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Datasheet for the decision of 21 February 2018

Case Number: T 1819/13 - 3.3.01

Application Number: 03723787.2

Publication Number: 1485040

IPC: A61D7/00, A61K31/545, A61K9/08, A61P31/04

Language of the proceedings: EN

Title of invention:
METHOD OF ADMINISTERING AN INJECTABLE ANTIBIOTIC TO THE EAR OF AN ANIMAL

Patent Proprietor:
Zoetis Services LLC

Opponent:
Intervet International BV

Relevant legal provisions:
EPC Art. 53(c), 54, 56, 114(2)
RPBA Art. 12(4)

Keyword:
Method for therapeutic treatment of the animal body - (no)
Novelty - (yes) - Swiss-type claim
Inventive step - (yes)
Late-filed document not admitted in first-instance proceedings

This datasheet is not part of the Decision.
It can be changed at any time and without notice.

Decisions cited:
G 0005/83, G 0002/08, T 1554/11

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Case Number: T 1819/13 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 21 February 2018

Appellant: (Opponent)	Intervet International BV Wim de Koerverstraat 35 5830 AA Boxmeer (NL)
Representative:	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Respondent: (Patent Proprietor)	Zoetis Services LLC 10 Sylvan Way Parsippany, NJ 07054 (US)
Representative:	Dörries, Hans Ulrich df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstrasse 16 80333 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 24 June 2013 rejecting the opposition filed against European patent No. 1485040 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	R. Hauss
	L. Bühler

Summary of Facts and Submissions

I. The publication of the grant of European patent No. 1 485 040 took place on 2 November 2006 (Bulletin 2006/44). The patent was granted with fifteen claims. Claim 1 reads as follows:

"1. Use of an antibiotic for the manufacture of a medicament for use in treating or preventing a bacterial infection in an animal by injection of the medicament subcutaneously at the junction of a pinna with the cranium of the animal."

II. The patent was subsequently opposed under Article 100(a) and (b) EPC on the grounds that the claimed subject-matter was not patentable pursuant to Article 52(4) EPC 1973, lacked novelty and inventive step and was insufficiently disclosed.

III. The patent proprietor's main request was the rejection of the opposition.

IV. The documents cited in the course of the opposition proceedings included:

D1: Neundorf/Seidel: Schweinekrankheiten, 3rd edn, Gustav Fischer Verlag, Jena 1987, pages 335, 338, 694-695

D2: WO 98/41207 A1

D6: New Zealand Veterinary Journal 43(2), 67-69 (1995)

D7: AJVR 61(10), 1169-1172 (2000)

D8: Cattlemen's Day 2000, 70-72

D10: Rev. Méd. Vét. 144(7), 599-605 (1993)

D11: WO 94/20505 A1

D15: Feed Lot Magazine Online, VII(5), Sept./Oct. 1999, "Clostridial ear injection site proven to reduce lesions"

V. The present appeal lies from the decision of the opposition division, announced on 11 April 2013 and posted on 24 June 2013, rejecting the opposition.

VI. According to the decision under appeal, document D15, submitted by the opponent during oral proceedings on 11 April 2013, was not admitted into the proceedings, since it was late-filed and did not appear to provide additional relevant information (Article 114(2) and Rule 116(1) EPC).

The opposition division held that none of the grounds for opposition raised by the opponent were prejudicial to the maintenance of the patent as granted:

- The opponent had not substantiated with verifiable evidence the existence of serious doubts as to the reproducibility of the claimed subject-matter (Article 100(b) EPC).

- The claims were correctly drafted in the "Swiss-type" format and thus they were not directed to a therapeutic method of treatment excluded from patentability (Article 53(c) EPC).

- Document D1 did not contain a specific disclosure anticipating the combination of technical features defined in claim 1 as granted. The claimed subject-matter differed from the disclosure of documents D2 and D11 in the technical feature indicating the specific site of injection (Articles 52(1) and 54 EPC).

- Document D2, which disclosed subcutaneous injection of an antibiotic medicament into the posterior of the ear of an animal, represented the closest prior art. The objective technical problem was to provide equally effective treatment of animals with antibiotics combining improved ease of administration with a significant reduction of residual drug levels in the

edible carcass. The technical solution of providing a medicament which was to be administered by subcutaneous injection at the junction of a pinna with the cranium of the animal was not obvious in the light of the available prior art, which did not suggest this particular site of injection as a solution to the technical problem of reducing residual drug levels (Articles 52(1) and 56 EPC).

VII. The opponent (appellant) lodged an appeal against that decision.

In the statement setting out the grounds of appeal, the appellant relied on the previously raised grounds under Article 100(a) EPC, but did not pursue the ground under Article 100(b) EPC. The appellant's arguments may be summarised as follows:

Exception to patentability

The use of the injection site specified in claim 1 of the patent in suit did not result in a new therapeutic effect of the antibiotic medicament. Hence, the exclusion from patentability under Article 53(c) EPC could not be circumvented by drafting the claim in the "Swiss-type" format as established by Enlarged Board of Appeal decision G 5/83 (OJ EPO 3/1985, 64, Order: 2). Irrespective of its formal disguise, the claim was actually directed to a method for treatment of the animal body within the meaning of Article 53(c) EPC, and therefore not allowable.

Novelty

The subject-matter of claim 1 as granted lacked novelty in view of documents D2 and D11, both disclosing the administration of antibiotics to animals (including cattle, swine, sheep and goats) by subcutaneous

injection. While the specific injection site at the junction of a pinna with the cranium was a new technical feature, injection at that site did not result in a specified new therapeutic application within the meaning of decision G 5/83, since the therapeutic effect of the antibiotic treatment remained the same. Using the injection site according to the patent in suit merely gave rise to non-therapeutic effects, namely the avoidance of drug residues in the meat of slaughtered animals. As a consequence, the claim was actually directed to the use of an antibiotic for the manufacture of a medicament which was merely suitable for the administration method using the specified injection site. Hence, novelty could not be established by defining the injection site.

Admission of document D15

Document D15 should be admitted into the appeal proceedings because of its high relevance for the evaluation of inventive step.

Inventive step

Starting from the teaching of document D2, the technical problem to be solved was to provide an alternative injection site for antibiotics with improved ease of administration compared with administration in the posterior of the ear. Selecting the junction of a pinna with the cranium as the injection site in order to solve that problem would have been obvious to the person skilled in the art in view of documents D1, D6, D7, D8, D10 and D15 which disclosed subcutaneous injection to the area of the ear and the ear base of animals without the need for a specific restraining mechanism. Thus it was known that it was fairly easy to administer injections at the ear

base. The junction of the pinna and the cranium was part of the area of the ear and the ear base. No specific benefit could be attributed to the selection of that specific site for injection beyond the fact that it was - together with the ear base - removed at slaughter together with the ear.

VIII. With letter dated 10 March 2014 the respondent (patent proprietor) requested that the appeal be dismissed and filed five sets of claims: auxiliary requests 1 to 5.

IX. In a communication issued in preparation for oral proceedings and advising the parties of its preliminary opinion, the board made the following points:

- Since the appellant had not contested the decision under appeal with regard to the conclusions drawn under Article 100 (b) EPC, the question of sufficiency of disclosure was not a subject of the appeal proceedings.

- Claim 1 as granted was drafted in the "Swiss-type" format; thus it was not directed to a method of treatment of the human or animal body excluded from patentability pursuant to Article 53(c) EPC.

- The claimed subject-matter was novel over the disclosure of documents D2 and D11, since it differed therefrom in the specified site of injection, namely the junction of a pinna with the cranium.

- Starting from the technical teaching of document D2, the objective technical problem with regard to claim 1 as granted could be defined as providing the use of an antibiotic for the manufacture of a medicament for use in treating or preventing a bacterial infection in an animal by an alternative method of administration.
It was known from documents D1 and D2 that the area of the posterior of the ear and of the ear base was

suitable for the subcutaneous injection of antibiotics in swine and other animals. There appeared to be no indication in the prior art of a technical prejudice against injection at the junction of a pinna with the cranium.

X. With letter of 21 December 2017, the respondent filed amended sets of claims: auxiliary requests 1 to 9.

Auxiliary request 1 consists of fourteen claims. Claim 1 reads as follows:

"1. Use of an antibiotic for the manufacture of a medicament for use in treating or preventing a bacterial infection in an animal by injection of the medicament subcutaneously at the junction of a pinna with the cranium of the animal, wherein the animal is selected from cattle, swine, sheep and goats."

The remaining claims 2 to 14 are dependent claims.

XI. By letter of 12 January 2018, the appellant stated its intention not to be represented at the oral proceedings scheduled for the following month, maintained the request that the patent be revoked and, for the rest, referred to its written submissions.

The appellant did not present any comments with regard to auxiliary requests 1 to 9 or in reply to the board's preliminary opinion.

XII. With letter of 19 February 2018, the respondent provided an amended version of auxiliary request 2 in which certain dependent claims had been modified.

XIII. Oral proceedings before the board took place on 21 February 2018 in the absence of the appellant.

During the oral proceedings, the respondent withdrew its main request.

XIV. The respondent's arguments with regard to auxiliary request 1 may be summarised as follows:

Exception to patentability

The claims in question were drafted in the accepted "Swiss-type" format which had been specifically established by EPO case law to avoid conflicts with the prohibition set out in Article 52(4) EPC 1973 and Article 53(c) EPC 2000.

Novelty

The specified injection site was a characterising functional technical feature of the claimed subject-matter which was not anticipated in documents D2 or D11.

Inventive step

In comparison with the subcutaneous injection of an antibiotic in the posterior of the ear, administration at the junction of a pinna with the cranium was easier to accomplish, safer and, according to example 1 of the patent in suit (which reported data from tests on beef cattle injected with a suspension of ceftiofur crystalline free acid and subsequently slaughtered), it provided therapeutic equivalence coupled with short withdrawal times before slaughter and low drug residue levels in the edible carcass. Since the animals to be treated (namely cattle, swine, sheep or goats) were anatomically similar and were all livestock typically used for meat production, it was credible that these

advantages were available over the entire scope claimed.

Starting from the teaching of document D2, the technical problem to be solved was thus the provision of an equally safe and effective treatment of bacterial infection in an animal, which was safe and easier to administer while achieving comparable drug residue levels in the carcass and short withdrawal times before slaughter.

It could not have been derived from any of the cited prior-art documents that subcutaneous administration at the site chosen for injection according to claim 1 provided therapeutic equivalence to the injection method disclosed in document D2, or that the amount of drug residue in the edible carcass would still be acceptable when the medicament was injected at a site closer to the neck of the animal. Neither document D1 nor any other document on file disclosed the junction of a pinna with the cranium as the precise injection site, nor did those documents therefore disclose the benefit of improved ease of administration which could be achieved when using that site for injection.

XV. The appellant had requested in writing that the decision under appeal be set aside and that European patent No. 1485040 be revoked. The appellant had further requested that document D15 be admitted into the appeal proceedings.

XVI. The respondent requested that the patent be maintained according to the claims of auxiliary request 1 filed with letter dated 21 December 2017, or, alternatively, the claims of auxiliary request 2 filed with letter dated 19 February 2018 or of one of auxiliary requests 3 to 9, all filed with letter dated 21 December 2017.

Reasons for the Decision

1. Amendments (Article 123(2) and (3) EPC)

1.1 Claim 1 of auxiliary request 1 is identical to claim 1 of the patent as granted, except that it additionally specifies that the animal is selected from cattle, swine, sheep and goats. Dependent claims 2 to 14 of auxiliary request 1 correspond to claims 3 to 15 of the patent as granted. Thus the amended set of claims has a more restricted scope than the granted version.

1.2 The basis in the application as filed for the amendment of claim 1 is found in the general disclosure of cattle, swine, sheep and goats on page 1, line 6, and page 4, lines 20 to 21, of the description.

1.3 Hence the board sees no reason for objection under Article 123(2) or (3) EPC.

2. Exception to patentability (Article 53(c) EPC)

2.1 From 13 December 2007, Article 52(4) EPC 1973 (see point II above) was superseded by Article 53(c) EPC 2000 which also applies to European patent applications pending at the time of its entry into force and to European patents already granted at that time (see Article 1 of the Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the EPC of 29 November 2000). Hence, Article 53(c) EPC 2000 (hereinbelow: Article 53(c) EPC) applies to the patent in suit (see point I above).

2.2 Pursuant to Article 53(c) EPC, "European patents shall not be granted in respect of [...] methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

2.3 Claim 1 of auxiliary request 1 (see point X above) is however not directed to a method for treatment as defined in Article 53(c) EPC, but to the use of a substance (namely an antibiotic) for the manufacture of a medicament for a therapeutic application (namely treating or preventing a bacterial infection in an animal by subcutaneous injection at a specified injection site).

2.4 Thus the wording of the claim conforms to the so-called "Swiss-type" format as instituted by decision G 5/83 of the Enlarged Board of Appeal, which ruled (see G 5/83, Order: 2) that "a European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application". The appellant did not dispute that this is a valid claim format for the patent in suit (see Enlarged Board of Appeal decision G 2/08, OJ EPO 10/2010, 456, Reasons: 7.1.4).

2.5 The appellant essentially argued that the characterising feature of claim 1 relating to the specific site for subcutaneous injection (namely the junction of a pinna with the cranium) did not represent a true therapeutic feature because it could only give rise to non-therapeutic effects, and therefore it did not result in a new therapeutic application or use of

the antibiotic. For that reason, the exception mentioned in Article 53(c) EPC ("this provision shall not apply to products, in particular substances or compositions, for use in any of these methods") did not apply, and consequently the claim was not patentable pursuant to Article 53(c) EPC.

2.6 This argument cannot succeed, for the following reasons:

(a) It is self-contradictory: If it were indeed correct that the claim relates to a non-therapeutic use, then it could not be in violation of Article 53(c) EPC.

(b) Actually, the claim does however relate to a therapeutic use but is correctly drafted in the Swiss-type format which is not prohibited by Article 53(c) EPC. The Swiss-type format is valid for the patent in suit and is established as a patentable claim format for second (or further) medical uses (see point 2.4 above), subject to compliance with the other provisions of the EPC, in particular novelty and inventive step under Articles 54 and 56 EPC (in this context, see also decision T 1554/11 of 23 July 2015, Reasons: 6).

(c) The therapeutic application mentioned in claim 1 is the treatment of an animal by injection of a medicament comprising an antibiotic. The site of injection is an integral technical element of the administration of the medicament and thus of the therapeutic application. Whether this feature might also give rise to non-therapeutic effects has no impact on the established eligibility of the Swiss-type claim format for overcoming the exception to patentability under Article 53(c) EPC.

(d) Points (a) to (c) equally apply to the dependent claims.

2.7 In view of these considerations, the board concludes that the subject-matter of the claims of auxiliary request 1 is not excluded from patentability pursuant to Article 53(c) EPC.

3. Novelty (Articles 52(1) and 54 EPC)

3.1 As established in point 2.6(c) above, the purpose defined in claim 1 of auxiliary request 1 (namely "treating or preventing a bacterial infection in an animal by injection of the medicament subcutaneously at the junction of a pinna with the cranium of the animal, wherein the animal is selected from cattle, swine, sheep and goats") is a therapeutic application within the meaning of Enlarged Board of Appeal decision G 5/83.

3.2 According to that decision and the established case law of the Boards of Appeal of the EPO, the therapeutic indication addressed in a Swiss-type claim relating to a second or further medical use is regarded as a functional technical feature, to be taken into account in the assessment of novelty and inventive step (see G 5/83, Reasons: 20 and 21; Case Law of the Boards of Appeal of the European Patent Office, 8th edition 2016, I.C.7.2.1: "special approach to the derivation of novelty", and I.C.7.2.4). In that context, a different mode of administration can render such a claim novel.

3.3 Hence, contrary to the appellant's view, a disclosure in a prior-art document of a medicament which is merely suitable for subcutaneous injection at the junction of a pinna with the cranium, without a disclosure of that

same injection site, does not anticipate the subject-matter of claim 1.

3.4 The appellant did not contest the fact that neither document D2 nor document D11 discloses the junction of a pinna with the cranium as the injection site.

3.5 The appellant's argument that the alleged technical effect concerning a reduction in drug residue levels in the animals after slaughter was not therapeutic (since it did not result in a therapeutic benefit for the treated animal) is not relevant in the context of novelty. The assessment of novelty merely consists in establishing whether the claimed combination of technical features is anticipated in the prior art.

3.6 Thus, the therapeutic indication specifying that the injection takes place at the junction of a pinna with the cranium establishes the novelty of the claims of auxiliary request 1 relative to documents D2 and D11, since the bacterial infection is to be prevented or treated by injection at an injection site which is not anticipated in those documents.

4. Inventive step (Articles 52(1) and 56 EPC)

Starting point for the assessment of inventive step

4.1 The board agrees with both parties that document D2 represents the closest prior art. According to document D2, an antibiotic is injected subcutaneously in the posterior of the ear of an animal, e.g. the middle third of the posterior of the ear (D2: see claims 1, 7; page 11). The animals targeted by D2 are, in particular, cattle, swine, sheep and goats (see D2: page 1, lines 4 to 5).

Technical problem and solution

4.2 As established above, the subject-matter of claim 1 of auxiliary request 1 differs from the disclosure of document D2 in the feature specifying that the site of subcutaneous injection is the junction of a pinna with the cranium of the animal.

4.3 While experimental data is provided in the patent in suit only with regard to one drug used on cattle (ceftiofur free acid in example 1, paragraph [0028]), the appellant did not contest that the antibiotic treatment is effective when the medicament is injected at the junction of a pinna with the cranium.

4.4 The respondent contended that the choice of the injection site according to the patent in suit, unlike that of D2, allowed the handler to grip the entire ear with one hand to stabilise the head of the animal, and to insert the needle with the other hand; furthermore, since the injection accessed a cavity which could accommodate the injection volume, no massaging of the bleb was required (unlike in D2: see page 12, lines 7 to 16), and the risk of self-injection was avoided. Finally, the risk of hitting blood vessels (which occupied a rather large proportion of the pinna), ear tags or implants was avoided. The board considers that these advantages relative to the injection method of document D2 are sufficiently plausible for the group of anatomically similar animals which consists of cattle, swine, sheep and goats. The appellant did not contest that the injection site at the junction of a pinna with the cranium provided improved ease of administration.

4.5 Hence, a technical problem to be solved when starting from the teaching of document D2 is the use of an antibiotic for the manufacture of a medicament for use

in treating or preventing a bacterial infection in an animal by a method of administration which provides improved ease of administration.

4.6 The board is satisfied (see point 4.4 above) that the problem is solved by the choice of the junction of a pinna with the cranium as the site for subcutaneous injection of the antibiotic.

Obviousness of the solution

4.7 While document D2 focuses on the administration of antibiotics by injection into the posterior of the ear, document D11, which relates to the use of ceftiofur free acid - an antibiotic listed in the patent in suit - as a veterinary antibiotic, mentions subcutaneous injection without specifying an injection site (see D11: claim 11). Thus there is no incentive to be found in documents D2 or D11 to consider the junction of a pinna with the cranium as an injection site providing improved ease of administration.

4.8 Documents D6, D7, D8 and D10 are concerned with the administration of vaccines or antiparasitic drugs to cattle or swine and thus do not relate to the administration of antibiotics. While it is mentioned in those documents that the drugs in question are administered at the base of the ear, in the ear or behind the ear, these terms are, as conceded by the appellant, less specific than the definition "junction of a pinna with the cranium" employed in claim 1 of auxiliary request 1. Nor do documents D6, D7, D8 or D10 mention the issue of ease of administration. Hence the board considers that the person skilled in the art seeking to solve the above-mentioned technical problem would not necessarily have been guided to consult any of documents D6, D7, D8 or D10, and in any case would

not have been able to derive from those documents the specific suggestion to consider the junction of the pinna with the cranium as an injection site which might be preferable for increased ease of administration.

4.9 Document D1 is an extract from a textbook on the diseases of swine. It teaches (see pages 694 to 695) that different methods for administering injections may be used for treating swine, including subcutaneous injection. The most common and practical sites of administration for subcutaneous injection are at the ear base, at the elbow and at the knee of the animal. The description of the injection site at the ear base, said to be the site most commonly used for treating larger animals, corresponds in the board's opinion to a location at the junction of the pinna with the cranium, since it is mentioned that the site is caudal to the ear base but very close to the pinna (see D1: page 694, column 2, paragraphs 1 to 3). On page 338 of D1 it is mentioned, in the context of infectious diseases and antibiotic treatment, that subcutaneous injection at the base of the ear has certain advantages in comparison with intramuscular injection in animals destined for slaughter.

Document D1 does not however discuss the issue of comparative ease of administration of different injection sites in and around the ear, and, as mentioned above, it discloses various routes for administering injections to swine, and several different locations deemed to be suitable for subcutaneous injection.

In view of this, the board comes to the conclusion that the information presented in document D1 does not contain a straightforward pointer and could thus not have suggested to the person skilled in the art seeking

to solve the above-mentioned technical problem (see point 4.5) that subcutaneous injection at the junction of a pinna with the cranium would improve ease of administration in comparison with the injection site favoured in document D2.

4.10 As a consequence, the subject-matter of claim 1 of auxiliary request 1 and of the dependent claims involves an inventive step within the meaning of Article 56 EPC.

4.11 In view of this outcome, it is not necessary to examine whether the alleged advantages of short withdrawal times and low drug residue levels in the edible carcass are obtained over the entire scope of the claims.

5. Admission of document D15 into the appeal proceedings (Article 114(2) EPC, Article 12(4) RPBA)

5.1 Like document D7, document D15 relates to clostridial vaccinations. The opposition division did not admit document D15 into the proceedings, because the information it provided was not more relevant than the content of document D7 already on file, and its submission at a very late stage of the proceedings had not been occasioned by any new development in the case (see point VI above and point 2 in the decision under appeal).

5.2 Late submission and *prima facie* relevance are appropriate criteria for deciding whether new evidence should be admitted; thus the board concludes that the opposition division exercised its discretion correctly in not admitting document D15.

5.3 Moreover, in respect of *prima facie* relevance, the board takes the view that D15, if admitted into the

appeal proceedings, would not make a difference in the assessment of inventive step: while using the term "base of the ear", D15 also states that "the injection is placed on the back of the ear in the bottom one-third". Thus D15 could at most corroborate the finding (see point 4.8 above) that the expression "base of the ear" as used in the prior art does not necessarily designate the junction of a pinna with the cranium.

5.4 In view of these considerations, document D15 is not admitted into the appeal proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent with the following claims and a description to be adapted thereto:

   Claims 1 to 14 of auxiliary request 1 filed with letter dated 21 December 2017.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated