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Datasheet for the decision of 18 January 2022

Case Number: T 1202/19 - 3.3.08

Application Number: 10773343.8

Publication Number: 2499233

C12N1/00, C12N1/20 IPC:

Language of the proceedings: EN

Title of invention:

METHOD TO GROW LAWSONIA INTRACELLULARIS BACTERIA IN PERSISTENTLY INFECTED MCCOY CELLS

Patent Proprietor:

Intervet International B.V.

Opponent:

Boehringer Ingelheim Vetmedica GmbH

Headword:

Lawsonia intracellularis in McCoy cells/INTERVET INTERNATIONAL

Relevant legal provisions:

EPC Art. 54, 56, 123(2) RPBA 2020 Art. 13, 17

Keyword:

Main request - added subject-matter (no), novelty (no); Auxiliary requests 1 to 3 and 8 - inventive step (no); Auxiliary requests 4 to 7 - novelty (no); Auxiliary requests 9 to 17 - admission into the proceedings (no);

Decisions cited:

G 0002/88, G 0002/10

Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 1202/19 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 18 January 2022

Appellant: Intervet International B.V.

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 1 February 2019 revoking European patent No. 2499233 pursuant to

Article 101(3)(b) EPC.

Composition of the Board:

Chairman B. Stolz Members: P. Julià

R. Winkelhofer

- 1 - T 1202/19

Summary of Facts and Submissions

- I. European patent no. 2 499 233 is based on European patent application no. 10 773 343.8 originally filed under the PCT and published as WO 2011/054951 (hereinafter "the patent application"). The patent was granted with 13 claims and opposed on the grounds of Articles 100(a) and 100(b) EPC. The opposition division held the main request and auxiliary requests 4 to 7, 9 to 11 and 14 to 17 not to fulfil the requirements of Article 54 EPC and auxiliary requests 1 to 3, 8, 12 and 13 not to fulfil those of Article 56 EPC. Thus, the patent was revoked (Article 101(3)(b) EPC).
- II. An appeal was lodged by the patent proprietor (appellant). With the statement setting out the grounds of appeal, the appellant maintained the main request and auxiliary requests 1 to 17.
- III. The opponent (respondent) replied to the appellant's appeal.
- IV. As an auxiliary measure, both parties requested oral proceedings (Article 116(1) EPC).
- V. The parties were summoned to oral proceedings. In a communication pursuant to Article 17 of the Rules of Procedure of the Boards of Appeal (RPBA 2020), the parties were informed of the board's provisional opinion on the issues of the appeal.
- VI. None of the parties replied in substance to the board's communication.

- 2 - T 1202/19

- VII. Oral proceedings were held on 18 January 2022 by video conference (VICO).
- VIII. Claims 1 and 4 of the main request read as follows:
 - "1. Use of McCoy cells persistently infected with Lawsonia intracellularis bacteria to grow and obtain these bacteria in purified form, comprising the steps of:
 - growing the persistently infected McCoy cells in a suitable medium at an oxygen concentration less than 18% to arrive at a first culture of McCoy cells infected with Lawsonia intracellularis bacteria, harvesting at least a part of the first culture to obtain a first batch of Lawsonia intracellularis bacteria,
 - passing another part of the first culture to fresh medium without adding uninfected McCoy cells,
 - growing the infected McCoy cells contained in the said another part of the culture in the fresh medium at an oxygen concentration less than 18% to arrive at a second culture of infected McCoy cells, and
 - harvesting at least part of the second culture to obtain a second batch of *Lawsonia intracellularis* bacteria."
 - "4. Use of McCoy cells persistently infected with Lawsonia intracellularis bacteria to grow and obtain these bacteria in purified form, comprising the steps of:
 - growing the persistently infected McCoy cells in a suitable medium at an oxygen concentration less than 18% to arrive at a first culture of McCoy cells infected with Lawsonia intracellularis bacteria, having

- 3 - T 1202/19

at least a predetermined density of infected McCoy cells,

- passing a part of the first culture to fresh medium without adding uninfected McCoy cells, growing the infected McCoy cells contained in the said part at an oxygen concentration less than 18%, to arrive at a second culture of infected McCoy cells and harvesting the second culture to obtain the Lawsonia intracellularis bacteria contained therein,

- adding fresh medium to a remaining part of the first culture, and growing the infected McCoy cells contained in that remaining part of the culture at an oxygen concentration less than 18%, to arrive at a culture which has at least substantially the same predetermined density of infected McCoy cells as the first culture."

Claims 2 and 3 and claims 5 to 8 are directed to preferred embodiments of claims 1 and 4, respectively.

IX. <u>Auxiliary request 1</u> is identical to the main request except for the deletion of claims 1 to 3.

Claims 3 and 2 of <u>auxiliary requests 2 and 3</u>, respectively, are identical to claim 1 of auxiliary request 1.

Claims 1 of $\underline{\text{auxiliary requests 4 to 7}}$ are identical to claim 1 of the main request.

Claim 1 of <u>auxiliary request 8</u> reads as claim 1 of the main request except for addition of the feature "in a continuously stirred tank reactor" in the penultimate paragraph of the claim, immediately after the feature referring to "an oxygen concentration less than 18%".

- 4 - T 1202/19

Claim 1 of <u>auxiliary requests 9 to 17</u> is directed to a method to obtain McCoy cells persistently infected with *Lawsonia intracellularis* bacteria. Auxiliary requests 9 to 11 and 14 to 17 contain a claim identical to claim 1 of the main request, and auxiliary requests 12 and 13 a claim identical to claim 1 of auxiliary request 1.

- X. The following documents are cited in this decision:
 - (3): Experimental evidence from Dr J. Kroll dated 27 September 2011;
 - (4): WO 96/39629 (publication date: 12 December 1996);
 - (12): WO 2009/049306 (publication date: 16 April 2009);

 - (24): EP 1 609 870 (publication date: 28 December 2005).
- XI. The arguments of the appellant, insofar as relevant to the present decision, may be summarised as follows:

Main request Article 123(2) EPC

It was disclosed throughout the patent application that there was no need to add uninfected McCoy cells when using persistently infected McCoy cells. It was directly and unambiguously derivable from the overall teaching of the patent application that this feature was associated with, and linked to, a passing step as in claims 1 and 4 of the main request (inter alia, page 4, lines 14 to 16; page 7, lines 17 to 20; and

- 5 - T 1202/19

examples of the patent application, such as on page 11, lines 3 to 5). According thereto, there was no need to add uninfected McCoy cells in any of the steps of the methods described; they could be added but they were not necessary, in particular, not in the passaging steps such as those in claims 1 and 4.

Article 54 EPC

The arguments put forward at the oral proceedings before the board were in response to the board's provisional opinion and they were already in the statement of grounds of appeal and thus, part of the appeal proceedings (Article 12 RPBA).

The patent aimed at improved methods to produce Lawsonia intracellularis in large amounts and it was the first in the art to recognise that McCoy cells could be persistently infected with this bacterium and that these cells grew and remained infected for an indefinitely long time without requiring repeated infection of fresh uninfected McCoy cells. All methods disclosed in the patent had in common that one part of a culture was harvested and the other part was grown without adding fresh uninfected McCoy cells.

According to the case law, for a disclosure to be novelty destroying, it had to be clear and not to leave room for any doubt or ambiguity. Moreover, if a feature was not explicitly disclosed, the implicit disclosure of this feature had to be immediately apparent to the skilled person, it had to be made available to that person. None of these conditions were fulfilled by document (4), in particular not by any of the two alternatives disclosed in Example 3 of this document. The first alternative was ambiguous and open to

- 6 - T 1202/19

interpretation because the fresh media and the beads could be added either to the harvested one half of the culture or to the remaining half of the culture. Both interpretations were meaningful and supported by document (4).

In the first interpretation, the addition of fresh media to the harvested culture was carried out in line with the harvesting step disclosed on page 14, wherein fresh growth media was added to prepare the harvested bacteria more suitable for passaging to fresh uninfected McCoy cells (page 14, lines 23 to 29). In the second interpretation, one half of the culture was harvested as indicated on page 34 and the fresh media was added to the remaining half of the culture. However, it was not derivable from page 33, whether the culture of the remaining half was carried out with or without adding fresh uninfected McCoy cells. According to page 13, if the culture had a high number of bacteria/ml, the culture was continued without splitting by adding fresh uninfected McCoy cells. Whilst, if fewer than 50% of the cells were infected, "passaging" was accomplished by splitting the culture 1:2 into a new flask and scaling-up the volume by adding fresh media. The term "passaging" was defined on page 13 and indicated that fresh uninfected McCoy cells were added. This was in line with document (18) which, in the paragraph bridging pages 8 and 9, explicitly mentioned what was already implicitly disclosed on page 13 of document (4). Thus, neither the first nor the second interpretation of the first alternative mentioned on page 33 of document (4) anticipated the claimed subject-matter. Nor was this subject-matter directly and unambiguously derivable from the first alternative mentioned on page 33 of document (4) in view of these interpretations.

- 7 - T 1202/19

Even if assuming that the first alternative was not ambiguous and open to interpretation, neither this alternative alone nor in combination with the whole disclosure of document (4) made the skilled person aware that the culture of infected McCoy cells with added fresh media and Cultisphere-G beads was growing, a condition explicitly required in claims 1 and 4.

There was no indication in the first alternative that the addition of fresh media and Cultisphere-G beads resulted in culture growth. According to this alternative, the culture was diluted 1:2 every 2-3 days. In the relevant technical field, culture dilution was known to be different from culture growth and a short time of only 2-3 days indicated that the purpose was not to grow - but only to maintain - the culture. This was in line with the disclosure in the paragraph bridging pages 15 and 16 of document (4) stating that, for maintenance of cultures with beads or microcarriers, part of the culture media was removed and replaced with fresh media 1-2 times weekly, whilst it was stated on page 16 that culture growth lasted at least 2 weeks. Indeed, in light of the known risks associated with culture passage, a skilled person would not have taken any risk by passaging the cell culture, if they would have been made aware by document (4) that the culture could grow without adding fresh uninfected McCoy cells. This feature was neither apparent nor immediately available to a skilled person from the disclosure of document (4).

- 8 - T 1202/19

<u>Auxiliary requests 1 to 17</u> Article 56 EPC

The difference between the closest prior art document (4) and the claimed subject-matter was that, after harvesting part of the first culture to obtain a first batch of *L. intracellularis*, the remaining part of the culture of infected McCoy cells was passaged to fresh medium and grown in that medium without adding uninfected McCoy cells in any of these steps. None of the prior art documents on file suggested to the skilled person that, for growing *L. intracellularis*, cell culture passage and growth could take place without adding uninfected McCoy cells. The claimed subject-matter was not obvious.

Admission of auxiliary requests 9 to 17

The appellant neither replied to the communication pursuant to Article 17 RPBA nor made any comments on this issue at the oral proceedings before the board.

XII. The arguments of the respondent, insofar as relevant to the present decision, may be summarised as follows:

<u>Main request</u> Article 123(2) EPC

The feature "without adding uninfected McCoy cells" in the third step of claim 1 and second step of claim 4 and not in any other step of these claims, was an arbitrary selection not directly and unambiguously derivable from the patent application. This selection linked this feature only to the passing step, leaving open all other steps of the claims; they could be carried out with or without adding uninfected McCoy

- 9 - T 1202/19

cells. This selection was neither consistent with the whole disclosure of the patent application nor reflected the alleged contribution of the patent application, namely that all steps could be carried out without adding uninfected McCoy cells, as disclosed in a general context in the paragraph bridging pages 2 and 3, as well as on page 7, lines 17 to 20, and in the examples of the patent application, such as on page 11, lines 3 to 5, referring to the passage and growing of the culture without adding uninfected McCoy cells.

The passages on page 4, lines 14 to 16, and page 7, lines 13 to 20 of the patent application referred to by the opposition division, informed the skilled person that McCoy cells infected with *L. intracellularis* could be grown and passaged without additional infection steps or re-starting cultivation of uninfected McCoy cells and fresh inoculum of *Lawsonia* bacteria. These passages however did not support a selection of only one of these steps, leaving open all other steps.

Article 54 EPC

The appellant's arguments at the oral proceedings before the board, such as the reference to document (18), were new in the proceedings and had not been submitted in the statement of grounds of appeal. They were an amendment to the appellant's case (Article 13 RPBA). The appellant had had ample time to react in writing to the board's opinion and inform the board and the respondent of these new arguments before the oral proceedings. Thus, the board, in exercise of its discretion, should not admit them into the proceedings.

- 10 - T 1202/19

From the data disclosed in the examples of the patent, it was not derivable that "persistently infected" McCoy cells were different from the infected McCoy cells described in document (4). The term "persistently infected" was not suitable to distinguish the claimed subject-matter from the prior art. Example 3 of document (4) described L. intracellularis infection and growth of the infected McCoy cells in conventional and in spinner flasks with growth medium and microcarriers. According to page 33, the culture was diluted 1:2 every 2-3 days and two alternatives were disclosed. In the first alternative, one half of the culture was harvested and fresh media and Cultisphere-G beads were added to the remaining half of the culture. The reference to beads indicated that the addition was to the remaining half of the culture; it made no technical sense to add beads to the harvested half of the culture which was then frozen. Contrary to the second alternative, no uninfected McCoy cells were added in the first alternative. This was consistent and in line with the disclosure on page 13 of document (4), wherein a culture with a low number of infected cells was split and scaled-up with addition of fresh media only, but not uninfected McCoy cells. There was no ambiguity in this first alternative; one half of the culture was harvested as indicated on page 34 and the remaining half of the culture was cultured for 2-3 days as indicated on page 33, namely without addition of uninfected McCoy cells. There was no need to refer to document (18) for interpreting this first alternative which had to be read as it stood. Moreover, the information provided in document (18) was incorrect as shown by document (24) which mentioned the disclosure on page 13 of document (4) without any correction.

- 11 - T 1202/19

According to this first alternative, the remaining half of the culture was incubated for 2-3 days with fresh media and Cultisphere-G beads. The addition of beads indicated that the culture was growing. The relevance of keeping the infected McCoy cells actively growing so as to permit continuous culture expansion and scale-up was stated on page 9, second paragraph, and in the paragraph bridging pages 14 and 15 of document (4). Thus, the skilled person was aware that the remaining half of the culture was actively growing for 2-3 days; there was no culture maintenance without culture growth. Indeed, culture growth was necessary for not losing the culture, which was not the case for the culture in Example 3 as shown by the results reported on page 34 (culture volumen scale-up from 1.0 to 3.0 liters in less than one month, wherein the culture contained up to one million of bacteria/ml). Further evidence was provided in document (3) showing that infectivity rate of cells increased (Table 1) and infected McCoy cells grew, when cultured for 2-3 days (Table 2).

Moreover, the use referred to in claim 1, namely to grow and obtain *L. intracellularis* in purified form, was defined by the method-steps of the claim, which comprised a passing step without addition of uninfected McCoy cells; all other steps were open, they could be carried out with or without addition of uninfected McCoy cells. The method-steps indicated for the first alternative of Example 3 of document (4), comprising a step without addition of uninfected McCoy cells, were the same as those of claim 1 and thus, they inevitably led to the same result as in the patent, regardless of their intended use or purpose. Therefore, according to the case law on novelty, the first alternative

- 12 - T 1202/19

disclosed on page 33 of document (4) anticipated the claimed subject-matter.

<u>Auxiliary request 1</u> Article 56 EPC

The sole technical difference, if any, between the first alternative disclosed on page 33 of the closest prior art document (4) and the claimed subject-matter was that the latter required that part of the infected McCoy cells be transferred to fresh medium without adding uninfected McCoy cells. The problem to be solved was the provision of an alternative method for producing L. intracellularis in which the cultivation was multiplied. Whilst the claimed subject-matter solved this problem, it was an obvious modification of the split embodiment disclosed in document (4). In view of the overall goal of this document, it was obvious for a skilled person that the enlarged culture volume arising from splitting the culture as indicated on page 33 would have been used for continuous cultivation as indicated on page 13 and ultimately harvest of the bacteria from the culture. In view of the results shown in Example 3 of document (4), there was also a reasonable expectation of success. Likewise, the claimed subject-matter was also obvious in view of document (4) in combination with document (12), which disclosed methods of growing L. intracellularis in non-mammalian cells and wherein, for scaling-up the production, the culture was transferred into larger vessels and supplemented with fresh media without adding uninfected host cells (page 10, third paragraph; Examples 3 and 4).

Auxiliary requests 2 to 8

The novelty objection against claim 1 of the main request applied to the corresponding claim present in auxiliary requests 4 to 7. The objection for lack of inventive step against claim 1 of auxiliary request 1 applied to the corresponding claim present in auxiliary requests 2 and 3. The feature "in a continuously stirred tank reactor" in auxiliary request 8, did not establish inventive step in view of document (4).

Admission of auxiliary requests 9 to 17

At the beginning of the oral proceedings at first instance, the order of the requests had been changed; thereby, a discussion of requests with claims directed to a method to obtain McCoy cells persistently infected with *L. intracellularis* bacteria was avoided and the opposition division took no decision on these requests. Since the appellant restricted the scope of the appealed decision on purpose by deleting the method claims in the main request, the introduction of this subject-matter in appeal proceedings contravened the overriding principle that appeal proceedings were judicial review proceedings and was not in line with the established case law.

XIII. The appellant (patent proprietor) requests that the decision under appeal be set aside and the patent be maintained on the basis of the main request, or that the case be remitted to the first instance for the assessment of inventive step of the main request, or that the patent be maintained on the basis of any of auxiliary requests 1 to 17.

- 14 - T 1202/19

XIV. The respondent (opponent) requests that the appeal be dismissed, that the case not be remitted to the first instance and that the auxiliary requests 9 to 17 not be admitted into the proceedings.

Reasons for the Decision

Main request

- 1. The main request is identical to the main request underlying the decision under appeal and thus, it already forms part of these proceedings.
- 2. The opposition division considered the main request to comply with Article 123(2) EPC and to be novel over document (20), but not over document (4). Whilst the appellant contested the decision on lack of novelty over document (4), the respondent contested the decision on Article 123(2) EPC but not that on document (20).

Article 123(2) EPC

3. It is not disputed that there is a basis in the patent application for the third step of claim 1 and the second step of claim 4 of the main request, namely "passing ... part of the first culture to fresh medium without adding uninfected McCoy cells". The so-called "passing step" is directly associated with the feature "without adding uninfected McCoy cells" in the disclosure of the patent application; inter alia page 2, line 24 to page 3, line 2, in particular page 2, line 35 to page 3, line 1; page 6, line 35 to page 7, lines 11, in particular page 7, lines 4 to 6; page 7, lines 17 to 20; and page 11, lines 3 to 7.

- 15 - T 1202/19

- 4. The respondent argued however that the feature "without adding uninfected McCoy cells" was disclosed in the patent application in connection with the method to grow and obtain McCoy persistently infected with Lawsonia intracellularis bacteria, but not with only one of all the steps of this method, namely the step of passing part of the culture to fresh medium. The selection of this step was arbitrary and not supported by the disclosure of the patent application.
- 5. The board does not agree with the respondent. In light of the disclosure of the patent application, there is a basis for the subject-matter of the main request:
- Claims 1 and 4 of the main request refer to a "first" and "second" culture, wherein at least part of the first culture is harvested and another part of this first culture is passed to fresh medium without adding uninfected McCoy cells, and grown to obtain a second culture, wherein at least part of this second culture is harvested. None of these claims refers to any other culture and thus, further growing of (persistently) infected McCoy cells, be it from another part of the second culture or yet another part of the first culture (other than the "another part" cited in these claims).
- The term "comprising" in the preamble of claims 1 and 4 must be given the meaning established in the case law (cf. "Case Law of the Boards of Appeal of the EPO", 9th edition 2019, II.A.6.2, 308) and, in accordance therewith, claims 1 and 4 are not limited to the steps explicitly recited in these claims, nor are any properties and/or limitations associated with the other parts of the first and second cultures. The term "comprising" does not exclude in (the use of) claims 1 and 4 further passing (to fresh medium) and growing

- 16 - T 1202/19

steps of infected McCoy cells starting with "another part of the second culture" and so obtain a third, fourth, etc. cultures of infected McCoy cells. Indeed, multiple passing and growing steps of infected McCoy cells are exemplified in the patent application and this is the subject-matter of claim 3 of the main request. Although, as observed by the respondent, the passing and growing steps described in the patent application are all carried out in line with the key contribution identified in the patent application, namely without adding uninfected McCoy cells, this is not required in claims 1 and 4 which thus, as also correctly observed by the respondent, are in this sense open-ended.

- 5.3 The term "comprising" is also present in the patent application when it refers to or describes both, a method for obtaining McCoy cells persistently infected with L. intracellularis (cf. page 2, lines 24 to 31; line 25; see also claim 1 of the patent application) and the use of McCoy cells persistently infected with L. intracellularis (cf. page 6, lines 25 to 35; line 27; see also claims 7 and 10 of the patent application). The description of this method and uses in these references are open-ended as in claims 1 and 4. These references in their overall context, which refer immediately to the passage of the persistently infected McCoy cells to fresh medium that does not contain uninfected McCoy cells (cf. paragraph bridging pages 2 and 3; page 7, lines 4 to 6), provide a basis for the open-ended definition of the subject-matter of claims 1 and 4.
- 6. Thus, the subject-matter of these claims is directly and unambiguously derivable from the patent application

- 17 - T 1202/19

as a whole (G 2/10, OJ EPO 2012, 376) and therefore, the main request complies with Article 123(2) EPC.

Article 54 EPC

- 7. The arguments put forward by the appellant at the oral proceedings before the board were already submitted in the appellant's statement of grounds of appeal. At the oral proceedings, the appellant simply elaborated them in more detail, taking into account the board's comments made in the communication pursuant to Article 17 RPBA, and considering them in the light of the case law. These arguments are not an amendment to the appellant's case (Article 13 RPBA) and thus, there is no room for the board to exercise its discretion not to take them into account, because they are already in, and form part of, the appeal proceedings.
- 8. The opposition division considered document (4) to anticipate the subject-matter of claim 1 with reference, in particular, to Example 3 of this document. For a review of the opposition division's decision, the board, in the communication pursuant to Article 17 RPBA, drew the parties' attention to the relevant case law and to the interpretation of claim 1, in particular of the feature "persistently infected". The board's observations were set forth as follows:

The interpretation of claim 1

9. According to the case law, when assessing novelty and inventive step of a claim, there is no reason to use the description to interpret an excessively broad claim more narrowly (cf. "Case Law", supra, I.C.4.8, 122). It is not appropriate to rely on the description for reading into a claim implicit restrictive or limiting

- 18 - T 1202/19

features which are not suggested by the explicit wording of the claim (cf. "Case Law", supra, II.A. 6.3.4, 312). The meaning of the term "comprising" as established in the case law is also relevant for assessing the scope of claim 1 (cf. "Case Law", supra, II.A.6.2, 308; see also point 5.2 supra).

- 9.1 The first step defined in claim 1 requires "growing the persistently infected McCoy cells ... to arrive at a first culture of McCoy cells infected with Lawsonia intracellularis bacteria". Apart from a suitable medium and oxygen concentration, there is no further definition of the parameters and conditions characterising the "growing" of these persistently infected McCoy cells. Nor is there any feature or property characterising the "first culture" of infected McCoy cells. These observations apply also to the "growing" of the infected McCoy cells for arriving at the "second culture" referred to in claim 1.
- 9.2 Claim 1 refers to "harvesting at least a part of the first culture" and "passing another part of the first culture", wherein neither the former nor the latter part of the first culture are further defined, such as, for instance, by a specific percentage or volume of the first culture of infected McCoy cells. Neither the first and second batches of *L. intracellularis* bacteria (yield, amount) nor the method to obtain these batches, i.e. the actual steps carried out after harvesting the first and second cultures, are defined in claim 1.
- 9.3 Therefore, in this sense and as stated above in the context of Article 123(2) EPC, the scope of claim 1 is open-ended, although it requires the presence of (only) one (passing) step wherein part of the (first) culture

- 19 - T 1202/19

is passed "to fresh medium without adding uninfected McCoy cells".

The feature "persistently infected"

- 10. Claim 1 is directed to the "use of McCoy cells persistently infected with Lawsonia intracellularis bacteria" and requires, as a first step, "growing the persistently infected McCoy cells". The feature "persistently infected" is the result of carrying out the process/method described on page 2, lines 24 to 31 of the patent application, which is further explained in the paragraph bridging pages 2 and 3, and exemplified in Example 1. Thus, the McCoy cells referred to in claims 1 and 4 are defined by an unusual process feature because, as argued by the appellant (cf. inter alia, page 2, fourth paragraph of the statement of grounds of appeal), it has not been previously described in the art.
- 10.1 According to the case law, a process feature not previously described in the art can establish novelty only if it causes a product to have different properties from the products previously described in the art (cf. "Case Law", supra, I.C.5.2.7, 133).

 Moreover, no benefit of doubt can be accorded when an unusual parameter/feature is used to define a product in a claim, which unusual parameter/feature is the only distinction over otherwise identical known products, and no evidence has been provided that the parameter/feature represents a difference in the claimed product from the known products (cf. "Case Law", supra, I.C. 5.2.3, 131).
- 10.2 In the present case, there is no technical difference distinguishing the "persistently infected McCoy cells"

- 20 - T 1202/19

referred to in claims 1 and 4 from the "infected McCoy cells" described in the prior art. Indeed, whilst the first step in claims 1 and 4 refers to "persistently infected McCoy cells", this term is not further used in these claims which refer then to the passaged (part of the) first culture to the fresh medium as "the infected McCoy cells". The terms "persistently infected" and "infected" are thus used interchangeably in the claims.

- 10.3 Moreover, the preamble of claim 1 and the steps recited in that claim do not require the persistently infected McCoy cells to be pure or homogeneous. In fact, there is no description in the patent application of any method for separating persistently infected McCoy cells from infected McCoy cells and/or from uninfected McCoy cells. In Example 1, it is stated that "the consecutive incubation under conditions that favour growth of the McCoy cells as well as the Lawsonia bacteria, leads to 90% of the McCoy cells being infected" (cf. page 10, lines 4 to 7 of the patent application); and a (part of the) culture obtained in Example 1, i.e. 90% of persistently infected McCoy cells and 10% of non-infected McCoy cells, is used in Examples 2 to 9.
- 10.4 In view thereof, the feature "persistently infected" in claim 1 of the main request implies nothing more than the term "infected" and cannot help in further distinguishing the claimed subject-matter from the prior art.
- 11. After these considerations, the board, in the communication pursuant to Article 17 RPBA, drew the parties' attention to the disclosure of document (4) which was summarised as follows:

- 21 - T 1202/19

The disclosure of document (4)

- Document (4) discloses "a method ... for cultivating L. intracellularis bacteria by inoculating an HEp-2, McCoys, or IEC-18 cell monolayer, which is at about 30 percent confluency, with an inoculum comprising L. intracellularis bacteria so as to infect the cells with bacteria. The infected cells are then incubated ... until the cells reach confluency. The infected cells and growth media are then placed in a fermentor, bioreactor, spinner flask or other container suitable for maintaining the cells in suspension. The infected cells are incubated while agitating the cells so as to cultivate the L. intracellularis bacteria while maintaining the infected cells in suspension." (emphasis by the board) (cf. page 4, lines 7 to 21).
- 13. The term "cultivation" is defined in the context of L. intracellularis bacteria as meaning the "process of promoting the growth, reproduction and/or proliferation of" said bacteria (cf. page 8, lines 10 to 12). It is further stated that "successful cultivation of L. intracellularis is enhanced by maintaining the culture cells in a constant state of growth" (emphasis by the board) (cf. page 9, lines 13 to 15). It is also stated that "[b]y maintaining the inoculated cells in a suspended state during incubation, maximum growth of the cells, and hence L. intracellularis, is achieved ... In a particularly preferred embodiment of the invention, the inoculated cells are incubated until the cells reach confluency and then the cells are placed in a spinner flask containing growth media and incubated ..." (emphasis by the board) (cf. page 12, lines 6 to 26).

- 22 - T 1202/19

- According to document (4), the passage of 14. L. intracellularis in suspension may be carried out in two different manners, depending on the number of infected cells. For a high number (50-100%) of infected cells, about 1 to 10% of the culture from the infected flask is added to a new flask containing fresh cells. "If fewer than 50% of the cells are infected, passaging is preferably accomplished by splitting the culture 1:2 into a new flask and scaling-up the volume by adding fresh media. In either case, cell lysis and other steps are not required" (emphasis by the board) (cf. page 13, lines 19 to 31). In the latter case, there is no reference to the addition or presence of any fresh (culture) cells. Moreover, it is stated that "using suspension cultures greatly facilitates keeping the cells actively growing and permits continuous culture expansion and scale-up ... We have also been able to keep the cultured bacteria actively growing for many months and expect to be able to do so indefinitely" (emphasis by the board) (cf. page 15, lines 6 to 13).
- 15. Example 3 of document (4) describes seeding of "25 cm² conventional flasks" with McCoy cells, growing these cells and, at 30% confluency, inoculating them with L. intracellularis bacteria (cf. page 32, lines 24 to 27). The advantages of inoculating at such confluency are described on page 9, lines 13 to 20.
- The cultures were then incubated for 6 days until confluency. The cells were scraped from the flasks and added to a 100 ml spinner flask containing microcarriers and growth medium (cf. page 33, lines 6 to 10; compare the medium with that on the same page, lines 25 and 26). As stated on page 12, lines 23 to 26 and page 15, lines 6 to 13, placing the inoculated McCoy cells in flasks of greater volume keeps the cells

- 23 - T 1202/19

actively growing and permits continuous culture expansion and scale-up.

- 15.2 According to Example 3, this "culture was diluted 1:2 every 2-3 days by either harvesting one half of the culture and adding fresh media and Cultisphere-G beads or by passing the culture into a larger spinner flask and adding more media and Cultisphere-G beads" (emphasis by the board) (cf. page 33, lines 12 to 16).
- 15.3 Example 3 further describes the "Passage of the culture", wherein the infected culture was passed to fresh McCoys cells, and the "Harvesting and storage of cultures", wherein description is made of the steps for harvesting the cultures and the quantitation of the bacteria (the latter under the heading "Estimation of viable *L. intracellularis* in tissue culture") (cf. page 33, line 22 to page 34, line 19).

Does Example 3 of document (4) anticipate claim 1?

As shown by the summary of the disclosure of document (4) in point 15 et seq. above, the method for obtaining infected McCoy cells disclosed in this document is identical to that disclosed in the patent for obtaining persistently infected McCoy cells and thus, in line with the considerations in point 10 et seq. above, the term "persistently" does not distinguish the persistently infected McCoy cells referred to in claim 1 of the main request from the infected McCoy cells disclosed in document (4). The relevant passage in Example 3 of this document is the second paragraph on page 33 (cf. point 15.2 supra), wherein two alternatives are disclosed for using the culture of infected McCoy cells present in the 100 ml

- 24 - T 1202/19

spinner flasks described in the first paragraph of the same page.

- 17. The second alternative mentioned in the second paragraph on page 33 of document (4) is a further expansion, amplification or scale-up of the culture of the (persistently) infected McCoy cells from the 100 ml spinner flask into a larger spinner flask, such as those described on page 11, line 25 to page 12, line 4 of document (4). This expansion or scale-up maintains the culture in suspension and in a constant state of growth (cf. page 9, lines 13 to 15; page 12, lines 22 to 26; and page 13, lines 25 to 31) and is carried out as indicated in the third paragraph of page 33 under the heading "Passage of the culture" and thus, by adding fresh uninfected McCoy cells. Therefore, this second alternative does not anticipate claim 1.
- 18. The first alternative mentioned in the second paragraph on page 33 of document (4) reads "harvesting one half of the culture and adding fresh media and Cultisphere-G beads" with no reference to fresh uninfected McCoy cells. Therefore, the addition referred to in this first alternative is "without adding uninfected McCoy cells" and thus, identical to that described in the second step of claim 1.

Is the first alternative ambiguous and open to interpretation?

19. The appellant argued that the first alternative mentioned in the second paragraph on page 33 of document (4) was ambiguous and open to interpretation because the addition of fresh media and Cultisphere-G beads could be understood to be either to the harvested

- 25 - T 1202/19

one half of the culture or to the remaining half of the culture.

- 20. The board cannot follow appellant's argument and sees no ambiguity in this first alternative, the guidance and instructions given to the skilled person are clear and not open to interpretation.
- 20.1 As explained under the heading "Harvesting and storage of cultures" on page 34, the first step of the harvested culture is a centrifugation followed by a resuspension of the pellet in a sucrose-phosphate-glutamate (SPG) solution which is then passed several times through a gauge needle in order to lyse the cells. The cultures are then aliquoted and frozen at -70°C. For further purification, the sample is centrifuged in order to remove the beads, cellular nuclei and debris (cf. page 34, lines 1 to 10).
- 20.2 The same protocol is described on page 14 in more detail, where reference is made to a first centrifugation and a resuspension of the pellet in a SPG solution and further purification with a centrifugation to remove cellular nuclei and debris (cf. page 14, lines 9 to 23). It is only at the end of the first paragraph on page 14, that reference is also made to an additional centrifugation of the so-treated harvested culture and a resuspension "in an appropriate diluent", wherein the appropriateness of said diluent is defined by the purpose of the resulting suspension, namely SPG with fetal bovine serum - for preparing harvested bacteria suitable for freezing or use as an inoculant, or growth media - for preparing harvested bacteria suitable for passaging to fresh cells (cf. page 14, lines 23 to 29).

- In view of all the steps carried out when "harvesting one half of the culture", such as the centrifugation for removing cell debris and beads, as well as the diluents or solutions used in these steps, such as the SPG solution/suspension (with or without bovine serum), the indication in the first alternative to simply add fresh media and Cultisphere-G beads without any other guidance can only be understood by a skilled person as referring to the remaining one half of the culture and not to the harvested one half of the culture. Thus, no ambiguity arises from this first alternative as regards the (one half of the) culture to which the fresh media and Cultisphere-G beads are added, namely to the remaining one half of the culture.
- 20.4 This is all the more so, since this first alternative is in line with the guidance given on page 13, last paragraph, of document (4) (cf. point 14 supra). According therewith, if fewer than 50% of the cells of the culture are infected, the culture is split 1:2 into a new flask and the volume scaled-up by adding fresh media. There is no reference to fresh McCoy cells in this disclosure, even though the term "passaging" is used in this context (cf. page 13, lines 25 to 28; line 26). This term is also used in the second alternative on page 33, not however in the first alternative which uses the term "adding". Indeed, the term "added" is used also in the preceding paragraph on page 33 of document (4) when describing the transfer of McCoy cells scraped from conventional flasks to spinner flasks containing the preferred growth medium (DMEM/ 2% FBS) and Cultisphere-G microcarriers or beads (cf. page 33, lines 7 to 9; line 8), wherein - as in the first alternative - there is no reference at all to (the addition of) uninfected McCoy cells. However,

- 27 - T 1202/19

contrary to the first alternative, this transfer is carried out without splitting the culture.

- As regards the disclosure on page 13 of document (4), the appellant referred to a corresponding disclosure in the paragraph bridging pages 8 and 9 of post-published document (18), wherein it is stated that both, fresh media and fresh tissue culture, i.e. uninfected McCoy cells, are added to the split 1:2 low infected culture. On the other hand, the respondent referred to yet another post-published document wherein the disclosure on page 13 of document (4) was repeated verbatim without any reference to the addition of uninfected McCoy cells (cf. page 3, paragraph [0018], of document (24)).
- These post-published documents may cast doubts, if at all, on the disclosure on page 13 of document (4). This ambiguity however does not arise from, and is not associated with, the first alternative on page 33 which, in light of all the reasons given above, clearly teaches to add fresh media and Cultisphere-G beads to the remaining one half of the culture without adding uninfected McCoy cells.
- 21. Thus, the first alternative disclosed on page 33 of document (4) is neither ambiguous nor open to interpretation.
 - Is the skilled person made aware that the culture obtained in this first alternative is growing?
- 22. The appellant further argued that, even if the first alternative mentioned in the second paragraph on page 33 of document (4) was neither ambiguous nor open to interpretation, this disclosure did not make the

- 28 - T 1202/19

skilled person aware that the (remaining one half of) culture - with (added) fresh media and Cultisphere-G beads - was growing; a feature or property that was explicitly required in the preamble of claim 1 of the main request as well as in the first and fourth step, the latter step concerning "said another part of the culture in fresh medium". In this context, the appellant referred to the case law of the Boards of Appeal establishing that for a prior art document to anticipate the claimed subject-matter, the relevant question is what has been made available to the public and not what remains hidden or what otherwise has not been made available to the public (G 2/88, OJ EPO 1990, 93).

- 23. However, the board cannot follow the appellant's argument, as the skilled person is made well aware that the culture of infected McCoy cells obtained when following the first alternative mentioned on page 33 of document (4) is growing.
- 23.1 Indeed, the whole disclosure of document (4) makes the skilled person aware of the relevance of maintaining the culture of infected McCoy cells in a constant state of growth for a successful cultivation of L. intracellularis (cf. inter alia, page 9, lines 13 to 15; page 12, lines 6 to 10; sentence bridging pages 14 and 15; page 15, lines 6 to 8; see points 13 to 15 supra). The indication in the first alternative disclosed on page 33 to add not only fresh media but also Cultisphere-G beads makes the skilled person aware that the (remaining one half of the) culture is actively growing. The addition of microcarriers or beads in a cell culture is known in the art to be advantageous for (large-scale) cultivation, i.e. cell culture growth (cf. page 8, lines 10 to 12), due to the

- 29 - T 1202/19

large surface area that microcarriers and beads provide (cf. page 15, lines 19 to 27).

- 23.2 The indication in the first alternative on page 33 of document (4) to dilute the culture every 2 to 3 days makes the skilled person aware that the culture is actively growing and not, as argued by the appellant, simply maintained. As stated above, the addition of Cultisphere-G beads is already a clear indication that the purpose is to have the culture actively growing; this is also the reason for adding fresh media. In Example 1, the sole medium used is DMEM/2% FBS, which is described as the preferred growth media (cf. page 9, lines 5 to 11). The same medium with Cultisphere-G beads is used in Example 1 for culturing, i.e. actively growing, the infected McCoy cells transferred into the spinner flasks, and likewise but for the absence of Cultisphere-G beads, for the initial culture of McCoy cells in conventional flasks (cf. page 32, lines 24 to 26). Indeed, for this first culture, the McCoy cells are said to be "allowed to grow 18-24 hours" (emphasis by the board) (cf. page 32, lines 25 and 26); a period of time much shorter than that indicated in the first alternative on page 33. Moreover, there is evidence on file showing an increased McCoy cell density, infectivity (cell) rate and L. intracellularis growth, when using cell culture conditions similar, if not identical, to those indicated in the first alternative on page 33, for a culture of 2 or 3 days (cf. Tables 1 and 2 of document (3)).
- 24. In addition, the subject-matter of claim 1 of the main request is open-ended not only as regards the multiple passing and growing steps of the McCoy cells (persistently) infected with *L. intracellularis* as mentioned above under Article 123(2) EPC, but also as

- 30 - T 1202/19

regards cell culture and *L. intracellularis* growth (yield), cell culture density or confluency, time of culture, etc. There is thus no feature in claim 1 requiring to obtain any specific level or degree of culture growth of the (persistently) infected McCoy cells.

Conclusion on Article 54 EPC

25. It follows from these considerations that document (4), in particular Example 3 of this document and the first alternative mentioned therein, discloses - directly and unambiguously - the use of McCoy cells (persistently) infected with *L. intracellularis* to grow and obtain these bacteria in purified form, comprising a passing step to fresh medium without adding uninfected McCoy cells. Thus, document (4) anticipates the subjectmatter of claim 1 and therefore, the main request does not fulfil the requirements of Article 54 EPC.

Auxiliary requests 1 to 17

Since none of the parties replied in substance to the communication pursuant to Article 17 RPBA and, at the oral proceedings before the board, the parties referred only to their written submissions for consideration and examination of all these auxiliary requests, the decision of the board on these auxiliary requests is based on the same grounds, arguments and evidence on which the board's opinion was based. They were neither questioned by the appellant, nor did other aspects come up that would require their re-consideration.

- 31 - T 1202/19

Auxiliary request 1

- 27. Auxiliary request 1 is identical to the auxiliary request 1 underlying the decision under appeal and thus, it already forms part of these proceedings.
- 28. The opposition division held auxiliary request 1 not to contravene Article 123(2) EPC and to fulfil the requirements of Articles 84 and 54 EPC, but not those of Article 56 EPC. The appellant contested the decision of the opposition division on Article 56 EPC.

Article 56 EPC

- In the decision under appeal, the opposition division identified document (4) as the closest prior art. Both, appellant and respondent, agreed therewith. Whilst the opposition division and the appellant considered that the technical difference between the disclosure of this document and the claimed subject-matter was that "the first (harvested) part of the infected McCoy cells is transferred to fresh medium without adding uninfected McCoy cells" (cf. page 9, point 26 of the decision under appeal, and paragraph bridging pages 4 and 5 of appellant's statement of grounds of appeal), the respondent did not agree therewith.
- 30. In view of the disclosure of document (4) as summarised above in the context of Article 54 EPC for the main request, in particular, the first alternative disclosed in Example 3, page 33 of this document, there can be no doubt that the technical difference identified by the opposition division and the appellant is already disclosed in document (4) and, indeed, in a direct and unambiguous manner.

- 32 - T 1202/19

- In the communication pursuant to Article 17 RPBA, the board observed that, in the formulation of the problem and solution approach, neither the opposition division nor the appellant referred to the features introduced into the steps of claim 1 of this auxiliary request 1, namely to arrive at a first culture "having at least a predetermined density of infected McCoy cells" (first step) and, as regards the second culture, "to arrive at a culture which has at least substantially the same predetermined density of infected McCoy cells as the first culture" (last step).
- 32. As regards these features, the board drew the parties' attention to the following points:
- 32.1 Document (4) refers to a preferred range of McCoy cells infected, namely 50-100% (cf. page 13, lines 24 and 25). In case fewer than 50% of the McCoy cells are infected, document (4) further discloses a method to achieve the preferred level of infection (cf. page 13, lines 25 to 31). On page 16, lines 5 to 10, it is assumed that "the culture cells become at least 70% infected within 2-3 weeks". In Example 3, the cultures were incubated for 6 days until confluency in conventional flasks and then passaged to a spinner flask and further cultured with 1:2 dilution every 2-3 days. Thus, the skilled person is provided with both, the information of a preferred level or density of infection and a method to achieve said level or density.
- No inventive skills are required for carrying out the instructions of document (4). The less so, since claim 1 of auxiliary request 1 does not define any specific level or density of (persistently) infected

- 33 - T 1202/19

McCoy cells which may thus well be below 70% and even less than 50%.

33. In view of these considerations, auxiliary request 1 lacks an inventive step.

Auxiliary requests 2 to 8

34. Auxiliary requests 2 to 8 are identical to auxiliary requests 2 to 8 underlying the decision under appeal and thus, they already form part of these proceedings.

Auxiliary requests 2, 3 and 8

- 35. The opposition division held auxiliary requests 2, 3 and 8 to lack inventive step (Article 56 EPC).
- 35.1 Claim 3 of auxiliary request 2 and claim 2 of auxiliary request 3 are identical to claim 1 of auxiliary request 1 and thus, the reasons given for lack of inventive step of auxiliary request 1 apply also to auxiliary requests 2 and 3.
- 35.2 Claim 1 of auxiliary request 8 is identical to claim 1 of the main request, except for requiring the fourth step mentioned in claim 1 to be carried out "in a continuously stirred tank reactor". In the decision under appeal, the opposition division stated that a skilled person who was told to use a bioreactor and to maintain the infected McCoy cells in suspension (page 4, lines 15 to 21 of document (4)) did not need any inventive skills to use a continuously stirred tank reactor. The board agrees that the relevance and advantages of maintaining the infected McCoy cells in suspension is directly derivable from document (4) which, inter alia, refers to "a fermentor, bioreactor

- 34 - T 1202/19

or rotary shaker containing at least about 2 litres media and capable of maintaining the culture cells in suspension *via* ... other means of mechanical agitation" (cf. page 11, line 25 to page 12, line 4; page 12, lines 17 to 20). Thus, there is no reason to deviate from the findings of the opposition division on auxiliary request 8 in this respect.

36. Therefore, none of auxiliary requests 2, 3 and 8 fulfils the requirements of Article 56 EPC.

Auxiliary requests 4 to 7

- 37. The opposition division held auxiliary requests 4 to 7 to lack novelty (Article 54 EPC).
- 38. Claim 1 of these auxiliary requests is identical to claim 1 of the main request. Therefore, the reasons given for the lack of novelty of the main request apply also to these auxiliary requests.

Admission and consideration of auxiliary requests 9 to 17

39. The opposition division admitted auxiliary requests 9 to 17 into the opposition proceedings and considered that they did not overcome the objections discussed at the oral proceedings before the opposition division. Indeed, whilst there was one claim in auxiliary requests 9 to 11 and 14 to 17 identical to claim 1 of the main request and thus, these auxiliary requests lacked novelty (Article 54 EPC), auxiliary requests 12 and 13 comprised a claim corresponding to claim 1 of auxiliary request 1 and thus, these auxiliary requests lacked inventive step (Article 56 EPC). These auxiliary requests were filed prior to the oral proceedings (as auxiliary requests 1 to 9) and renumbered at the

- 35 - T 1202/19

beginning of the oral proceedings. The opposition division further stated that the patent proprietor intended to maintain these auxiliary requests for an eventual appeal and therefore, these auxiliary requests were legitimate fall-back positions. Thus, the opposition division admitted them into the proceedings (cf. page 2, point 6, and page 11, point 30, of the decision under appeal).

- 40. The respondent contests this decision and maintains the objection against their admission already raised before the opposition division. Reference is made to the established case law and to the course of events at first instance, in particular the renumbering of the auxiliary requests at the beginning of the oral proceedings which had as a consequence the avoidance of a discussion and thus, a decision on the subjectmatter of granted claim 1.
- 41. Auxiliary requests 9 to 17 were admitted into the proceedings and a decision on their non-allowability was taken by the opposition division. The respondent's request not to admit them into the appeal proceedings is understood mainly as a request to review the discretionary decision of the opposition division.
- 42. According to the case law, the board should only overrule the way in which the opposition division has exercised its discretion if it has done so according to the wrong principles, or without taking into account the right principles, or in an unreasonable way, and has thus exceeded the proper limits of its discretion. It is not for the board to decide whether or not in light of the particular facts and circumstances of the case it would have exercised such discretion in the

- 36 - T 1202/19

same way (cf. "Case Law", *supra*, IV.C.4.5.2, 1092, and V.A.3.5.1, 1198).

- 42.1 The filing of claim requests within the time limit set out by the opposition division under Rule 116(1) EPC in preparation of the oral proceedings does not directly result in these requests being admitted into - and thus becoming part of - the opposition proceedings. It is at the discretion of the opposition division to refuse amendments and/or claim requests, if they are not a fair attempt to overcome the objections made; the patent proprietor has no right to have amendments and/ or new claim requests admitted at any stage of the opposition proceedings (see Rule 79(1) EPC) (cf. "Case Law", supra, IV.C.5.1.3, 1101). Thus, the fact that auxiliary requests 9 to 17 were filed - as auxiliary requests 1 to 9 - within the time limit set out by the opposition division is, as such, not the decisive criterion for admitting them into the opposition proceedings.
- 42.2 There is also a large body of case law considering the prima facie allowability of a new claim request, procedural expediency and an opponent's familiarity with the subject matter as the main criteria for deciding on its admission into the proceedings (cf. "Case Law", supra, IV.C.4.5, 1091, and IV.C.5.1, 1097). In the present case, the opposition division noted that auxiliary requests 9 to 11 and 14 to 17 comprised a claim corresponding to claim 1 of the main request, while auxiliary requests 12 and 13 comprised a claim 1 corresponding to claim 1 of auxiliary request 1. The opposition division concluded that the reasons given for considering claim 1 of the main request and auxiliary request 1 not to fulfil the requirements of Articles 54 and 56 EPC, respectively, applied to these

- 37 - T 1202/19

auxiliary requests. None of them was considered to fulfil the requirements of the EPC and to overcome the grounds of opposition. Therefore, auxiliary requests 9 to 17 were also *prima facie* not allowable.

- 42.3 The convergence of claim requests is another criterion established in the case law for assessing the admittance of new claim requests into the proceedings. In the present case, it is not disputed that auxiliary requests 9 to 17 comprise several method-claims of the patent as granted which are neither in the main request nor in any of auxiliary requests 1 to 8. Auxiliary requests 9 to 17 thus diverge from the main request and the higher ranking auxiliary requests.
- 42.4 The opposition division stated that "[m]erely renumbering these requests does ... not amount to the filing of a new request" (cf. page 11, point 30, first paragraph, in the decision under appeal). This may be true as far as the subject-matter claimed is concerned. The renumbering and hence the change of the order of auxiliary requests is however not negligible but an important procedural action that has consequences for the progress or course of the proceedings. This is so because the order of the claim requests determines the order and the extent to which the opposition division examines them. In the present case, the renumbering of the auxiliary requests resulted in the opposition division not having to decide on subject-matter present in the claims as granted, namely the method-claims, but not in the main request or any of auxiliary requests 1 to 8.
- The sole reason for the opposition division for admitting auxiliary requests 9 to 17 into the proceedings appears thus to be the fact that "the

patentee intends to maintain these requests for an eventual appeal against the decision of the opposition division" and so the opposition division considered it "legitimate to maintain the auxiliary requests as fall-back positions" (cf. page 11, second paragraph, in the decision under appeal). The board, though, considers that it is not reasonable to admit claim requests into the opposition proceedings for the sole reason of providing fall-back positions in possible appeal proceedings; the less so, if these claim requests not only do not fulfil the criteria established in the case law for admitting them but clearly contravene them.

43. In view of these considerations and in line with the board's provisional opinion, departing from the decision of the opposition division to admit auxiliary requests 9 to 17 into the opposition proceedings, these auxiliary requests cannot be considered in the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



L. Malécot-Grob

B. Stolz

Decision electronically authenticated