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Datasheet for the decision of 17 September 2020

Case Number: T 1995/17 - 3.3.04

Application Number: 07794592.1

Publication Number: 2037946

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Language of the proceedings: EN

Title of invention:
Phage derived antimicrobial activities

Patent Proprietor:
Bactoclear Holdings Pte. Ltd.

Opponent:
Wächtershäuser & Hartz, Patentanwaltspartnerschaft mbB

Headword:
Chimeric peptide having bactericidal activity/BACTOCLEAR

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13(1)

Keyword:
Main request: inventive step (no)
auxiliary request 1: admitted (no)
auxiliary request 2: inventive step (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
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Office européen des brevets

Beschwerdekammern

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Case Number: T 1995/17 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 17 September 2020

Appellant: (Opponent)	Wächtershäuser & Hartz Patentanwaltspartnerschaft mbB Weinstrasse 8 80333 München (DE)
Respondent: (Patent Proprietor)	Bactoclear Holdings Pte. Ltd. 1 Robinson Road 17-00, AIA Tower Singapore 048542 (SG)
Representative:	Mewburn Ellis LLP Aurora Building Counterslip Bristol BS1 6BX (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 24 July 2017 rejecting the opposition filed against European patent No. 2037946 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chair	B. Claes
Members:	R. Morawetz
	R. Romandini

Summary of Facts and Submissions

I. The appeal lodged by the opponent ("appellant") lies from the opposition division's decision rejecting the opposition against European patent No. 2 037 946 ("the patent"). The patent, entitled "*Phage derived antimicrobial activities*", derives from European patent application No. 07 794 592.1, which was filed as an international application under the PCT with the application number PCT/US2007/010972, published as WO 2007/130655 ("application as filed" or "application") and claiming the priority dates of US Provisional application 797885 filed on 5 May 2006, and US Provisional application 909340 filed on 30 March 2007.

II. The patent was opposed under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), and under Article 100(b) and 100(c) EPC.

III. In their statement of grounds of appeal, the appellant submitted arguments to the effect that, *inter alia*, the subject-matter of claim 1 as granted lacked inventive step and the patent did not disclose the invention in claims 1 to 12 as granted in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

IV. The patent proprietor is the respondent in these appeal proceedings. In reply to the statement of grounds of appeal, the respondent maintained the patent as granted as their main request, stated that they maintained "*the auxiliary claim requests that were filed in opposition*" and provided their counter-arguments with respect to

the subject-matter of the set of claims of the main request.

Claim 1 of the main request (claims as granted) reads as follows:

"1. A chimeric polypeptide comprising
(i) a muralytic domain (MD) having at least 90% identity to amino acids 669-808 of SEQ ID NO:1; and
(ii) a heterologous cell binding domain (CBD) that binds to a target bacterium, said chimeric polypeptide having bactericidal activity."

V. The board summoned the parties to oral proceedings and issued a communication pursuant to Article 15(1) RPBA, informing the parties, *inter alia*, that it was of the preliminary opinion that the auxiliary claim requests filed during the opposition proceedings did not need considering pursuant to Article 12(4) RPBA 2007 because the requirements of Article 12(2) RPBA 2007 were not met.

VI. In response, by letter of 2 June 2020 the respondent filed sets of claims of auxiliary requests 1 to 6.

VII. The appellant provided their counter-arguments with respect to the sets of claims of auxiliary requests 1 to 6.

VIII. The respondent submitted arguments as to why the auxiliary claim requests were suitable for addressing the appellant's inventive step objections.

IX. During the oral proceedings before the board the respondent filed sets of claims of new auxiliary

request 1, new auxiliary request 2 and auxiliary request 2 15:10, replacing the previously filed new auxiliary request 2.

Claim 1 of auxiliary request 1 reads as follows:

"1. A chimeric polypeptide having bactericidal activity against *Staphylococcus aureus* comprising SEQ ID NO:4."

Auxiliary request 2 15:10 (referred to in the following as "auxiliary request 2") consists of three claims which read as follows:

"1. A chimeric polypeptide consisting of SEQ ID NO:4.

2. An isolated nucleic acid encoding the polypeptide of claim 1.

3. An expression vector comprising the nucleic acid of claim 2."

At the end of the oral proceedings, the Chair announced the board's decision.

X. The following documents are referred to in this decision:

D2 UniProt, Accession number Q6Y731 (14 October 2015), ORF56 phageK_109, Staphylococcus phage K

D5 Donovan D.M. et al., Applied and Environmental Microbiology (2006), vol. 72, pages 2988 to 2996

D7 GenBank, Accession number AAO47505 (6 May 2004), ORF56 [Staphylococcus virus K]

XI. The appellant's arguments are summarised as follows.

Main request

Claim interpretation - claim 1

As a consequence of the term "*comprising*", the claimed subject-matter covered chimeric polypeptides that comprise the full-length lysostaphin protein containing a cell-wall binding domain (CBD).

Inventive step (Article 100(a) and Article 56 EPC) - claim 1

Closest prior art

Document D5 disclosed chimeric proteins based on the *Streptococcus agalactiae* bacteriophage B30 endolysin containing an endopeptidase domain, i.e. a Cysteine-Histidine dependent Aminohydrolase/Peptidase (CHAP), and the lysostaphin protein of *Staphylococcus simulans*. The chimeric polypeptide depicted in Figure 1 of document D5, consisting of the 182 amino acids of the B30 endolysin truncated down to the CHAP domain, B30-182, and fused to the mature form of secreted lysostaphin, had bactericidal activity and represented the closest prior art.

Objective technical problem

The difference between the chimeric polypeptide of document D5 and the claimed chimeric polypeptide was the muralytic domain (MD), which included the CHAP

domain of the lysin of a different phage, namely of the bacteriophage K.

There were no data on file comparing the polypeptide of document D5 and the claimed polypeptide with respect to bactericidal activity.

The data obtained with construct 1 of the patent merely related to one embodiment of claim 1.

The objective technical problem was providing an alternative chimeric polypeptide having bactericidal activity.

Obviousness of the claimed solution

Document D5 taught that in order to obtain a chimeric protein showing bactericidal activity it was necessary and sufficient to fuse the CHAP domain of a phage lysin to the lysostaphin protein.

Document D5 provided an incentive to try different CHAP domains (see page 2989, right-hand column, line 1 to 5).

The CHAP domain of bacteriophage K was known from documents D2 and D7 and was one of the obvious alternatives.

Document D7 confirmed that, before the priority date of the patent in suit, it was known that a CHAP domain was present in the region of amino acids 691 to 779 of ORF56. The application on which the patent in suit is based confirmed that the presence of a CHAP domain at the C-terminal end of ORF56 was known; see paragraphs [0159] and [0160].

In view of the teaching of document D5 the skilled person would expect a fusion of lysostaphin and a CHAP domain to display bactericidal activity.

While there might have been other known CHAP domains of suitable lysin phages available, arbitrarily selecting one of them and confirming what was expected from document D5 without providing any additional benefit was not inventive.

The skilled person was looking for an alternative chimeric polypeptide having bactericidal activity, not for an alternative chimeric polypeptide having dual lytic activity.

Sufficiency of disclosure - claims 1 to 12

Not all claimed chimeric polypeptides had bactericidal activity. The example chimeric polypeptides tested showed bactericidal activity only against *Staphylococcus aureus* strains.

Auxiliary request 1

Admittance (Article 13 RPBA 2007)

The request was filed at a very late stage in the proceedings and was not clearly allowable.

Auxiliary request 2

Admittance (Article 13 RPBA 2007)

The request was filed at a very late stage in the proceedings and it could not be quickly ascertained whether it was clearly allowable.

Inventive step (Article 56 EPC)

The fusion protein consisting of the truncated B30 endolysin and mature lysostaphin disclosed in document D5 represented the closest prior art.

The claimed polypeptide differed from that fusion protein in that the CHAP domain of a different phage was linked to the CBD domain of lysostaphin.

There were no comparative data on file showing that the claimed polypeptide had an effect beyond that of the fusion protein of document D5.

The objective technical problem to be solved was thus again providing an alternative chimeric polypeptide having bactericidal activity.

The claimed chimeric polypeptide was an obvious alternative for the skilled person.

Sufficiency of disclosure (Article 83 EPC)

The objections raised in the statement of grounds of appeal against the patent as granted (main request) also applied to this request.

XII. The respondent's arguments are summarised as follows.

Main request

Claim interpretation - claim 1

The claim did not cover chimeric polypeptides comprising full-length lysostaphin.

Inventive step (Article 100(a) and Article 56 EPC) - claim 1

Closest prior art

It was agreed that the disclosure in document D5 of a fusion of the truncated *S. agalactiae* bacteriophage B30 endolysin to the mature lysostaphin protein of *S. simulans* was the closest prior art.

Objective technical problem

The claimed polypeptide differed from the fusion protein in document D5 in that the MD was from ORF56 CHAP and not from B30, and in that it comprised the CBD of a heterologous endolysin whereas the chimeric polypeptides of document D5 contained the full-length lysostaphin.

There was no side-by-side comparison of the bactericidal activity of the claimed polypeptide and the peptide disclosed in document D5.

However, the patent provided data on the stability of chimera 128 (see paragraphs [0180] and [0182]), which fell under claim 1 and was more stable than the polypeptide of document D5 (see page 2991, right-hand column, first paragraph).

The objective technical problem to be solved was providing a fusion protein with a minimal catalytic domain that retained good bactericidal activity and could be purified and stored conveniently.

Obviousness of the claimed solution

Documents D2 and D7 did not disclose that ORF56 comprised a CHAP domain (see reasons set out in point 3.2., third paragraph, of the decision under appeal).

The teaching of document D5 discouraged the skilled person from producing the claimed chimeric polypeptides.

Starting from the disclosure in document D5, the skilled person was only taught to produce fusion proteins that would have activity against *S. agalactiae* and *S. aureus*.

The skilled person looking to provide further polypeptides with bactericidal activity would not replace the CHAP-containing portion of B30 endolysin from document D5 with a domain having the same activity as the second domain, and thus would not swap the B30 endolysin domain for the MD of ORF56.

Auxiliary request 1

Admittance (Article 13 RPBA 2007)

The amendments made were clearly allowable under Article 123(2) EPC. The basis for the subject-matter was found in paragraphs [0014], [0033], [0052], [0174], [0175] and [0177], and on page 4, lines 18 to 20 and page 69, lines 15 to 16 of the application as filed.

The request addressed the inventive step issue raised with respect to claim 1 of the main request.

Auxiliary request 2

Admittance (Article 13 RPBA 2007)

The claimed subject-matter was based on page 69, lines 15 to 23, paragraphs [0037], [0088] and [0133], and page 27, lines 26 to 28 of the application as filed.

The request met the requirements of Article 123(2) EPC and addressed the board's concerns with regard to the inventive step of the subject-matter of claim 1 of the main request.

Inventive step (Article 56 EPC)

The claim was limited to a chimeric polypeptide consisting of SEQ ID NO:4, the sequence of construct 1 of the examples.

The claimed polypeptide differed from the polypeptide disclosed in document D5 on account of two structural modifications: the CHAP domain was of a different phage and only the CBD binding domain of lysostaphin was present.

The objective technical problem to be solved was providing an alternative chimeric polypeptide having bactericidal activity.

Starting from the disclosure in document D5 the skilled person would not arrive in an obvious manner at the claimed polypeptide because document D5 provided no teaching to undertake either of those modifications.

Sufficiency of disclosure (Article 83 EPC)

The claimed polypeptide could be made by the skilled person.

XIII. The appellant requested that the decision under appeal be set aside and the patent be revoked in its entirety.

The respondent requested that the appeal be dismissed and the patent be maintained as granted or, alternatively, that the patent be maintained in amended form on the basis of the claims of auxiliary request 1 or auxiliary request 2 15:10, both filed during the oral proceedings, or, further alternatively, on the basis of the claims of one of auxiliary requests 3 to 6 submitted with the letter of 2 June 2020.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is admissible.

2. A new version of the Rules of Procedure of the Boards of Appeal (RPBA 2020; hereinafter "RPBA"; OJ EPO 2020, Supplementary publication no. 1, III.2) entered into force on 1 January 2020. The transitional provisions are set out in Article 25 RPBA. In the case in hand the parties were notified of the summons to oral proceedings before 1 January 2020. Therefore, Article 13(1) and (3) RPBA 2007 apply.

Main request (claims as granted) - claim 1

Claim interpretation

3. The claim defines the chimeric polypeptide as "*comprising*" (i) a muralytic domain ("MD") and (ii) a heterologous cell binding domain ("CBD") that binds to a target bacterium, said chimeric polypeptide having bactericidal activity (see section IV. above).

4. The board concurs with the appellant that as a consequence of the word "*comprising*" feature (ii) does not restrict the chimeric polypeptide to chimeric polypeptides comprising an isolated heterologous CBD. On the contrary, feature (ii) also covers full-length endolysins which contain a CBD, such as the mature lysostaphin protein of *Staphylococcus simulans*.

Inventive step (Article 100(a) and Article 56 EPC) - claim 1

Closest prior art

5. In the decision under appeal the disclosure of a "*chimeric construct B30-lysostaphin with activity against S. aureus*" in document D5 was held to represent the prior art closest to the claimed polypeptide. This view was shared by the appellant on appeal and was not contested by the respondent. The board sees no reason to diverge from this finding.

6. The ultimate goal of the work described in document D5 was to create transgenic cattle that are resistant to mastitis caused by *Staphylococcus aureus* and *Streptococcus agalactiae* through expression of antimicrobial proteins in their milk. Two antimicrobial proteins were created and tested for their bactericidal

activity. The first fusion protein consisted of the full-length ("B30-443") *S. agalactiae* bacteriophage B30 endolysin fused to the mature lysostaphin protein of *S. simulans*. By contrast, in the second fusion protein a 182-amino acid ("B30-182"), C-terminally truncated *S. agalactiae* bacteriophage B30 endolysin, was fused to the mature lysostaphin protein (see abstract; page 2991, left-hand column, second paragraph; Figure 1). Both fusion proteins were shown to be bactericidal for streptococcal pathogens, *S. aureus* and multiple human pathogens (see abstract; page 2991, left-hand column, second paragraph; Figure 1).

7. The full-length B30 endolysin contains a CHAP endopeptidase domain which is also present in the C-terminally truncated B30 endolysin (see Figure 1). The mature lysostaphin protein contains a lytic domain (see page 2989, left-hand column, second paragraph) and a CBD that binds to the target bacterium *S. aureus* (see page 2994, left-hand column, first paragraph).

8. The board considers that the teaching in the state of the art closest to the claimed invention is the fusion protein that consists of the truncated B30 endolysin containing the CHAP domain and the mature lysostaphin protein containing a CBD domain.

Objective technical problem

9. The respondent's submission that the claimed chimeric polypeptide differed from the chimeric polypeptide of document D5 in that it comprised the CBD of a heterologous endolysin whereas the chimeric polypeptides of document D5 contained the full-length lysostaphin fails in view of the claim interpretation

adhered to by the board (see point 4. above).

10. The claimed chimeric polypeptide, therefore, differs from the fusion protein of document D5 solely in that it comprises a different CHAP domain, namely an MD having at least 90% identity to amino acids 669 to 808 of SEQ ID NO:1, i.e. the amino acid sequence encoding the CHAP domain of the ORF56 lysin of bacteriophage K.

11. As regards the effect(s) linked to this difference, the respondent did not dispute that there was no evidence on file comparing the claimed chimeric polypeptide directly with the fusion polypeptide disclosed in document D5 with respect to their bactericidal activity or any other effect. The respondent did, however, point to stability data disclosed in the patent in suit for purified construct 1, which is also referred to in the patent as chimera 128 (see paragraphs [0180] and [0182]). They compared these data with the stability data disclosed in document D5 for purified B30-182 and B30-443 protein (see page 2991, right-hand column, first paragraph) and argued that the particular construct 1 showed an improvement in storability and that this effect should be taken into account for the formulation of the problem.

12. According to the case law of the boards of appeal if a technical effect is relied on for the formulation of the objective technical problem, this effect should, in principle, be achievable over the whole area claimed (see Case Law of the Boards of Appeal, 9th edition 2019, section I.D.4.3). Construct 1 is just one embodiment of claim 1 while the structure of the claimed chimeric polypeptides is largely undefined. It is therefore not self-evident that any effect achieved with construct 1 is achieved by all polypeptides

covered by claim 1. The respondent's line of reasoning thus fails.

13. The board concurs with the appellant that the objective technical problem to be solved by the claimed subject-matter is providing an alternative chimeric polypeptide having bactericidal activity.

Obviousness of the claimed solution

14. When seeking an alternative chimeric polypeptide having bactericidal activity, the skilled person is taught by document D5 that a fusion protein consisting of a heterologous CHAP domain linked to a mature lysostaphin protein has bactericidal activity (see Figure 1). Moreover, document D5 discloses that enzymatic domains of phage endolysins act "*independently*" and can be used to make chimeric fusion proteins that maintain the hydrolase activity against the parent organisms, i.e. fusion proteins that are bactericidal (see page 2989, right-hand column, first sentence).

15. Therefore, in the board's view, the skilled person faced with the technical problem would have readily used another available CHAP domain instead of the B30 CHAP domain in the fusion protein consisting of the truncated B30 endolysin and the mature lysostaphin protein.

16. One such available CHAP domain is that from ORF56 of Staphylococcus phage K disclosed in document D7, a print-out of the GenBank database entry concerning ORF56 of Staphylococcal phage K which bears the date 6 May 2004.

17. The respondent submitted that no proof "beyond reasonable doubt" had been provided in relation to the date on which the CHAP domain of ORF56 referred to in document D7 had been identified as such. In this context the respondent referred to document D2, the last page of which stated, "*This is version 34 of the entry and version 1 of the sequence*".

18. The general standard of proof applicable in proceedings before the boards of appeal for assessing questions of fact is the "balance of probabilities". Exceptions to this principle apply only where all evidence supporting a specific statement of fact, for instance a public prior use, is within the power and knowledge of one party, for instance the opponent. For these scenarios the boards of appeal have adopted a stricter standard of proof - "beyond reasonable doubt" (see e.g. decision T 472/92, OJ EPO 1998, 161, point 3.1 of the Reasons and Case Law of the Boards of Appeal, 9th edition 2019, III.G.4.3.2.b)). In this case, however, the relevant evidence is not in the sphere and the control of just one of the parties. For this reason, the ordinary standard is applicable.

19. The date on document D7 (see point 17) is before the earliest priority date of the patent in suit (see section I. above). Document D7 disclosed the amino acid sequence of ORF56 of Staphylococcal phage K and indicates that the region of 691 to 779 amino acids contains a CHAP domain. Furthermore, paragraph [0159] of the application on which the patent in suit is based discloses that "*Accession Number YP_024486 reported a putative ORF56 found in a Staphylococcus phage K. Based upon this report, a full length Phage K ORF56 was PCR amplified from an appropriate phage source*" while paragraph [0160] states that "[t]*he report describing*

Accession Number YP_024486 identified a domain described as Cysteine-Histidine dependent Aminohydrolase/Peptidase (CHAP). (...) The CHAP domain is on the C proximal region of the putative ORF56 and should correspond to the designated amino acids from about amino acids 690 to 805."

20. Document D2 is a print-out of the UniProt database entry concerning ORF56 of Staphylococcal phage K, which also includes information on the CHAP domain. Document D2 indicates that the sequence information was last updated on 5 July 2004 (see page 5, line 3) and also that the database entry itself was last modified on 14 October 2015 (see page 5, lines 4 and 5), i.e. after the earliest priority date of the patent in suit (see section I. above). Therefore, in the board's view, it cannot be concluded from document D2 that the information it discloses about the CHAP domain was available to the public before the earliest priority date of the patent in suit.

21. However, in view of the disclosure of document D7 and the statement in paragraph [0160] of the application as filed (see point 19. above), the board considers it more likely than not that before the effective date of the patent the information that a CHAP domain is present at the C-terminal end of ORF56 of phage K was available to the public.

22. In the decision under appeal the opposition division held that the skilled person had no particular reason to choose the CHAP domain from ORF56 among the "*full palette of CHAP domains existent*".

23. The board notes, however, that it has seen no evidence that the CHAP domain from ORF56 imparts any additional

technical effect on the claimed chimeric polypeptide beyond ensuring that it has bactericidal activity, i.e. the very technical effect that the skilled person is aiming to provide. In these circumstances, any available CHAP domain constitutes an equally obvious solution to the technical problem, so it was obvious to choose one of these.

24. The board is also not persuaded by the respondent's further arguments that, when starting from the disclosure in document D5, the skilled person was merely taught to produce fusion proteins that would have activity against *S. agalactiae* and *S. aureus* and that they would not substitute one domain for a second domain with the same activity as the second domain, and thus would not swap the B30 endolysin domain for the CHAP domain of ORF56.

25. The claim does not specify the bacterial target. Therefore, in the board's opinion, the skilled person looking for an alternative chimeric polypeptide having bactericidal activity was not restricted in their choice of the CHAP domain by any considerations concerning bactericidal activity against particular pathogens. That document D5 provided fusion proteins with bactericidal activity against two specific pathogens, *S. agalactiae* and *S. aureus*, would thus not deter the skilled person from replacing the B30 CHAP domain with any other available CHAP domain.

26. In view of the above considerations, the claimed subject-matter does not involve an inventive step (Article 56 EPC). The ground of opposition under Article 100(a) EPC thus prejudices the maintenance of the patent as granted.

Auxiliary request 1

Admittance (Article 13 RPBA 2007)

27. Auxiliary request 1 was filed during the oral proceedings, after the board had announced its opinion with respect to the main request and had indicated that it was minded not to admit into the appeal proceedings any of the pending auxiliary requests 1 to 5 submitted with the letter of 2 June 2020. Submitting this claim request represented an amendment to the respondents' case.

28. Pursuant to Article 13(1) RPBA 2007, an amendment to a party's case after the the statement of grounds of appeal or reply has been filed may be admitted and considered at the board's discretion. That discretion is to be exercised in view of, *inter alia*, the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

29. Claim 1 of auxiliary request 1 had been restricted to a chimeric polypeptide having bactericidal activity against *S. aureus* comprising SEQ ID NO:4 (see section IX.).

30. The respondent referred to paragraphs [0014], [0033], [0052], [0174], [0175] and [0177], and page 4, lines 18 to 20 and page 69, lines 15 to 16 of the application as filed as providing a basis for the claimed subject-matter.

31. Paragraph [0033] discloses that "*in one embodiment, the polypeptide comprises SEQ ID NO: 4*". SEQ ID NO:4 is the amino acid sequence of chimera 128, which consists of

the 16kDa ORF56 catalytic fragment linked by the amino acids Leu-Glu to the lysostaphin binding fragment (see paragraphs [0174] and [0175], and page 69, lines 15 to 16). This construct was tested and shown to have bactericidal activity against *S. aureus* (see paragraph [0177]). Paragraphs [0014] and [0052] disclose that *S. aureus* is one of the possible bacterial targets, while page 4, lines 18 to 20 discloses a "*chimera consisting of the murein-degrading catalytic domain of ORF56 and the non-catalytic cell-wall binding domain (CBD) of the lytic Staphylococcal bacteriocin, lysostaphin*", i.e. construct 1.

32. The board concludes that the application as filed discloses a polypeptide comprising SEQ ID NO:4 and having bactericidal activity against *S. aureus* because it contains the 16kDa ORF56 catalytic fragment and the lysostaphin binding fragment. However, as a consequence of the feature "*comprising SEQ ID NO:4*", the subject-matter of claim 1 covers chimeric polypeptides in which the domains causing bactericidal activity against *S. aureus* are not necessarily those of SEQ ID NO:4. In other words, claim 1 covers all sorts of chimeric polypeptides that have bactericidal activity against *S. aureus* and also comprised SEQ ID NO:4; however, the application as filed provides no basis for these.

33. Therefore, the board held this request to be not clearly allowable and considered that admitting it into the appeal proceedings would thus not serve the need for procedural economy.

34. In view of the above considerations, the board, exercising its discretion pursuant to Article 13(1) RPBA 2007, decided not to admit auxiliary

request 1 into the appeal proceedings.

Auxiliary request 2

Admittance (Article 13 RPBA 2007)

35. Auxiliary request 2 was also filed during the oral proceedings before the board and likewise represented an amendment to the respondents' case.

36. Claim 1 of auxiliary request 2 is restricted to a chimeric polypeptide consisting of SEQ ID NO:4, the sequence of construct 1 of the examples of the patent in suit. Dependent claims 2 and 3 are directed, respectively, to an isolated nucleic acid encoding the polypeptide of claim 1 and to an expression vector comprising the nucleic acid of claim 2 (see section IX.).

37. The claimed subject-matter meets the requirements of Article 123(2) EPC. The application as filed discloses a chimeric polypeptide consisting of SEQ ID NO:4 (see page 69, lines 15 to 23 and paragraph [0175]), nucleic acids encoding the polypeptides of the invention (see paragraphs [0037] and [0133]) and expression vectors comprising the nucleic acids (see paragraph [0088] and [0133]).

38. It was also immediately apparent to the board that the amendments serve to address the board's concerns with regard to the inventive step of the subject-matter of claim 1 of the main request.

39. Therefore, exercising its discretion pursuant to Article 13(1) RPBA 2007, the board decided to admit

auxiliary request 2 into the appeal proceedings.

Inventive step (Article 56 EPC)

Closest prior art and objective technical problem to be solved

40. The parties agreed that the fusion protein consisting of the truncated B30 endolysin and mature lysostaphin protein disclosed in document D5 also represented the prior art closest to the subject-matter now being claimed. The board sees no reason to diverge from this.

41. The claimed polypeptide differs from this fusion protein on account of two structural modifications: first, the CHAP domain is from a different phage (ORF56 lysin of bacteriophage K), and second, only the CBD binding domain of lysostaphin is present while the enzymatic domain had been removed.

42. The claimed chimeric polypeptide has bactericidal activity against various *Staphylococcus aureus* strains (see paragraph [0181] of the patent in suit and points 31. and 32.).

43. However, because the board has not been presented with data directly comparing the claimed chimeric polypeptide with the fusion polypeptide disclosed in document D5 with respect to their bactericidal activity or any other effect, the objective technical problem to be solved is the same as set out above for claim 1 of the main request (see point 13.)

Obviousness of the claimed solution

44. As set out in points 14. and 15. above, the teaching in document D5 prompted the skilled person to replace the

truncated B30 endolysin CHAP domain with another CHAP domain in a fusion protein comprising the mature lysostaphin protein. However, as set out in points 6. and 7. above, the fusion proteins of document D5 each comprise the mature lysostaphin protein, which includes both a CBD and a lytic domain. In other words, the fusion proteins disclosed in document D5 always comprise two lytic domains. The board is therefore satisfied that document D5 does not prompt the skilled person, faced with the technical problem of providing an alternative chimeric polypeptide having bactericidal activity, to also remove the enzymatic domain from the mature lysostaphin protein.

45. The board concludes that starting from the disclosure in document D5 the skilled person would not arrive in an obvious manner at the claimed polypeptide. The board has not heard any argument that this conclusion would be incorrect were the disclosure in document D5 to be combined with the teaching in any of the other cited documents.

46. Therefore, the subject-matter of claim 1 involves an inventive step (Article 56 EPC). The same conclusion applies equally to the subject-matter of dependent claims 2 and 3.

Sufficiency of disclosure (Article 83 EPC)

47. In this regard, during the oral proceedings the appellant merely referred to the objections they made as to a lack of sufficiency of disclosure of the patent in relation to the invention claimed in the patent as granted (see section XI.).

48. However, in view of the amendments to claim 1, these objections do not appear to be applicable to the claimed subject-matter. While claim 1 does not require the claimed construct to have any bactericidal activity, the claimed construct possesses bactericidal activity for *Staphylococcus aureus* strains (see point 42.). Furthermore, specifying the amino acid sequence SEQ ID NO:4 enables the skilled person to make the claimed polypeptide.

49. The board thus concludes that the patent discloses the claimed invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art as required by Article 83 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the set of claims of the "second auxiliary request 15:10" filed during the oral proceedings and a description to be adapted thereto.

The Registrar: The Chair:

I. Aperribay B. Claes

Decision electronically authenticated