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Datasheet for the decision of 15 January 2014

Case Number: T 0270/10 - 3.3.08

00958787.4 Application Number:

Publication Number: 1210445

IPC: C12N15/67, C12N1/21, A61K39/02,

C12N1/20

Language of the proceedings: ΕN

Title of invention:

RECOMBINANT MICROORGANISMS

Patent Proprietor:

THE SECRETARY OF STATE FOR DEFENCE

Opponent:

Nobilon International B.V.

Headword:

Salmonella mucosa IgA immune response/SECRETARY STATE DEFENCE

Relevant legal provisions:

EPC Art. 54 RPBA Art. 12(4), 13(1)

Keyword:

Admissibility of a new ground of opposition (no) Main Request - novelty (no) Admissibility of Auxiliary Request 1 (yes) Auxiliary Request 1 - fulfils all requirements of the EPC (yes)

Decisions cited:

G 0005/83, G 0002/88, G 0001/95, T 0423/01, T 1092/01, T 0708/02, T 0870/02

Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

European Patent Office D-80298 MUNICH GERMANY Tel. +49 (0) 89 2399-0 Fax +49 (0) 89 2399-4465

Case Number: T 0270/10 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 15 January 2014

Appellant: Nobilon International B.V.

(Opponent) Exportstraat 39b 5830 AH Boxmeer (NL)

Representative: Janssen, Paulus J. P.

Intervet International B.V.
Intellectual Property Department

P.O. Box 50

5830 AB Boxmeer (NL)

Respondent: THE SECRETARY OF STATE FOR DEFENCE

(Patent Proprietor) DSTL

Doil

Porton Down

Salisbury, Wiltshire SP4 0JQ (GB)

Representative: Beckham, Robert William

D/IPR Formalities Section,

Poplar 2,

MOD Abbey Wood 2218 Bristol BS34 8JH (GB)

Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on 15 December 2009 concerning maintenance of the European Patent No. 1210445 in amended form.

Composition of the Board:

Chairman: M. Wieser Members: P. Julià

J. Geschwind

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Summary of Facts and Submissions

- I. European patent 1 210 445, based on European patent application No. 00 958 787.4 and published as International patent application WO 01/19974, was granted with 16 claims. Claims 1 and 2 read as follows:
 - "1. A method of enhancing expression of a desired protein at mucosal effector sites, said method comprising placing the protein to be expressed under the control of a promoter having SEQ ID NO 2 or SEQ ID NO 3 or a fragment or variant having at least 60% homology or any of these which has promoter activity, and causing expression in mucosal cells."
 - "2. A construct comprising a promoter selected from the P_{phoP} and P_{pagC} or fragments or variants thereof which can act as promoters, operatively interconnected with a nucleic acid which encodes a protein, able to induce a protective immune response against an organism, in a mammal to which it is administered, wherein said construct contains no further elements of the phoP or pagC gene."

Claims 3 to 9 were directed to a recombinant gut colonising microorganism which had been transformed with a construct according to claim 2. Claims 10, 11 and 15 were preferred embodiments of claims 2 and 3 to 9. Claims 12 to 14 were directed to a vaccine comprising a recombinant gut colonising microorganism according to any of claims 3 to 11. Claim 16 was directed to the use of a promoter selected from $P_{\rm phoP}$ and $P_{\rm pagC}$ in the production of a vaccine comprising a recombinant gut colonising organism.

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- II. An opposition against the patent was filed based on grounds under Article 100(a) EPC, namely lack of novelty and lack of inventive step (Articles 54 and 56 EPC). The opposition division considered the Main Request (granted claims) not to fulfil the requirements of Article 54 EPC and Auxiliary Request 1 to contravene Article 56 EPC. Auxiliary Request 2 was considered to fulfil all the requirements of the EPC. Both Auxiliary Requests 1 and 2 were filed on 13 November 2009 at the oral proceedings before the opposition division.
- III. Claim 1 of Auxiliary Request 2 read as granted claim 1 except for the introduction of the feature "to induce mucosal IgA antibody response" after the reference to "at mucosal effector sites" (supra). Claim 2 read as granted claim 2 except for the deletion of all references to P_{pagC} and P_{pagC} gene. Subject-matter related to P_{pagC} and P_{pagC} gene was also deleted from all other granted claims, and the claims of this request were renumbered accordingly.
- IV. An appeal was lodged by the opponent (appellant). With the statement of Grounds of Appeal, the appellant requested the board to set aside the decision under appeal and to revoke the patent.
- V. In its reply to the appellant's Grounds of Appeal, the patentee (respondent) requested the board to dismiss the appeal.
- VI. On 8 July 2013, the board summoned the parties to oral proceedings. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to the summons to oral proceedings, the board informed the parties of its preliminary opinion on the issues of the case. In particular, the board

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considered that the introduction of a new ground of opposition (Article 53(c) EPC) into the appeal proceedings was not admissible and that the subject-matter of claim 1 was anticipated by the disclosure of document D1 (*infra*). The board further noted that, in appeal proceedings, objections were raised only against the subject-matter of claim 1.

- VII. With a letter dated 10 November 2013, the respondent informed the board of its intention not to attend the scheduled oral proceedings. No substantive submissions were made in this letter. However, the respondent filed an Auxiliary Request 1 with claims identical to those upheld by the opposition division (Main Request) except for the deletion of claim 1.
- VIII. With a letter dated 18 November 2013, the appellant informed the board of its intention not to attend the scheduled oral proceedings. The appellant maintained all its requests and argued against the admissibility of Auxiliary Request 1 into the appeal proceedings. If this auxiliary request were to be admitted into the proceedings, the appellant considered it not to fulfil the requirements of Articles 54 and 56 EPC.
- IX. On 22 November 2013, the board cancelled the scheduled oral proceedings.
- X. The following documents are cited in the present decision:
 - D1: E.L. Hohmann et al., Proc. Natl. Acad. Sci. USA, March 1995, Vol. 92, pages 2904 to 2908;
 - D3: L. Cárdenas and J.D. Clements, Clin. Microbiol. Rev., July 1992, Vol. 5(3), pages 328 to 342;

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D8: C.M. Pereira et al., Microbiology, 2001, Vol. 147, pages 861 to 867.

XI. Appellant's submissions, insofar as relevant to the present decision, may be summarised as follows:

Admissibility of a fresh ground of opposition

In its statement of Grounds of Appeal, the appellant raised, for the first time in the proceedings, an objection under Article 53(c) EPC against the patentability of the subject-matter of claim 1 which, in its view, was directed to a method of treatment. No comments were made by the appellant to the respondent's reply to the statement of Grounds of Appeal in which the introduction of a new ground of opposition was objected. Likewise, no submissions on this issue were filed by the appellant in reply to the board's communication pursuant to Article 15(1) RPBA in which the board informed the parties that the objection raised under Article 53(c) EPC was considered not to be admissible into the appeal proceedings.

Main Request - Article 54 EPC

The feature "to induce mucosal IgA antibody response" in claim 1 did not represent a new therapeutic use. According to the established case law, for a newly discovered effect to represent a new therapeutic use, it had to lead a skilled person to a new activity. This was not so in the present case. Claim 1 required the administration of a vaccine so as to elicit a protective immune response. It was irrelevant whether the protection was the result of mucosal, humoral or systemic immune responses. The type of response was

only the explanation why the individual was protected, i.e. the mechanism of action underlying the protective effect of a vaccine, but it did neither affect the way in which the vaccine was used nor did it lead to a new use.

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Moreover, it was common general knowledge that oral (recombinant) Salmonella vaccines elicited an IqA immune response. The production of IqA was known in the art to represent a mucosal immune response induced at mucosal effector sites. Document D1 disclosed the oral administration of a Salmonella vaccine for the purpose of inducing a protective response against infection, i.e. to provoke an immune response, either humoral, cell-mediated, and/or mucosal. No additional effect was disclosed in the patent. The alleged new purpose ("to induce mucosal IgA antibody response") did not lead to the treatment of a different pathology. The same vaccine was used to prevent infection by the same gut colonizing microorganism as in document D1 and did not lead to the treatment of a new patient group when compared with document D1. The alleged new purpose did not result in new physical means or measures either, the same vaccine was administered in the same way as it was administered in document D1.

Thus, claim 1 did not represent a new therapeutic effect or a new therapeutical use and lacked novelty over the disclosure of document D1.

Admissibility of Auxiliary Request 1

Auxiliary Request 1 was late filed as it could have been already filed at the first instance proceedings. The objections raised against the subject-matter of the Main Request equally applied to this request. The

subject-matter claimed by this request was both, not novel and obvious in the light of document D1 in the context of the common general knowledge (Articles 54 and 56 EPC). Moreover, the claims of this request did not solve the problem underlying the invention over their full scope. Claims 1 and 2 used overly broad terms without any further essential technical features.

XII. Respondent's submissions, insofar as relevant to the present decision, may be summarised as follows:

Admissibility of a fresh ground of opposition

The new ground of opposition (Article 53(c) EPC) went beyond the grounds covered by the original Notice of Opposition, it did not result from amendments made in the opposition proceedings and it could have been raised in the opposition proceedings. In line with the established case law, it was not admissible into the appeal proceedings.

Main Request - Article 54 EPC

Claim 1 was directed to a new use of a known compound. The expression of a protein/antigen at mucosal effector sites "to induce mucosal IgA antibody response" was not an inherent feature disclosed in the prior art and not made available by document D1. This document disclosed the use of a (partially deleted) pagC fused to an heterologous antigen to elicit a humoral IgG antibody response and the detection of antibodies circulating in the blood stream. There was no disclosure of mucosal site induction to elicit a mucosal IgA antibody response. The delivery of a protein to elicit a humoral immune response or the production of a humoral immune response by a protein, did not lead to the conclusion

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that the same protein delivered to a mucosal effector site could elicit a mucosal immune response, and especially not an induction of a mucosal IgA antibody response.

The contested patent demonstrated that the mucosal and humoral responses elicited by an antigen could be markedly different. Figure 3b illustrated that IgG serum (circulating) antibodies were elicited against F1 antigen (taken from mouse blood) through expression of the promoter lacZ, whereas Figures 5 and 7a illustrated that the expression of the same lacZ promoter was not sufficient to elicit a mucosal IgA antibody response (taken from gut and lung wash samples). Contrary to appellant's assertions, it was not common general knowledge that oral Salmonella vaccines inherently elicited an IgA (mucosal) immune response. Indeed, document D8 showed that oral Salmonella vaccines did not inherently elicit such response.

Since inducing an IgA antibody mucosal response at mucosal effector sites was a functional technical feature which was not disclosed in document D1, not even inherently, the subject-matter of claim 1 was novel over document D1.

Admissibility of Auxiliary Request 1

The sole amendment introduced in this request was the deletion of claim 1 of the Main Request, the sole claim against which objections had been raised in the appeal proceedings.

XIII. The opponent (appellant) requested that the decision under appeal be set aside and that the patent be revoked.

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XIV. The patentee (respondent) requested that the appeal be dismissed, i.e. that the patent be maintained on the basis of the set of claims upheld by the opposition division (Main Request), or in the alternative, that the patent be maintained on the basis of Auxiliary Request 1 filed on 10 November 2013.

Reasons for the Decision

Admissibility of a new Ground of Opposition (Article 53(c) EPC)

- 1. In the statement of Grounds of Appeal, the appellant has raised an objection under Article 53(c) EPC 2000 against the subject-matter of claim 1 which, in its view, is a method of treatment (cf. point XI supra). The amendment introduced into claim 1 of the request upheld by the opposition division does not change the nature or character of the original method of claim 1 as granted (cf. points I and III supra).
- 2. According to the decision G 1/95 (OJ EPO 1996, page 615), in a case where a patent has been opposed on the grounds set out in Article 100(a) EPC, but the opposition has only been substantiated on the grounds of lack of novelty and lack of inventive step, the ground of unpatentable subject matter based upon Articles 53 EPC is a fresh ground for opposition and accordingly may not be introduced into the appeal proceedings without the agreement of the patentee (cf. G 1/95, supra, see the Headnote, points 4.4 and 4.6 of the Reasons and the Order).
- 3. In the present case, the respondent/patentee does not agree to admit the new ground of opposition into the appeal proceedings (cf. point XII supra) and thus,

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appellant's objection under Article 53(c) EPC cannot be admitted into the appeal proceedings.

Main Request

Article 54 EPC, Article 100(a) EPC

- 4. Document D1 is the sole document cited as anticipating the subject-matter of claim 1. This document discloses the oral administration of the attenuated Salmonella typhimurium LH491 strain to BALB/c mice. The LH491 strain bears an engineered pagC-phoA fusion gene which contains the pagC promoter and expresses, in a stable and phoP-regulated manner, the PagC-alkaline phosphatase antigen (first 84 amino acids of the PaC protein fused to the heterologous alkaline phosphatase) (cf. page 2905, right-hand column, second paragraph of document D1). The S. typhimurium LH491 strain is evaluated in document D1 as a prototype vaccine vector in BALB/c mice and, after a single-dose oral immunization, an IgG response is obtained, wherein IgG antibodies directed against alkaline phosphatase are primarily of the IgG2a and IgG2b subclasses (cf. page 2906, paragraph bridging left- and right-hand columns, page 2907, Figure 5 of document D1). There is no explicit disclosure in document D1 of: i) an enhanced expression of the antigen at mucosal effector sites, and ii) the induction of mucosal IqA antibody response, which are both technical features of the method of claim 1.
- 5. In its statement of Grounds of Appeal, the appellant argues that the method of claim 1 does not represent a new non-medical use (cf. G 2/88, OJ EPO 1990, page 93 and, inter alia, T 1092/01 of 26 April 2005) or a further medical use (cf. G 5/83, OJ EPO 1985, page 64 and T 708/02 of 4 April 2006). The mechanism of mucosal

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immune response was common general knowledge at the priority date of the patent-in-suit and thus, according to the appellant, it was known that oral recombinant Salmonella vaccines induced the expression of heterologous antigens at mucosal effector sites and thereby, an IgA response. The patent-in-suit measured only the IgA response in the context of the known use (cf. point XI supra).

- 6. According to the respondent, claim 1 is directed to a new use of a known compound. The respondent argues that an antigen capable of eliciting a humoral immune response will not necessarily elicit a mucosal immune response when delivered to a mucosal effector site, and especially not an induction of a mucosal IqA antibody response. An antigen (F1) can elicit different humoral and mucosal immune responses as shown in the patent-in-suit, wherein an oral administration of $\rm SL3261/pP_{lacZ}-F1$ produces (humoral) circulating IgG and IgA anti-F1 antibodies but no (mucosal) IgA antibodies in gut or lung (cf. Figures 3b, 5 and 7b of the patent). With reference to document D8, the respondent further argues that not all oral Salmonella vaccines induce a mucosal IgA immune response. Thus, in the respondent's view, document D1 does not disclose to the public the intended purpose (functional technical feature) of claim 1, i.e. the ability to induce a mucosal IgA antibody response (cf. point XII supra).
- 7. In view of the prior art on file, the board considers that:
- 7.1 The mucosal immune system, properties and steps underlying a mucosal immune response or the induction of a mucosal response to orally administered antigens, were indeed common general knowledge of a person

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skilled in the art at the relevant date. The use and the advantages of using attenuated *Salmonella* spp. as carriers for oral administration of heterologous antigens were also known in the art (cf. page 2904 of document D1, review document D3).

- 7.2 The first step in the induction of a mucosal immune response is the transport of the antigens across the epithelial barrier, followed by the processing and presentation of the antigen by antigen-processing cells (APCs) which results in antigen-specific IgA-committed lymphocytes that proliferate locally in the mucosal inductive sites. These primed lymphocytes then migrate through the lymph and thereafter through the bloodstream to local and distant mucosal and secretory tissues, where they differentiate primarily into IgA-producing plasma cells (cf. page 329, Figure 1 and page 330, left-hand column, second paragraph to page 331, right-hand column of document D3). The first steps of a mucosal immune response, always and necessarily, induce the production of an IgA antibody response. The prior art documents on file support this conclusion (cf. inter alia document D3 with oral administration of recombinant S. tyhimurium strains with induction of mucosal IgA antibodies).
- 7.3 The relevance of the carrier, delivery system, adjuvant, (nature and properties, dose or amount of) antigen, vector, immunization site, etc. used for the immunization was also known in the art. A skilled person working in the field of vaccine development was well-aware of the possible effects and the importance of each of these elements on the transport of the vaccine through the mucosal barrier, the processing of the antigen in the APCs, the lymphoid response, etc. and their possible relevance for achieving optimal

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results. This is also derivable from the prior art documents on file and further reflected in the cautious comments made in document D1 and referred to by the opposition division (cf. page 2908, left-hand column, lines 14 to 24 of document D1).

- 8. As noted in points 4 and 6 supra, document D1 discloses the oral administration of the attenuated S. typhimurium LH491 strain in which the heterologous antigen is expressed under the control of the pagC promoter. Thus, there is no doubt that the antigen is administered at a mucosal effector site and, in view of the properties of the pagC promoter which are explicitly acknowledged in document D1 (cf. page 2904, right-hand column of document D1), there is no reason not to consider that the expression of the antigen is enhanced at a mucosal effector site. In the light of this common general knowledge and in particular the comments made in point 9.2 infra, there is also no reason to consider that the expression of the antigen will not result in the induction of a mucosal IqA antibody response. As for the arguments of the respondent, the board considers that:
- and 5 of the patent-in-suit are those obtained by administration of SL3261/pP_{lacZ}-F1 in which the protein of interest is under the control of the *lacZ* promoter. This promoter does not have the advantageous properties of the *pagC* promoter and thus, the results obtained with these two different promoters are not comparable. If a comparison is to be made, it should be made with the results obtained in the patent-in-suit when administering SL3261/pP_{pagC}-F1, since it has the *pagC* promoter used in document D1. When this is done, Figure 3b shows circulating serum IgG antibodies and Figure 5

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shows both circulating serum IgA antibodies and mucosal IgA antibodies in the gut. Figure 7 is also relevant, since it shows the presence of both anti-F1 (Figure 7a) and anti-Salmonella IgA (Figure 7b) antibodies in Peyer's patch cells, i.e. an induction of mucosal IgA antibody response fully in line with the common general knowledge (cf. points 7.1 and 7.2 supra).

- 8.2 Even if the results of the patent-in-suit show that IgA antibodies are not found in all mucosal tissues (only in gut but not lung, Figure 5) and that the level of IgA antibodies depends on the antigen used (Figures 7a and 7b), these results only support the possible effects of the elements and factors outlined in point 7.3 supra on the mucosal IgA immune response, such as the site of immunization (oral, nasal, rectal, vaginal) and the type of antigen used. These results are not surprising and they do not cast any doubt on the results of document D1 (oral administration, attenuated Salmonella, pagC promoter, immunogenic antigen).
- 8.3 Indeed, the nature of the antigen explains the difficulties for achieving a mucosal immune response in the studies of document D8. The heat-stable toxin (ST) produced by E. coli strains is described as "a non-immunogenic low-molecular-mass peptide (2kDa); however, its conjugation to different carriers can lead to the induction of neutralizing antibodies" (c. page 861, right-hand column of document D8). In fact, "sera and mucosal secretions from mice immunized orally with an attenuated Salmonella strain carrying this genetic fusion [between ST and heat-labile (LT) toxins] were able to neutralize the biological activity of native ST" and an "enhancement of the specific mucosal IgA immune response by expression of interleukin-5 by an attenuated Salmonella strain has been recently

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demonstrated" (emphasis added by the board) (cf. paragraph bridging pages 861 and 862, page 866, left-hand column of document D8). This disclosure is fully in line with the common general knowledge as outlined in points 7.1 and 7.2 supra, the encountered difficulties support the known relevance and effects of the elements outlined in point 7.3 supra. In view of the nature of the antigen used in document D8, these results are not surprising and they also do not cast any doubt on the results of document D1 (pagC promoter, oral administration, attenuated Salmonella, immunogenic antigen).

- 9. In view of the arguments of the respondent, the board also considers the following points to be relevant:
- 9.1 The method of claim 1 does not quantify the enhanced expression of the desired protein nor does it require any specific level of the induced mucosal IgA antibody response, i.e. there is no specific requirement in claim 1 for the efficiency, yield or production of any of these features, let alone a requirement to achieve any immunologic (vaccine) protection. Moreover, the claimed method is completely silent on a possible induction of an additional humoral immune response or the additional presence of (humoral) circulating IgG antibodies which are not excluded by the method of claim 1. According to the established case law, when novelty is assessed, there is no reason to use the description to interpret an excessively broad claim more narrowly, if it is a question not of understanding concepts that require explanation but rather examining an excessively broad request in relation to the state of the art (cf. "Case Law of the Boards of Appeal of the EPO", 7th edition 2013, I.C.3.8, page 114).

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- Apart from the specific promoters P_{phoP} (SEQ ID NO: 2) and P_{pagC} (SEQ ID NO: 3) (or fragments or variants thereof having promoter activity) and the expression at a mucosal effector site in mucosal cells, which is considered to limit the administration site for immunization to mucosal tissues, there is no other limiting requirement in the method of claim 1. It is not limited to any specific delivery system (such as attenuated Salmonella), antigen or protein of interest (and thus, includes the alkaline phosphatase and the ST of documents D1 and D8, respectively), mucosal tissue (oral, nasal, rectal, vaginal), adjuvant, etc.
- 9.3 The board has no reason to doubt that the experiments reported in document D1 result in a mucosal IgA immune response in line with the common general knowledge (cf. points 7.1 and 7.2 supra) which is also supported by the results of document D8 (cg. point 8.3 supra). Also the results of the patent itself do not point in another direction (cf. points 8.1 and 8.2 supra). If, however, this should not be correct, the question arises which other technical features, besides those indicated in claim 1, allow a skilled person to achieve the desired effect and result of the claimed method, i.e. expression at mucosal effector site and induction of a mucosal IgA antibody response. According to the established case law, a claim must indicate all the essential technical features necessary for solving the technical problem with which the patent is concerned (cf. "Case Law", supra, II.A.3.2., page 252).
- 10. Thus, in view of all the above considerations and applying, as required by the established case law, the same standard when assessing the disclosure of a prior art document and that of the patent specification (cf. inter alia, T 870/02 of 16 September 2004, point 6 of

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the Reasons; T 423/01 of 25 March 2004, point 21 of the Reasons), the subject-matter of claim 1 is considered to be anticipated by the disclosure of document D1 (Article 54 EPC).

Admissibility of Auxiliary Request 1

- 11. Auxiliary Request 1 was filed by the respondent in direct reply to the board's communication pursuant to Article 15(1) RPBA. In this communication, the board noted that, in the appellant's statement of Grounds of Appeal, objections were raised only against the subject-matter of claim 1 and that these objections were considered to be relevant (cf. point VI supra). The objected claim 1 has been deleted and is not present in Auxiliary Request 1. No other amendments have been made in this auxiliary request, which thus overcomes all the objections raised in the appellant's Grounds of Appeal and noted in the board's communication.
- 12. Thus, the board, in the exercise of its discretion, decides to admit Auxiliary Request 1 into the appeal proceedings (Article 13(1) RPBA).

Patentability of Auxiliary Request 1

13. This request is distinguished from Auxiliary Request 2 (claims 1 to 15) before the opposition division, which was considered to meet all requirements of the EPC (cf. points II and III supra), by the deletion of claim 1 only. According to the decision under appeal (cf. pages 8-9, points 7-8), the appellant/opponent did not raise any objection against the claim request upheld by the opposition division. Apart from claim 1, all claims of this request were limited to embodiments concerning

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only and exclusively the P_{phoP} promoter and gene (cf. point III supra). The appellant/opponent's reaction on this request is also reflected in the Minutes of the oral proceedings before the opposition division (cf. page 3, point 25).

- 14. In reply to the board's communication, the appellant has raised, for the first time in appeal proceedings, several objections against the subject-matter of Auxiliary Request 1 concerned with the P_{phoP} promoter and gene (cf. point VIII supra). Although the objected subject-matter was already present in the requests underlying the decision under appeal and thus considered by the opposition division, none of these objections were raised at first instance proceedings (cf. point 13 supra). The objections have been raised by the appellant in very general terms, without giving a detailed analysis (P_{phoP} promoter and gene, problem solution approach, etc.) and without providing reasons to explain why they have been raised at this late stage of the proceedings.
- The board takes the view that appellant's objections raised after the filing of its Grounds of Appeal represent an amendment to its case (Article 13(1) RPBA), and that these objections could, and should, have been raised in the first instance proceedings (Article 14(2) RPBA). In view thereof, the board, in the exercise of its discretion, considers that these objections are not admissible at this late stage of the proceedings.
- 16. The Board sees no reason to deviate from the decision of the opposition division as regards the patentability of the particular subject-matter of present Auxiliary Request 1.

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Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of claims 1 to 14 of the Auxiliary Request 1 filed with letter dated 10 November 2013 and a description to be adapted thereto.

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated