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Datasheet for the decision of 14 November 2006

Case Number: T 0029/06 - 3.3.08

Application Number: 96902830.7

Publication Number: 0813603

IPC: C12N 15/74

Language of the proceedings: EN

Title of invention:
Expression of gene products from genetically manipulated strains of Bordetella

Applicant:
Aventis Pasteur Limited

Opponent:
-

Headword:
Bordetella/AVENTIS

Relevant legal provisions:
EPC Art. 83
EPC R. 28

Keyword:
"Sufficiency of disclosure (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0029/06 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 14 November 2006

Appellant: Aventis Pasteur Limited
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 6 May 2005 refusing European application No. 96902830.7 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: C. Rennie-Smith
Members: T. J. H. Mennessier
M. R. Vega Laso

Summary of Facts and Submissions

I. The Applicant (Appellant) lodged an appeal against the decision of the Examining Division of 6 May 2005 refusing the European patent application No. 96 902 830.7 with publication number 0 813 603. The application, entitled "*Expression of gene products from genetically manipulated strains of Bordetella*" was published as the international PCT application WO 96/26282.

II. The application had been refused for reason of non-compliance with the requirements of Articles 84 and 56 EPC, basis for the refusal being the claim request filed with letter of 18 March 2005 (claims 1 to 20).

III. The claim request consisted of 20 claims.

Claim 1 read:

"1. A nucleic acid molecule comprising a *Bordetella* promoter operatively coupled to a heterologous nucleic acid sequence encoding a non-*Bordetella* gene product and a leader sequence for secretion of the non-*Bordetella* gene product, wherein the non-*Bordetella* gene product is selected from the group consisting of proteins and peptides and which is an immunogen, and wherein the heterologous nucleic acid sequence is transcriptionally regulated by the promoter in *Bordetella*, said nucleic acid molecule having a first DNA sequence corresponding to a 5' flanking sequence of a selected *Bordetella* gene and disposed at the 5' end of the nucleic acid molecule and a second DNA sequence corresponding to a 3' flanking sequence of the selected

Bordetella gene and disposed at the 3' end of the nucleic acid molecule, the first and second DNA sequence permitting specific integration of the nucleic acid molecule into a *Bordetella* genome at a locus corresponding to the selected *Bordetella* gene."

Claims 2 to 12 were, directly or indirectly, dependent on claim 1 and were directed to particular embodiments thereof.

Claim 13 was directed to a plasmid adapted for transformation of a *Bordetella* strain comprising the nucleic acid molecule claimed in any one of claims 1 to 12.

Claim 14 read:

"14. The plasmid claimed in claim 13, which selected from the group consisting of DS-546-1 as shown in Figure 2 and described in relation thereto, JB-898-2-1 as shown in Figure 4 and described in relation thereto, DS-729-1-1 as shown in Figure 6 and described in relation thereto, DS-729-2-1 as shown in Figure 8 and described in relation thereto, JP-1201-4 as shown in Figure 10 and described in relation thereto, JB-1141-5 as shown in Figure 12 and described in relation thereto, JB-1957-27 as in Figure 16 and described in relation thereto, JB-1989-R-1 as shown in Figure 16 and described in relation thereto, DS-1719-28 as shown in Figure 17 and described in relation thereto, and DS-1732R-14 as shown in Figure 18 and described in relation thereto.".

IV. On 15 September 2005, the Appellant filed a statement setting out the grounds of appeal. Claims 1 to 20, on the basis of which the application was refused by the examining division, were maintained as the sole claim request. In the event that the Board did not intend to allow this request, oral proceedings were requested.

V. The Examining Division did not rectify its decision and referred the appeal to the Board of Appeal (Article 109 EPC).

VI. The appellant was summoned to oral proceedings. A communication under Article 11(1) of the Rules of Procedure of the Boards of Appeal (RPBA) presenting some preliminary and non-binding views of the Board was sent with the summons. In the communication, the Board indicated *inter alia* that, exercising its discretion, it would like to discuss the issue of sufficiency of disclosure in connection with the subject-matter of claim 14, despite the fact that the Examining Division had not raised any objection of insufficiency of disclosure. The Board regarded it as doubtful whether a skilled person would be capable of reproducing in detail anyone of the plasmids for which protection was sought in claim 14.

VII. The Appellant did not submit any observations in reply to the Board's communication but informed the Board with a letter dated 1 September 2006 that it withdrew its request for oral proceedings and requested that a decision be given based on the written proceedings.

VIII. Oral proceedings were held on 14 November 2006, at the end of which the Board announced its decision. They were not attended by the appellant.

IX. The appellant had requested in writing that the decision under appeal be set aside and the case be remitted to the examining division with the order to grant a patent on the basis of claims 1 to 20 as filed with its letter of 18 March 2005.

Reasons for the Decision

1. Although insufficiency of disclosure was not given as a reason for the refusal in the decision under appeal, the Board, exercising its discretion (see Decision G 10/93, OJ EPO 1995, 172, Order) and as announced in its communication under Article 11(1) RPBA, regards it as appropriate to assess whether the present application discloses the aspect of the invention, to which claim 14 is directed, in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, as required in Article 83 EPC.

2. Claim 14 being directed to a number of specific plasmids, which are circular DNA molecules having a definite nucleotide sequence, the question to be answered is whether a skilled person, reading the application and considering in turn each of the plasmids, would have found in the application as filed adequate information for constructing a given plasmid or, as an alternative, for obtaining it from a biological material containing it, if a deposit of such a material had been made with a recognised depositary

institution in accordance with the provisions of Rule 28 EPC.

3. As a first step the assessment will be carried out with plasmid DS-546-1 which is the first mentioned in claim 14.

4. The construction of plasmid DS-546-1 is described in Example 2 (see from line 25 on page 15 to line 28 on page 28) and schematically represented on Figure 2 (see drawing sheet 2/22). For the construction of this plasmid, the skilled person has to be provided with 14 distinct oligonucleotides, referred to as oligonucleotides 2769 to 2782 in Figure 2 and as oligonucleotides "2769.SL (SEQ ID NO: 3)" to "2782.SL (SEQ ID NO: 16)") in Example 2, as well as with 3 of the 6 plasmids represented on Figure 2, namely plasmids S-3616-2, pUC18 and S-3484-3-27, the 3 other plasmids involved in the construction, namely plasmids JB-867-1-1, DS-525-1-1, and DS-534-1, being only intermediate constructs.

5. The Board is of the opinion that a person skilled in the art, on the basis of the information contained in Example 2 and at the top of Figure 2 (showing that oligonucleotides can hybridize two by two, for example oligonucleotide 2769 being complementary with 2782), would be provided with sufficient information to identify in Figure 3 each of the 14 oligonucleotides required (see also the comment made on page 9, lines 11 to 13 with respect to Figure 3).

6. The Board is aware that plasmid pUC18 is well-known in the art and was commercially available years before the priority date.

7. While it may be concluded that the skilled person would be in a position to be provided with the 14 oligonucleotides and plasmid pUC18, it remains to be assessed whether plasmids S-3616-2 and S-3484-3-27 would also be available to him.

8. No deposit of a biological material containing either of the two plasmids is referred to in the application. Therefore, for those two plasmids to become available to the skilled person, sufficient information should be present in the application to allow him to construct them.

9. Information regarding plasmid S-3616-2 is contained on pages 15 (see lines 33 to 36), 16 (see lines 3 to 4), 17 (see lines 10 to 11), 19 (see line 15), 20 (see lines 4 to 5) and 23 (see lines 17 to 18). It is merely stated without further details that S-3616-2 is an 8.6 kb pBR322-based plasmid containing 2.5 kb of the 5'- and 1.3 kb of the 3'-flanking regions for the fha structural gene between Bgl II and Kpn I sites, a 4.8 kb fragment being obtained upon digestion of the plasmid by the Bgl II and Kpn I restriction enzymes and a sequence recognised by the EcoR I restriction enzyme being also present.

10. Information regarding plasmid S-3484-3-27 is found on pages 16 (see lines 18 to 21), 17 (lines 35 to 36) and 18 (see lines 22 to 23). It is merely stated without further details that S-3484-3-27 is a 14.2 kb pUC-based

plasmid containing a mutant tox gene between the 5'- and 3'- tox flanking regions, and that digestion with the Kpn I and BamH I restriction enzymes excised ~4.7 kb of the tox structural gene.

11. In the Board's view, this information, which gives only a general idea of the structure and organisation of the plasmid with no detailed indication as to the nucleotide sequence, in particular of the non-coding portions of the DNA molecule, is too vague and imprecise to enable the skilled person to construct the two plasmids.

12. Thus, neither plasmid S-3612-2 nor plasmid S-3484-3-27 would be available to the skilled person and, therefore, he would not be in a position to construct plasmid DS-546-1.

13. Moreover, whereas plasmid DS-546-1 was introduced into a tox-deleted Bordetella pertussis strain, generating strain 492-320 (see page 16, lines 24 to 28 and page 20, lines 14 to 34), the application fails to indicate whether that latter biological material has been deposited with a recognised depositary institution. Therefore, it would not be possible for the skilled person to obtain that material from which he might have expected to retrieve plasmid DS-546-1.

14. For these reasons, the Board comes to the conclusion that the application lacks information necessary for the skilled person to construct or be provided with plasmid DS-546-1. Since that negative conclusion has been reached regarding one of the plasmids for which protection is sought in claim 14, it is not necessary

to repeat the assessment for the other plasmids which are referred to in that claim.

15. Therefore, the present application does not disclose the invention to which claim 14 is directed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Consequently, the application does not comply with Article 83 EPC and should be refused.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Wolinski C. Rennie-Smith