Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 19 September 2018

Case Number: T 1305/14 - 3.3.04

Application Number: 07871240.3

Publication Number: 2076280

IPC: A61K39/00, A61K39/145, A61K39/395

Language of the proceedings: EN

Title of invention:
Feline Influenza Vaccine and Method of Use

Applicant:
Intervet International BV

Headword:
Vaccination of cats against H3N8 influenza A virus/INTERVET

Relevant legal provisions:
EPC Art. 123(2), 54, 56, 83, 84

Keyword:
Sole Request - requirements of the EPC met (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1305/14 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 19 September 2018

Appellant: (Applicant)	Intervet International BV Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Representative:	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 28 February 2014 refusing European patent application No. 07871240.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	G. Alt
Members:	A. Chakravarty
	M. Blasi

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division to refuse European patent application EP 07 871 240.3, entitled "*Feline influenza vaccine and method of use*". The application was filed as an international patent application, published as WO 2008/070332.

II. The examining division considered a single claim request and decided that the claims of this request met the requirements of Article 84 EPC (see minutes of the oral proceedings, point 16), but not those of Article 56 EPC. No decisions regarding Articles 123(2), 54 and 83 were taken.

III. The reason for the lack of compliance with the requirements of Article 56 EPC, given in the decision under appeal, was that the closest prior art could be represented by document D19 which disclosed the use of a H3N8 vaccine for the protection of horses. The problem to be solved was the provision of a product for the protection from influenza infection in felines and the claimed solution to this problem was obvious since (i) vaccines against H3N8 infection were known, (ii) influenza strain H3N8 "*was known from D2 and D3 to be enzootic and possibly panzootic*" and (iii) "*[a]dapting current horse vaccines for other animals to prevent the spread of H3N8 is in fact suggested in D3*" (see point 2.5 of the decision under appeal).

IV. With the statement of grounds of appeal, the appellant submitted a claim request, amended with respect to that considered by the examining division, having a one independent claim and five dependent claims.

V. Independent claim 1 of the claim request reads:

"1. Vaccine comprising a therapeutically effective amount of whole inactivated H3N8 influenza virus particles and/or H3N8 influenza virus-like particles and/or H3N8 influenza defective virus particles, an adjuvant and a pharmaceutically acceptable excipient, for use in protecting a feline from shedding influenza H3N8 virus caused by an influenza H3N8 infection, said use comprising the step of administering said vaccine to a feline."

The dependent claims specify that virus particles are from more than one isolate, the route and number of administration(s) and other antigens of feline pathogens that the vaccine may comprise.

VI. The board issued a communication informing the appellant of its preliminary opinion that the appeal appeared allowable and that the subject-matter of the claim request filed with the notice and statement of grounds of appeal met the requirements of Article 56 EPC and also of Articles 54, 83, 84 and Article 123(2) EPC. Furthermore, the board indicated its intention to set the decision under appeal aside and to remit the case to the examining division with an order to grant a patent on the basis of the pending set of claims with a description to be adapted thereto. The appellant was asked to clarify the requests in the appeal.

VII. The appellant replied to the board's communication confirming that the course of action described therein complied with their request. They also confirmed that if the board set aside the decision under appeal and remitted the case to the examining division with an

order to grant a patent on the basis of this set of claims with a description to be adapted thereto, there was no need to hold oral proceedings.

VIII. The following documents are mentioned in this decision:

D1: Gore T.C. *et al.*, Veterinary Therapeutics, 1 September 2006, vol. 7, no. 3, pages 213 - 222.

D2: Crawford P.C. *et al.*, Science, 21 October 2005, vol. 310, no. 5747, pages 482 - 485.

D3: Enserink M., Science, 30 September 2005, vol. 309, no. 5744, page 2147.

D5: Kuiken T. *et al.*, Science, 8 October 2008, vol. 306, no. 5694, page 241.

D6: Songserm T. *et al.*, Emerging Infectious Diseases, 1 April 2006, vol. 12, no. 4, pages 681 - 683.

D18: Daly J. *et al.*, Veterinary Research, 1 July 2004, vol. 35, no. 4, pages 411 - 423.

D19: Newton J.R. *et al.*, Preventive Veterinary Medicine, 1 July 2000, vol. 46, no. 2, pages 129 - 141.

IX. The arguments of the appellant, insofar as relevant for the present decision, are dealt with in the reasons for the decision, below.

X. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims filed with the statement of grounds of appeal.

Reasons for the Decision

1. The appeal is admissible.

Article 123(2) EPC - Amendments

2. The subject-matter of the six claims of the sole request is based on the application as filed ("the application") as follows.

3. Basis for "*a vaccine comprising a therapeutically effective amount of whole inactivated H3N8 influenza virus particles and/or H3N8 influenza virus-like particles and/or H3N8 influenza defective virus particles*" in claim 1 can be found in claims 1, 2, 3 and 5 of the application.

4. The features that the vaccine comprises an adjuvant and a pharmaceutically acceptable excipient are to be found, *inter alia*, in paragraph [51] of the application.

5. The claim further defines (i) the constituents of the vaccine as "comprising a therapeutically effective amount of whole inactivated H3N8 influenza virus particles and/or H3N8 influenza virus-like particles and/or H3N8 influenza defective virus particles, an adjuvant and a pharmaceutically acceptable excipient", (ii) that the vaccine's purpose is the prevention of shedding of virus "caused by an influenza virus infection" and (iii) that the use comprises administering the vaccine to a feline animal.

6. That the subject-matter of the invention is directed to a vaccine for use in protecting a feline animal from shedding influenza virus and that the cause of the

shedding is a previous infection with that virus is derivable from paragraphs [6] and [7] of the application in the section headed "*Summary of the invention*", which state that the invention relates to "*vaccines and methods for protecting felines from influenza [virus infection]*" and that protection from infection also means "*preventing the spread of infection from one feline to another feline*".

7. That the use aimed at is protection from shedding is further supported by paragraphs [63], [74], [75], [77] and [78] of the application, in particular paragraphs [74] to [78] where virus shedding is measured in the context of immunisation experiments.

8. That the vaccine of the invention has the constituents according to claim 1 and that the use includes its administration is derivable from claims 1 to 3 and 5 and paragraph [51] of the application.

9. The subject-matter of claim 2 is disclosed in claims 1 to 5 of the application, while the subject-matter of claims 3 to 6 is disclosed in claims 6 to 9 of the application.

10. Thus, the claims meet the requirements of Article 123(2) EPC.

Article 84 EPC - clarity and support in the description

11. The examining division considered that the claims of the main request met the requirements of Article 84 EPC (see section II above). The board considers this finding to be correct and also that the amendments to claim 1 do not generate unclarity.

12. Thus, claims 1 to 6 meet the requirements of Article 84 EPC.

Article 54 EPC - Novelty

13. In the decision under appeal, the examining division gave no reasoning on the novelty of the subject-matter of claims 1 to 6. The board considers that the subject-matter of present claims 1 to 6 is novel when taking the disclosure of the prior art documents in the file of the examining division into account - none of them discloses a vaccine for use in protecting a feline against H3N8 infection.

14. The requirements of Article 54 EPC are therefore fulfilled.

Article 83 EPC - Disclosure of the invention

15. In the decision under appeal, the examining division gave no reasoning on the sufficiency of the disclosure of the invention claimed in the application. The board considers the requirements of Article 83 EPC to be met for the following reasons.

16. Claim 1 is in the format of a purpose-limited product claim provided for by Article 54(5) EPC and is directed to a vaccine for (the second medical) use of protecting a feline from shedding influenza H3N8 virus caused by an influenza H3N8 infection.

17. The requirements of Article 83 EPC are complied with if the patent application discloses the claimed invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In the present case this means that the skilled person at the

relevant date of the application should be able to make the vaccine to be used and "*the application must disclose the suitability of the product to be manufactured for the claimed therapeutic application*", i.e. for protecting a feline animal from shedding influenza H3N8 virus caused by an influenza H3N8 infection, unless "*this is already known to the skilled person at the priority date*", see Case Law of the Boards of Appeal of the European Patent Office, 8th edition, 2016, II.C.6.2.

18. The constituents of the claimed vaccine are "whole inactivated H3N8 influenza virus particles and/or H3N8 influenza virus-like particles and/or H3N8 influenza defective virus particles" and are all components well known to the skilled person. Indeed, a commercial equine H3NA influenza A vaccine was available comprising whole inactivated H3N8 influenza virus (see e.g. paragraph [33] of the application). The board is therefore satisfied that the skilled person was able, at the relevant date, to make the vaccine as claimed.

19. The application also discloses both that feline animals are susceptible to H3H8 influenza virus infection (Example 1) and that they can be effectively vaccinated against said infection using an H3N8 virus vaccine (Example 2), thus preventing shedding of that virus.

20. Therefore, in respect of invention of claims 1 to 6, the application meets the requirements of Article 83 EPC.

Inventive step - Article 56 EPC

Closest prior art

21. The closest prior art for assessing inventive step is normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications (Case Law of the Boards of Appeal of the European Patent Office, 8th edition, 2016, I.D.3.1).

22. The purpose of the claimed vaccine is protecting feline animals, including cats, from shedding of influenza H3N8 virus thereby also protecting other animals from being infected by influenza H3N8 by said feline animals.

23. Taking the disclosure of the prior art documents in the file of the examining division into account, the board has the following considerations.

24. Document D19, held by the examining division to represent the closest prior art, discloses the vaccination of horses against influenza A infection using a commercial vaccine containing whole inactivated H3N8 influenza virus of the strains A-equine-2/Miami/63 and A/equine-2/Newmarket-2/93 (see also document D18, page 412). The purpose of the vaccine disclosed is the protection of horses against H3N8 influenza virus.

25. Document D1 on the other hand discloses the vaccination of cats with feline origin attenuated virus components of feline calicivirus (FCV), feline rhinotracheitis virus (FRV) and feline panleukopenia virus (FPV) with

the aim of protecting them against those viruses and the resulting infections of their upper respiratory tracts (see page 214, left hand column, final paragraph ff). The vaccinations disclosed in both document D19 and D1 inherently also prevent virus shedding and thus reduce the potential for virus spread.

26. Both document D1 and the application have the aim of vaccinating cats against viral infections of the upper respiratory tract. Document D19 has the aim of protecting horses against H3N8 influenza virus infection. Given the common aims of the vaccination disclosed in document D1 and the invention at hand, document D1 must be regarded as closer to the claimed subject-matter than document D19. Thus, contrary to the view expressed by the examining division in the decision under appeal (see section 2.1), document D1 is considered to represent the closest prior art for the claimed subject-matter.

The objective technical problem

27. The difference between the closest prior art and the claimed subject-matter is the nature of the viral infection that the feline animals are vaccinated against, i.e. influenza A virus subtype H3N8, instead of FCV, FRV and FPV. The technical effect associated with this difference is the ability to protect feline animals against influenza H3N8 infection and as a result also preventing the animals from shedding that virus.

28. In view of the above differences and the technical effects thereof, the board considers that the technical problem to be solved by the subject-matter of claim 1

may be formulated as the provision of a further vaccine for protection against infection with a virus responsible for an upper respiratory tract infection in cats and other feline animals and its subsequent shedding.

Obviousness

29. The skilled person starting from the disclosure in document D1 of vaccines for use in protecting cats against FCV, FRV and FPV and faced with the problem formulated above, would have found no suggestion in that document that would have led them seek vaccines against H3N8 influenza virus, the document being exclusively concerned with vaccination against the three viruses mentioned above.

30. It was known from the disclosure of documents D5 and D6 (see titles) that cats were susceptible to the avian influenza virus H5N1 and from document D19 that H3N8 influenza virus infected horses, which could be protected by vaccination with a commercially available vaccine comprising whole inactivated H3N8 influenza virus (see section 2.2). It was further known, *inter alia* from documents D2 and D3, that H3N8 influenza virus was also able to infect dogs (see titles).

31. However, there is no disclosure in any of the above mentioned documents that would have led the skilled person to believe that cats and feline animals were susceptible to infection by the H3N8 influenza virus. The skilled person would have known from document D2 that inter-species transmission of influenza A virus was not common. It describes the inter-species transmission complete of equine H3N8 equine influenza virus from horses to dogs as "*unprecedented*" (see page

482, right column). In view of this, the board concludes that the claimed subject-matter was not obvious to the skilled person at the relevant date of the application, starting from the closest prior art, represented by document D1, even when this document is considered in the light of the disclosure of any of documents D2, D3, D5, D6 or D19.

32. The examining division considered that the skilled person, at the relevant date, would have known from documents D2 and D3 that strain of H3N8 was enzootic, and possibly panzootic, and that it was therefore not surprising that this influenza strain, like others, could infect and replicate in felines.

33. The board is not persuaded by this reasoning. When *inter* species transmission is mentioned in documents D2 and D3, a danger of an infection of humans is perceived, although no such transmission had been documented. The last sentence of document D2 reads: "*Evidence of canine influenza infection in pet dogs, a primary companion animal for humans, raises the possibility that dogs may provide a new source for transmission of novel influenza A viruses to humans.*" The last sentence of document D3 is along the same lines: "*The CDC researchers plan to test people who were in contact with sick dogs as soon as they have approval from an ethics panel. If any of them turns out to be infected - even asymptomatically - says Perdue, "that would raise a big red flag*"."

34. Thus, while both documents D2 and D3 disclose the infection of dogs with equine influenza virus H3H8 and raise concern over the potential of transmission to humans, there is no evidence in either of these documents that the virus was able to infect any animal

species other than horses and dogs. In particular, there is no disclosure or suggestion in either document that feline animals might be susceptible to infection.

35. The above considerations apply equally to the subject-matter of dependant claims 2 to 6.

36. The board therefore concludes that the subject-matter of claims 1 to 6 meets the requirements of Article 56 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 with the order to grant a patent on the basis of the set of claims filed with the statement of grounds of appeal and a description to be adapted thereto.

The Registrar: The Chairwoman:

P. Cremona G. Alt

Decision electronically authenticated