

(b) The priority application contains the name of the depositary institution and the deposit number, yet does not contain the name of the depositor. It also does not state that the depositor has authorised the applicant to refer to the deposited material. The priority application was filed in the name of AKZO NOBEL NV, Arnhem, Netherlands. No inventor is named.

(c) The patent application was filed in the name of INTERVET INTERNATIONAL B.V., Boxmeer, Netherlands, and designates ARE NYLUND as the inventor.

(d) The inventor has authorized the depositary institution to furnish samples pursuant to Rule 11.2(ii) of the Regulations under the Budapest treaty on 5 February 2007 (letter signed on 24 January 2007). A copy of this authorisation has been attached to applicant's letter to the EPO, dated 17 September 2009.

(e) In a declaration dated 8 February 2016 (document D8) and submitted to the board on 9 February 2016, the inventor declares that at the filing date of the priority application he had authorized AKZO NOBEL N.V., now INTERVET INTERNATIONAL B.V., to refer to the deposit under number CNCM I-3511 in European patent application No. EP 06 819 369.7 and the priority document thereof.

23. For the following reasons, the Board concludes that the invention was not sufficiently disclosed under the legal provisions of the EPC, neither at the priority date (10 November 2005) nor at the international filing date (6 November 2006).

24. According to Rule 28(1)(d) EPC 1973, the invention shall only be regarded as sufficiently disclosed if "*where the biological material has been deposited by a person other than the applicant, the name and address of the depositor are stated in the application and a document is submitted satisfying the European Patent Office that the latter has authorised the applicant to refer to the deposited biological material in the application and has given his unreserved and irrevocable consent to the deposited material being made available to the public in accordance with this Rule.*" Rule 28(2) (a) EPC 1973 allows the above information to be submitted *"within a period of sixteen*

months after the date of filing the application, or, if priority is claimed, after the priority date...".

25. As apparent from the above facts, neither Rule 28(1) (d) nor Rule 28(2) (a) EPC 1973 has been complied with.

26. The only document on file directly confirming authorization of the applicant to refer to the deposited microorganism is declaration D8 of the inventor filed on 9 February 2016. This declaration has however been made and submitted outside the time limit of sixteen months from the priority or filing date set by Rule 28(2) (a) EPC 1973. It can therefore not help the appellant's case.

27. In examination and in appeal proceedings, the appellant furthermore argued that the above deficiencies had been remedied within the period stipulated under Rule 28(2) (a) EPC 1973 through the submission on 17 September 2009 of a declaration by Professor Nylund.

28. The declaration submitted to the EPO on 17 September 2009 shows that on 24 January 2007 an authorisation was given to the depositary institution by Professor Nylund to furnish samples under the provisions of the Budapest treaty to any requester for a period of 20 years after the date of deposit. This authorisation has been submitted to the depositary institution on 5 February 2007.

29. This declaration only concerns the furnishing of samples and does not expressly authorise the patent applicant to refer to the deposited material in the patent application, as required by Rule 28(1)(d) EPC 1973. Moreover, this authorisation is valid only as of 24 January 2007, and thereby cannot count as an

authorisation given at the filing date of the priority document (see below).

30. Rule 28(2) (a) EPC 1973 concerns the submission of the information specified under Rule 28(1)(d) EPC 1973. It allows the patent applicant to submit information about the authorisation to refer to the deposited material up to sixteen months after the actual priority or filing date. This rule, however, does not change the substantive requirements of Rule 28(1) d) EPC 1973, namely that the authorisation has to be given at the priority date, or at the filing date. The authorisation dated 24 January 2007 cannot cover acts allegedly performed before this date no matter when it has been supplied to the Office. In other words, Rule 28(2) (a) EPC 1973 allows the authorization to be ***submitted*** *to the Office* until such later date but it does not allow the authorisation to be ***granted*** up to 16 months after the filing or priority date. If this were not so this would create a fictitious, retroactive authorisation where in fact there was none.

31. In conclusion, neither the applicant of the priority application, nor the applicant of the international application were properly authorised by the depositor of the microorganism to refer to the deposited material in accordance with Rule 28(1)(d) EPC 1973, since the depositor's declaration of 8 February 2016 was submitted outside the 16 months from the priority and the international filing date, respectively, as requested by Rule 28(2) (a) EPC 1973. The declaration of 24 January 2007 is no authorisation on behalf of either of the two applicants and post-dates the priority and the filing date in any case. Furthermore, the declaration of 24 January 2007 reached the Office

on 17 September 2009 which is again outside the 16 months time limit set by Rule 28(2) (a) EPC 1973.

32. Since the claimed microorganism cannot be re-isolated readily and without unde burden (cf. points 4 to 16 above) and since no documents were submitted to the European Patent Office within the time limits foreseen by Rule 28(2) (a) EPC 1973 that the applicants of the priority and of the patent application were authorized to refer to the microorganism deposited under accession number CNCM I-3511 at the CNCM (Institut Pasteur, Paris), the claimed invention is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Wolinski M. Wieser

Decision electronically authenticated