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Datasheet for the decision of 23 July 2015

Case Number: T 1554/11 - 3.3.01

Application Number: 98912889.7

Publication Number: 0969844

IPC: A61K31/545, A61K9/10

Language of the proceedings: EN

Title of invention:
ADMINISTRATION OF AN INJECTABLE ANTIBIOTIC IN THE EAR OF AN ANIMAL

Patent Proprietor:
Zoetis P&U LLC

Opponents:
VIRBAC
Intervet International BV

Headword:
Site of injection/ZOETIS

Relevant legal provisions:
EPC R. 115(2), 80
RPBA Art. 15(3), 15(6)
EPC Art. 100(c), 53(c), 123(2), 54, 54(5), 56, 100(b), 83, 113(1)
EPC 1973 Art. 52(4)

Keyword:
Main request: method for treatment of animal by therapy (no); allowable (yes)

Decisions cited:
G 0002/08, G 0005/83, T 1020/03, T 1704/06

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Case Number: T 1554/11 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 23 July 2015

Appellant: (Opponent 1)	VIRBAC 1ère Avenue, 2065m, L.I.D. 06516 Carros (FR)
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Representative:	Stumm, Karin Intervet International BV Patent Department Wim de Körverstraat 35 P.O. Box 31 5830 AA Boxmeer (NL)
Respondent: (Patent Proprietor)	Zoetis P&U LLC 100 Campus Drive Florham Park, NJ 07932 (US)
Representative:	Mannion, Sally Kim Zoetis UK Limited Walton Oaks Dorking Road Tadworth Surrey KT20 7NS (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 30 May 2011 concerning maintenance of the European Patent No. 0969844 in amended form.**

Composition of the Board:

Chairman	A. Lindner
Members:	L. Seymour
	M. Blasi

Summary of Facts and Submissions

I. European patent No. 0 969 844, with the application number 98 912 889.7, is based on the international application published as WO 98/41207. It was granted on the basis of one independent and eleven dependent claims; claims 1 and 8 read as follows:

"1. Use of an antibiotic for the manufacture of a medicament for the treatment or prevention of a bacterial infection in an animal, wherein the medicament is to be injected subcutaneously in the posterior of the ear of the animal, wherein the medicament is an injectable suspension of a sparingly water-soluble antimicrobial agent in a sterile oil.

...

8. The use of any preceding claim, wherein the antibiotic is selected from procaine penicillin, benzathine penicillin, ceftiofur crystalline free acid, ceftiofur hydrochloride, ampicillin trihydrate, amoxicillin trihydrate, oxytetracycline, erythromycin, tylosin, tilmicosin, florfenicol, enrofloxacin, danofloxacin, premafloxacin, ceftiofur sodium and lincomycin hydrochloride."

II. The following documents, cited during the opposition proceedings, are referred to below:

(1) WO 94/20505

(2) US-A-4 902 683

(3) FR 2 239 988

(4) ZA-A-88/9601

(6) US-A-3 428 729

(16) D Waltner-Toews, S A McEwen, Preventive Veterinary Medicine, 1994, 20, 235-247

(17) H H D Meyer et al., Food Additives and Contaminants, 1984, 1(3), 261-275

(18) Product information sheet for EXCEDE®

III. Revocation of the patent in suit was sought pursuant to Article 100(c) EPC, Article 100(b) EPC, and Article 100(a) EPC in conjunction with Articles 53(c), 54 and 56 EPC.

IV. The present appeals of opponents 1 and 2 lie from the interlocutory decision of the opposition division that the patent could be maintained in amended form based on the claim set filed as main request with letter of 9 February 2011, which differed from that as granted in the shortening of the list of compounds in claim 8.

V. With its reply of 29 March 2012 to the statements of grounds of appeal, the respondent (patentee) resubmitted the main request on which the decision under appeal was based (see above point IV), and also filed a number of auxiliary requests.

VI. In its letter of 15 February 2013, appellant opponent 1 reiterated its objections.

VII. With letter dated 22 May 2015, the respondent filed two replacement auxiliary requests.

VIII. Oral proceedings were held before the board on 23 July 2015. As announced with letters of 3 April and 21 May 2015, the appellants did not attend. During the course of these proceedings, the board expressed its preliminary opinion that the application as originally filed only appeared to directly and unambiguously disclose "injectable suspensions" in combination with some, but not all, of the antibacterial agents appearing in paragraphs [0024] or [0037] of the patent in suit; the objections submitted by the respondents in this respect under Article 100(b) EPC could therefore be viewed as posing a problem of added matter pursuant to Article 100(c) EPC. Thereafter, the respondent filed amended pages 4 and 5 of the patent specification with handwritten amendments.

IX. The appellants' arguments submitted in writing, insofar as they are relevant to the present decision, may be summarised as follows:

The amendment consisting in the deletion of embodiments from claim 8 as granted could not be seen as having been occasioned by a ground for opposition, contrary to the requirements of Rule 80 EPC, since it did not address the objection raised under Article 100(b) EPC with respect to the corresponding term "sparingly water-soluble antimicrobial agent" in claim 1.

The appellants maintained an objection pursuant to Article 100(c) EPC, according to which there was no basis in the application as originally filed for the link in claim 1 of the main request between the features "in a sterile oil" and "an injectable suspension of a sparingly water-soluble antimicrobial agent".

On the issue of sufficiency of disclosure (Article 100(b) EPC), the appellants generally argued that the subject-matter of claim 1 was very broadly defined with respect to the nature, dose and formulation of the antibiotic, and the type of disease and animal to be treated. The patent in suit disclosed only a single example, and it would be an undue burden for the skilled person to determine suitable combinations amongst the host of variable parameters that would allow the invention to be performed in the whole range claimed. In particular, the term "sparingly water-soluble" was not a recognised technical term, and the patent in suit did not provide any guidance as to how such agents should be selected and identified. Indeed, the description of the patent in suit listed a number of antimicrobial agents having a high water solubility. Hence, the requirements of Article 83 EPC were not fulfilled, since the invention was not described in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

The appellants further argued that the subject-matter claimed was excluded from patentability for reasons of Article 53(c) EPC. The alleged novelty of claim 1 lay only in the selection of the injection site, namely, in the posterior of the ear, and the only technical effect achieved thereby related to food safety. The invention did not therefore relate to a novel therapeutic application, but only to particular method of putting into practice a known antibiotic therapy, which was not patentable under the provisions of Article 53(c) EPC. This was in line with decision G 2/08, which outlined, with reference to decision T 1020/03, that a new use could only be considered to be patentable if the novel feature resulted in a new technical effect, linked to

the substance or composition. Moreover, according to decision G 2/08, point 7.1.2, Article 54(5) EPC enabled the applicant to frame its claims in order to obtain patent protection for **a** new therapeutic application of **a** known medicament. However, the present claims were very broad, and could not be said to relate to a specific use or to **a** known medicament. Indeed, decision G 2/08 listed several examples of novel, specific applications, including treatments relating to a new route or mode of administration. However, this was clearly intended only to relate to truly distinct embodiments, such as oral versus nasal routes, or different modes of injections, such as intramuscular, intradermal, intravenous or subcutaneous, but not merely to an anatomical site of injection not explicitly described in the prior art. Consequently, the present invention related to a method of therapeutic treatment excluded from patentability under Article 53(c) EPC.

In their assessment of inventive step of the main request (Article 56 EPC), the appellants started from document (1) as closest prior art. The problem to be solved was defined as lying in the selection of an injection site that allowed therapeutically effective concentrations of the antibiotic to be achieved and which was in a readily identifiable non-edible tissue of the animal, such that antibiotic residues did not remain with the edible carcass. Alternatively, the problem could more generally be defined as lying in the provision of a mode of administration that avoided safety issues due to the presence of residues in the edible parts of the animal. The solution proposed, namely, the subcutaneous administration in the posterior of the ear instead of to conventional sites of injection, such as the neck, could not be considered

to be inventive. Document (1) itself already taught, in Example 6, that subcutaneous administration of a composition identical to the composition used in the opposed patent provided the desired prolonged release of ceftiofur crystalline free acid (CCFA); similar results had also been obtained in Examples 8 and 9. Additionally, from general knowledge or from the appropriate USDA regulations, the skilled person would have been aware of the parts of an animal that were not used to produce human food, such as, lips, tongue, snout, ear, udder, penis, vulva, tail, and feet. It was self-evident that, of these possibilities, the ear would be the most suitable site of injection, since it was readily accessible and readily identifiable. Moreover, as acknowledged in paragraph [0012] of the patent specification, administration of drugs in the posterior of the ear had been well known to the skilled person before the present priority date. This was confirmed in documents (3), (4), (6), (16) and (17), from which it could be derived that the subcutaneous administration in the posterior of the ear generally resulted in controlled release of therapeutic effective blood levels. In particular, document (16) specifically addressed the problem of residue avoidance in the edible portion of carcasses of cattle, and taught, with reference to document (17), that "The location of the implant influences the residue levels in plasma ...; injection at the middle of the pinna results in lower levels than injection at the base". Therefore, in view of the teaching of the prior art, the skilled person would expect that said mode of administration could be applied to other products facing residue issues. Contrary to the assertions of the respondent, no prejudice had existed in this respect with regard to the present prolonged-release antibiotic formulations. In particular, from the figures of the patent in suit

and document (18), it could clearly be seen that the number of blood vessels in the ear was significant. Moreover, the volume of the present formulation was not a feature of the claim, and could not be invoked to justify an inventive step. Consequently, it must be concluded that it would have been obvious for the skilled person to inject the known formulations subcutaneously in the ear, in order to achieve a shorter withdrawal period before slaughter and to avoid antibiotic residues in the edible carcass after slaughter.

X. The respondent disputed the appellants' submissions:

The objection under Rule 80 EPC was not justified, since the deletions in claim 8 sought to address issues raised by the appellants under Article 100(b) EPC.

In connection with the issue of added matter (Articles 100(c) and 123(2) EPC), the respondent emphasised that the skilled reader would clearly recognise that the passages of the description as originally filed relating to "injectable suspensions of a sparingly water-soluble antimicrobial agents" and to "a sterile oil suspension" were meant to be read together.

The respondent further submitted that the objection under Article 100(b) EPC was unfounded since clear and complete instruction was provided in the patent in suit to enable the skilled person to carry out the use as claimed. Any remaining objections in this respect had now been rendered moot by the amendments introduced in the description of the patent in suit.

The claimed subject-matter fell outside the provision of Article 53(c) EPC. Decision G 2/08 had established

that a new mode of administration may provide the basis for a second medical use invention, and did not represent a method of treatment by therapy when claimed in the format instituted by decision G 5/83, even where the same disease was being treated.

The respondent reiterated that the subject-matter of the main request was novel with respect to the cited prior art (Article 54 EPC). In particular, there was no direct and unambiguous disclosure in either documents (1) or (2) of the injection of the antibiotic into the ear of an animal.

On the issue of inventive step (Article 56 EPC), the respondent agreed that document (1) represented the closest prior art. The problem to be solved was defined in the provision of an effective antibiotic treatment of animals, which minimised the negative effects of residues. The solution as claimed was characterised in the site of injection into the posterior of the ear. Evidence that the problem had been credibly solved was to be found in paragraphs [0045] to [0050] of the patent in suit, and in Table 2 of document (18). None of the prior art documents highlighted by the appellants would have motivated the skilled person to arrive at the claimed subject-matter as a solution to the problem posed. For example, document (16) related to the subcutaneous administration to the ear of an animal of solid dosage forms containing a hormone, which typically only had volumes of 100 to 600 µL. Such formulations were designed to release small amounts of hormone over an extended period of time, with the aim of increasing body weight. The teaching of this document would therefore be of no value to the skilled person seeking a curative antibiotic treatment with the present liquid dosage forms, where therapeutic plasma

levels needed to be reached rapidly. Of the cited documents, only document (4) related to the administration of antimicrobial agents to the ear. However, the formulations employed therein were solid and semi-solid implants, rather than suspensions in an oil. Moreover, it was taught that the antibacterial agent was released very slowly, due to the poor blood supply to the ear. This would reinforce the skilled person's understanding that injection of an antibiotic oil suspension in the ear would be unlikely to provide therapeutic plasma levels of the drug rapidly. The skilled person would not therefore adapt the teaching of document (4) in order to solve the objective technical problem posed.

XI. The appellants (opponents 1 and 2) requested in writing that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the decision be set aside and that the patent be maintained on the basis of the set of claims of the main request filed with the response to the statements of grounds of appeal and a description adapted in accordance with the pages submitted during the oral proceedings before the board (main request), alternatively, that the patent be maintained as granted (auxiliary request 1), or in amended form on the basis of one of auxiliary requests 2 to 12, all filed with letter dated 29 March 2012, auxiliary request 13 filed with letter dated 22 May 2015, auxiliary request 14 filed with letter dated 29 March 2012, or auxiliary request 15 filed with letter dated 22 May 2015.

XII. At the end of the oral proceedings, the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. Oral proceedings were held in the absence of the appellants (cf. above point VIII). Pursuant to Rule 115(2) EPC, if a party duly summoned to oral proceedings before the European Patent Office does not appear as summoned, the proceedings may continue without that party. Reference is further made to Article 15(3) of the Rules of Procedure of the Boards of Appeal (RPBA), which stipulates that the board shall not be obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case.

   Although the appellants did not attend the oral proceedings, the principle of the right to be heard pursuant to Article 113(1) EPC is observed since it only affords the opportunity to be heard and, by absenting itself from the oral proceedings, a party gives up that opportunity (see explanatory note to Article 15(3) RPBA cited in T 1704/06, point 7.3 of reasons; see also the Case Law of the Boards of Appeal, 7th edition 2013, section IV.E.4.2.3.c).

   Therefore, the present decision could be taken at oral proceedings, as foreseen by Article 15(6) RPBA.

Main request

3. *Rule 80 EPC*

As outlined in the decision under appeal (see Facts and Submissions, points 12.2; Reasons, point 3.1, first paragraph), an objection was raised under Article 100(b) EPC with respect to the then pending main request (claims as granted), *inter alia* owing to a contradiction between claims 1 and 8. The respondent's amendment of claim 8 sought to address this issue, and can therefore fairly be said to be occasioned by a ground for opposition. It is noted that it is not a requirement of Rule 80 EPC that the proposed amendment must actually overcome the objection raised or perceived.

The corresponding amendments to the description of the patent in suit in paragraphs [0024] and [0037] can also be seen as being occasioned by objections maintained under Article 100(b) EPC by the appellants in view of the disclosure in the description (see above point IX), and also by concerns raised under Article 100(c) EPC by the board (see above point VIII).

Accordingly, the amendments introduced are considered to be admissible under Rule 80 EPC.

4. *Articles 100(c), 123(2) EPC*

The passages of the application as originally filed referred to by the respondent in its letter dated 29 March 2012, point 1 (note: in point 1.2, page 8 of the application as originally filed is erroneously referred to as page 3) provide an accurate basis for the subject-matter of the claims of the main request.

Furthermore, paragraphs [0024] or [0037] of the description as amended during oral proceedings before the board (cf. above point VIII) recite the formulation type "injectable suspensions" in combination with the antimicrobial agents as specifically disclosed on page 1, lines 5 to 8 of the application as originally filed.

During the appeal proceedings, the appellants and the respondent disagreed on the question of whether a direct and unambiguous link was established in the application as originally filed between the following features relating to the formulation and the medium, respectively:

- "injectable suspensions of a sparingly water-soluble antimicrobial agents" (page 1, lines 5 to 8, and page 9, lines 32, 33),

and

- "sterile oil" (page 8, line 8).

The board notes that, in the passages on page 1, lines 5 to 12, and page 9, line 33 to page 10, line 3, three types of injectable antibiotic formulations are listed, as follows (emphasis added):

- "injectable **suspensions** of sparingly water-soluble antimicrobial agents";

- "sustained-release non-aqueous **solutions** of sparingly water-soluble antimicrobial agents";

and

- "injectable **solutions** of zwitterionic antimicrobial agents".

Only the first of these formulations relates to suspensions. The board therefore concludes that a

direct and unambiguous link is thereby established between this formulation and the preferred embodiment "sterile oil suspension" as disclosed on page 8, line 8 of the application as originally filed. Consequently, the formulation as defined in claim 1 of the main request, namely, "an injectable suspension of a sparingly water-soluble antimicrobial agent in a sterile oil" is not considered to present the skilled person with new information which was not unambiguously derivable from the application as originally filed.

Consequently, the main request does not contain subject-matter which extends beyond the content of the application as originally filed.

5. *Sufficiency of disclosure (Articles 100(b), 83 EPC)*

5.1 In order to assess whether the requirement of sufficiency of disclosure is fulfilled in the present case, it must be assessed whether the patent in suit as a whole discloses the second (further) medical use as claimed in claim 1 (cf. above point I) in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, in the light of his common general knowledge in the veterinary field.

In the present case, guidance as to the animals and bacterial infections to be treated are, for example, provided in paragraphs [0001], [0025], [0032] and [0036]. Details of suitable "sparingly water-soluble antimicrobial agents", and formulations and dosages thereof are given in paragraphs [0024], [0026], [0033], to [0037], [0053], and [0054]. The administration thereof is described in detail in paragraphs [0038] to [0044].

Consequently, the board sees no reason to doubt that the skilled person, in view of said disclosure, combined with his common general knowledge, would be in a position to carry out the claimed invention over the whole scope claimed without undue burden.

5.2 The appellants' arguments cannot alter this assessment for the following reasons:

The appellants firstly raised a general objection of undue burden based on an alleged inordinate breadth of the claims in relation to the single example. However, as outlined above, the disclosure of the patent in suit is not limited to the specific examples, but also encompasses all the information provided in the further specification as a whole, and account must also be taken of the common general knowledge of the skilled person. Therefore, in the absence of substantiation by verifiable facts, it is concluded that this line of argumentation cannot adequately establish a case for lack of sufficiency of disclosure.

With respect to the more specific objection relating to the term "sparingly water-soluble", the board notes that, according to the main request, paragraphs [0024] and [0037] of the patent in suit have been amended such that the antimicrobial agents objected to by the appellants as having a high water solubility have been deleted or clearly designated as not being in accordance with the claimed invention (cf. above point VIII). Based on the guidance now provided in said paragraphs, the board again sees no reason to doubt that the skilled person would be able to select other suitable antibiotics with a similar level of water solubility to those specifically disclosed, by

consulting standard reference works in the veterinary field, and to apply them in the methods claimed.

5.3 In view of the above considerations, the requirement of sufficiency of disclosure is considered to be met.

6. *Article 53(c) EPC*

The present claims are second medical use claims in Swiss-type format, as instituted by Enlarged Board of Appeal decision G 5/83 (OJ EPO 1985, 64). It was not disputed by the appellants that this is a valid format for the present patent (cf. Enlarged Board of Appeal decision G 2/08, OJ EPO 2010, 456, paragraph 7.1.4 of the Reasons).

The central argument brought forward by the appellants was that the characterising feature of present claim 1 relating to a specific site for subcutaneous injection, namely, "in the posterior of the ear", did not represent a true therapeutic feature, and therefore fell foul of Article 53(c) EPC.

However, in decision G 2/08 (point 5.10.9 of the Reasons) the following position taken in decision T 1020/03 (OJ EPO 2007, 204, point 36 of the Reasons) was specifically endorsed (emphasis added; note: the applicable law in T 1020/03 was Article 52(4) EPC 1973, rather than corresponding Article 53(c) EPC 2000 applicable to the present case):

"... there is a **seamless fit**, either a method of using a composition is not a treatment by therapy and therefore falls outside the provision of Article 52(4) EPC [1973] first sentence, and so is patentable subject to compliance with the other provisions of the EPC, or

else a method is a treatment by therapy and therefore inside the provision of Article 52(4) EPC [1973] first sentence, and so not itself patentable, but **use of a composition for making a medicament for use in such treatment by therapy is patentable** for unspecified therapy as a first medical indication or for a specified therapy as a further medical indication, again **subject to compliance with the other provisions of the EPC, in particular novelty and inventive step.**"

In other words, when a claim is correctly drafted in the format foreseen for second (further) medical use claims, the question of whether a specific feature or technical effect can be recognised as conferring novelty or inventive step are matters to be considered under Articles 54 and 56 EPC. This is also emphasised in section 6.3 of decision G 2/08, in the context of claims characterised by a dosage regime.

In view of this clear rationale, the appellants' reading of decision G 2/08 is untenable:

In particular, no basis can be derived therefrom for imposing additional restrictions on the types of features that may be used to characterise a Swiss-type claim. In section 5.10.7, referred to by the appellants, "well-established case law" is reviewed, including cases relating to "a novel group of subjects treated" or "a new route or mode of administration". However, the list provided is not presented as being in any way exhaustive, nor is it implied that a particular type or level of detail with respect to the treatments concerned is required in order to be eligible for protection as a Swiss-type claim.

The appellants further sought to derive support for their position, with reference to section 7.1.2 of decision G 2/08, from the use of the term "specific" in Article 54(5) EPC. However, as analysed in detail in section 5.9.1 of G 2/08, this article "does not define any degree of distinctiveness the new use would be required to have in order to qualify as a specific use". Moreover, the board notes that Article 54(5) EPC refers to "any substance or composition" (emphasis added). There is no basis in the wording of this article to support the contention that the medicament employed must be defined with a particular degree of specificity. Therefore, the significance that was attached by the appellants to the use of the singular in the passage cited in decision G 2/08, point 7.1.2, is not justified (cf. also, e.g., point 5.9, first paragraph, where the plural is used).

Finally, in view of the fact that the site of injection is clearly an integral technical element of the overall administration of the medicament to the animal, the board concurs with the opposition division that the issue of whether this feature produces further effects, which are not therapeutic, has no impact on the question of whether the Swiss-type claim format is suitable to overcome the exclusion from patentability under Article 53(c) EPC.

For the above reasons, the board concludes that the subject-matter of the main request is not excluded from patentability pursuant to Article 53(c) EPC.

7. *Novelty (Articles 52(1) and 54 EPC)*

As set out above in point 6, the feature "in the posterior of the ear" is to be taken into account when

assessing the novelty of the claimed subject-matter. The conclusion in the decision under appeal (point 3.4 of the Reasons), according to which documents (1) and (2) do not disclose this feature, was not challenged by the appellants in the written appeal proceedings.

Accordingly, the subject-matter of the main request is considered to meet the requirements of novelty.

8. *Inventive step (Articles 52(1) and 56 EPC)*

8.1 The present invention relates to the veterinary field. Claim 1 is in a Swiss-type format and concerns "the treatment or prevention of a bacterial infection in an animal" by subcutaneous injection of a "suspension of a sparingly water-soluble antimicrobial agent in a sterile oil" (cf. above point I).

8.2 The board considers, in agreement with all parties, that document (1) represents the closest state of the art.

Document (1) relates to compositions comprising the antibiotic ceftiofur crystalline free acid (CCFA), and in particular sustained-release oil suspensions, preferably administered by subcutaneous or intramuscular injection, given once per treatment (see page 10, line 16 to page 11, line 10; claims 7 to 14). Subcutaneous administration of such suspensions is exemplified in Examples 6, 8 and 9, and therapeutic plasma concentrations are shown to be sustained for about between 100 to 120 hours (i.e. about 4 to 5 days).

The site of injection is not specified in document (1). However, according to the patent in suit (paragraphs

[0007] and [0009]), the oil suspensions of the type disclosed in documents (1) and (2) were conventionally administered to the edible tissues of the animals, such as the neck.

8.3 The problem to be solved in the light of the closest prior art can be seen as lying in the provision of an alternative antibiotic treatment of animals that avoids food safety issues.

The solution as defined in claim 1 is characterised by the site of injection "in the posterior of the ear of the animal".

8.4 The patent in suit provides a comparison between subcutaneous injection of cattle in the posterior of the ear and in the neck (paragraph [0046] to [0049]). This choice of comparison is considered to fairly reflect the impact of the essential feature distinguishing the present method from that of the closest prior art (cf. above points 8.2 and 8.3). In particular, it is disclosed in the patent in suit that, although not strictly bioequivalent, the methods compared provide similar plasma disposition (see, in particular, page 7, lines 29 to 31, 41 to 43, and 50 to 52).

This is confirmed in document (18), in which subcutaneous injection at the base of the ear, which is part of the neck (see Figure 5; and also patent in suit, page 4, lines 13 to 17), is compared with administration in the middle third of the ear (see Figure 2). With reference to Table 2, the two methods are disclosed to be therapeutically equivalent (see sentence in second column, above Figure 6).

Consequently, the board is satisfied that the first aspect of the problem posed, namely, that of providing an alternative, comparably effective treatment to that of document (1), has been successfully solved.

Concerning the second aspect of the problem to be solved, it is disclosed in paragraphs [0045] and [0050] of the patent in suit that the present method allows a shorter withdrawal period before slaughter and improves food safety, owing to the fact that the injection site resides in tissue of the animal that is readily removed from the carcass after slaughter (cf. also paragraph [0002], last sentence).

In view of the above considerations, the board is satisfied that the problem posed has been successfully solved.

8.5 It remains to be investigated whether the proposed solution would have been obvious to the skilled person in the light of the prior art.

8.5.1 As outlined above in point 7, documents (1) and (2) do not suggest the subcutaneous administration of the disclosed suspensions "in the posterior of the ear".

8.5.2 Documents (3), (6), (16) and (17) were cited by the appellants as combination documents that would lead to the subject-matter claimed.

The relevant passages of these documents are:

- Document (3): page 1, lines 1 to 3, 13 to 16, 30 to 36; paragraph bridging pages 3 and 4; page 4, lines 23 to 34.

- Document (6): column 2, lines 10 to 12 and 24 to 62; column 3, lines 43 to 62; claims 1 to 4.

- Document (16): paragraph bridging pages 236 and 237; page 241, second complete paragraph.

- Document (17): page 261, abstract; page 262, first complete sentence; Figures 4 to 6.

The appellants highlighted that these documents disclose administration in the posterior of the ear, and address the issue of residues in the edible tissues of the animals; it is further noted that documents (6) and (16) specifically mention the possibility of discarding the ear as a measure for residue avoidance (see passages cited above).

However, these documents all relate to the treatment of livestock with hormones, in order to achieve weight gain, or as part of a breeding programme. In addition, the formulations used are all solid implants, designed for very slow release of the hormone over prolonged periods of time of up to 180 days (see document (6)).

In contrast, the antibiotic therapy according to document (1) relates to a distinct liquid formulation type, and a different purpose of application, for which therapeutic plasma concentrations need to be sustained for periods of about 5 days (cf. above point 8.2).

In view of these multiple differences, it is concluded that the skilled person would not have looked to documents (3), (6), (16) or (17) when considering how to modify the method of document (1) in order to solve the problem posed.

8.5.3 Document (4) was similarly cited by the appellants as a combination document. However, in the antimicrobial therapy disclosed therein, the formulations employed for subcutaneous implantation in the ear of the animal are solid or semi-solid, and are designed to provide very slow release over long periods, of desirably 1 to 4 weeks (see page 3, penultimate paragraph to page 4, second complete paragraph). Therefore, the above analysis for documents (3), (6), (16) and (17) applies *mutatis mutandis*.

8.5.4 Contrary to the appellants' contention, the mere knowledge that the ear may be regarded as inedible tissue cannot be considered to provide a pointer to the claimed invention, since, in the absence of information as to the release profile that would result from selecting this site of injection for the present formulation types, the skilled person would have no reasonable expectation that this would provide a solution to the problem posed.

The appellants further referred in this context to the figures of the patent in suit and document (18), which depict the blood circulation to the ears of cattle. However, this alone does not allow any conclusions to be drawn as to the relative blood supply compared to other potential sites of injection. Indeed, document (4) emphasises that blood supply in the ear is poor, leading to very slow release (page 3, bottom paragraph).

Similarly, the appellants cited a passage from the review article document (16) summarising the disclosure of document (17) (cf. above point IX). In the latter document, the hormone release profiles are compared for implants at the base of the ear and on the ear of veal

calves (see pages 267 to 270, see Trials I vs. II to IV), and the differences between the two modes of administration are highlighted, for example on page 272 as follows (emphasis added, see also abstract):

"Whereas implanting at the base of the ear causes an initial burst of steroid release, implantation in the pinna guarantees a **more continuous**, **reduced release** and potential risks due to residues within the first days are diminished."

Consequently, based on this teaching, the skilled person would derive an expectation of therapeutic differences rather than equivalence of said modes of administration.

8.5.5 Accordingly, since no teaching can be found in the cited prior art that would have led the skilled person to the present solution of the problem posed, it is concluded that the subject-matter of the main request involves an inventive step.

9. Since the main request is considered to be allowable, it is not necessary to comment on the auxiliary requests.

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 as amended in the following version:
   - Claims:
     claims 1 to 12 filed as main request together with the letter dated 29 March 2012
   - Description:
     - pages 2, 3, 6 to 8 of the patent specification
     - pages 4 and 5 as filed during the oral proceedings on 23 July 2015 before the board
   - Drawings:
     Drawing sheet of the patent specification.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated