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**Datasheet for the decision  
of 25 January 2022**

**Case Number:** T 1598/16 - 3.3.01

**Application Number:** 06755735.5

**Publication Number:** 1907534

**IPC:** A61K35/76, C12N7/00

**Language of the proceedings:** EN

**Title of invention:**  
BACTERIOPHAGE AND THEIR USES

**Patent Proprietor:**  
Micareos B.V.

**Opponent:**  
Potter Clarkson LLP

**Headword:**  
Bacteriophage for acne treatment/MICREOS

**Relevant legal provisions:**  
EPC Art. 123(2), 83, 56  
RPBA 2020 Art. 13(2)

**Keyword:**

Amendments - added subject-matter (MR: yes)  
Amendment after summons - taken into account (no)  
Sufficiency of disclosure - (yes)  
Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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Case Number: T 1598/16 - 3.3.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.01**  
**of 25 January 2022**

**Appellant:** Potter Clarkson LLP  
(Opponent) The Belgrave Centre  
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**Representative:** Potter Clarkson  
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**Respondent:** Microeos B.V.  
(Patent Proprietor) Nieuwe Kanaal 7P  
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**Representative:** Nederlandsch Octrooibureau  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
17 May 2016 concerning maintenance of the  
European Patent No. 1907534 in amended form**

**Composition of the Board:**

**Chairman** A. Lindner  
**Members:** T. Sommerfeld  
L. Bühler

## **Summary of Facts and Submissions**

- I. European patent 1907534 is based on application 06755735.5, which was filed as an international application and published as WO 2007/007055. The patent is entitled "Bacteriophage and their uses" and was granted with 43 claims.
- II. An opposition was filed against the granted patent, the opponent requesting revocation of the patent in its entirety on the grounds of exclusion from patentability and lack of novelty and inventive step (Articles 53(c), 54(2), 56 and 100(a) EPC), insufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).
- III. By an interlocutory decision announced at oral proceedings, the opposition division decided that the patent could be maintained in amended form on the basis of the claims of auxiliary request 1 filed during the oral proceedings (Articles 101(3) (a) and 106(2) EPC).
- IV. The opponent (appellant) lodged an appeal against the decision of the opposition division. With the statement of the grounds of appeal, the appellant requested that the decision be set aside and that the patent be revoked in its entirety.
- V. The patent proprietor (respondent) replied with a letter dated 2 February 2017, requesting that the appeal be dismissed (main request) or, alternatively, that the patent be maintained according to auxiliary requests 1 to 5, all filed with the letter of reply.

VI. Summons for oral proceedings before the board were issued, followed by a communication pursuant to Article 15(1) RPBA. In this communication, the board provided a preliminary opinion on some issues, in particular added subject-matter and novelty.

VII. The respondent sent a further letter, dated 6 April 2020, submitting a new auxiliary request 6.

VIII. Oral proceedings before the board took place by videoconference as agreed with the parties.

During the oral proceedings, the respondent withdrew the pending auxiliary requests 1 to 4 and 6 and submitted a new auxiliary request 1. The previous auxiliary request 5 became auxiliary request 2. At the end of oral proceedings, the chairman announced the board's decision.

IX. The **main request** is the set of claims which were filed as auxiliary request 1 at oral proceedings before the opposition division and which were considered allowable by the opposition division. It differs from the claims as granted in that granted claims 40 to 43 were deleted.

Claim 1 of the main request reads as follows:

"1. A bacteriophage capable of lysing a *P. acnes* bacterium and incapable of lysing any bacterium which is not *P. acnes*, and which is incapable of sustaining lysogeny in a bacterium, wherein the bacteriophage has (i) a genome having overall sequence identity of at least 88% with the genome of the bacteriophage deposited under Accession No. NCIMB 41349, (ii) a genome which comprises the DNA sequence of SEQ ID NO.

5, or a genome having at least 88% overall sequence identity with the DNA sequence of SEQ ID NO:5, (iii) a genome having overall sequence identity of at least 87% with the genome of the bacteriophage deposited under Accession No. NCIMB 41350, (iv) a genome which comprises the DNA sequence of SEQ ID NO:3, or a genome having at least 87% overall sequence identity with the DNA sequence of SEQ ID NO:3, (v) a genome having overall sequence identity of at least 88% with the genome of the bacteriophage deposited under Accession No. NCIMB 41351, or (vi) a genome which comprises the DNA sequence of SEQ ID NO: 4 or a genome having at least 88% overall sequence identity with the DNA sequence of SEQ ID NO:4."

The claims of **auxiliary request 1** differ from the claims of the main request in that claims 1 to 7, 12 to 17 and 19 to 25 have been deleted while the remaining claims were amended by insertion of features and/or amended dependencies.

The claims of **auxiliary request 2** differ from the claims of the main request in that claims 1 to 7, 12 to 27 and 31 have been deleted and the necessary amendments concerning claim dependencies have been made to the remaining claims. Moreover, claim 8 of the main request (claim 1 in auxiliary request 2) has been amended as shown:

"18. A bacteriophage capable of lysing a *P. acnes* bacterium and incapable of lysing any bacterium which is not *P. acnes*, and which is incapable of sustaining lysogeny in a bacterium according to any preceding claim which is isolated and selected from: 103609 (Accession no. NCIMB 41350); 103672 (Accession no. NCIMB 41351); and 1894 (Accession no. NCIMB 41349)."

X. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

D8: Jedrzkiewicz, B. & Davies, M.A. 2000: 54th Annual Eastern Colleges Science Conference, Staten Island NY

XI. The appellant's submissions, in so far as they are relevant to the present decision, may be summarised as follows.

*Main request, Article 123(2) EPC*

The feature "overall sequence identity" did not find a basis in the application as filed in combination with the remaining features of the claim. Sequence identity and overall sequence identity were distinct, and the application as filed did not use the two expressions interchangeably. The expression "sequence identity" was defined on page 13, and there was no guidance as to why the skilled person would deviate from this meaning. In the originally filed claims, "sequence identity" was used, and this expression was also used e.g. on page 9, lines 12 to 25 and page 12, lines 21 to 34. The expression "overall sequence identity" only occurred in the context of Figures 5 and 6 and in the corresponding legend on page 36, in experiments which related to a comparison of three bacteriophages, which was different from the claimed subject-matter.

*Auxiliary request 1, admission*

Auxiliary request 1 was filed very late without an explanation for the late filing. The respondent could not have been taken by surprise by the decision

regarding Article 123(2) EPC since this outcome was foreseeable in view of the board's preliminary opinion. The respondent had had plenty of time to react and had in fact done so by submitting auxiliary request 6. The amendments did not overcome the objections under Articles 56 and 83 and raised new issues, such as problems in connection with Article 84 EPC with respect to claim 6.

*Auxiliary request 2, Articles 83 and 56 EPC*

The objections had been raised against the main request during written proceedings and concerned the feature "incapable of lysing any bacteria other than *P. acnes*", i.e. the species specificity, which was a functional feature that had to be taken into account. There was no evidence in the application as filed rendering it plausible that the bacteriophages had this property, so there was insufficiency of disclosure. As to inventive step, it was also not plausible that the problem had been solved. The difference to D8 was the deposited bacteriophages, but since there was no evidence for a technical effect, the problem could only be formulated as a mere alternative. The aim of the invention had not been achieved. Alternatives could not be considered inventive just because they were new.

- XII. The respondent's arguments, in so far as they are relevant to the present decision, may be summarised as follows.

*Main request, Article 123(2) EPC*

The expression "sequence identity" had been replaced by "overall sequence identity" during prosecution following a suggestion of the examining division for



clarity. The skilled person, a molecular biologist, would know that the two expressions had the same meaning. The examples in the application always used "overall sequence identity" and, of course, concerning the claiming of sequences for a genome, the skilled person would look to the overall sequence identity as it was clear that the entire genomes had to be compared. Figures 5 and 6 and their legend on page 36 below Table 6 used the expression "overall sequence identity" for percentages which corresponded to the percentages of claim 1. Moreover, claim 1 was directed to a functional bacteriophage with given properties, so it was clear that a complete genome was needed. Nothing in the application as filed or the cited prior art taught the differences alleged by the appellant regarding sequence identity and overall sequence identity; there was no textbook evidence on file supporting that the two expressions had different meanings. To the contrary, it was clear in the application that the sequence identity was to be assessed over the whole length of the molecules.

*Auxiliary request 1, admission*

This request was not very different to auxiliary request 5 submitted with the reply to the grounds of appeal, having only one more independent claim which was directed to the polynucleotides. It addressed all objections on file and was filed in reaction to the unexpected decision of the board regarding Article 123(2) EPC.

*Auxiliary request 2, Articles 83 and 56 EPC*

The feature "incapable of lysing any bacteria other than *P. acnes*" was not relevant for Article 83 EPC

because it did not constitute a functional limitation for the claims which were in fact restricted to the deposited bacteriophages. As to inventive step, the difference to the closest prior art D8 was that three completely different bacteriophages were provided which had the functional properties as claimed. The technical problem when starting from D8 did not have to include the species specificity. It could also be just an alternative, and, in any case, there was no suggestion in D8 that allowed arriving at the specific bacteriophages, which were shown in the application to be functional. It would hence not be obvious to obtain these bacteriophages starting from D8.

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

The respondent (patent proprietor) requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained according to the claims of auxiliary request 1, filed during the oral proceedings, or auxiliary request 2, filed as auxiliary request 5 with the letter of reply dated 2 February 2017.

### **Reasons for the Decision**

1. The appeal is admissible.
2. Main request, Article 123(2) EPC
  - 2.1 Claim 1 of the main request is based on originally filed claims 1, 9, 10, 15, 16, 21 and 22. In the

originally filed claims, however, the expression "sequence identity" is used and not "overall sequence identity" as now in claim 1. The expression "overall sequence identity" is used in the description as filed but in a different context, namely when describing the sequence comparison between the genomes of two or three different, specific bacteriophages (e.g. in the description of Figures 5 and 6 on page 36). It is not used to define a group of sequences around the given specific sequences as being part of the invention. There is no disclosure in the application as filed stating that the two expressions should be interpreted as synonyms or that reference to "sequence identity" as such implicitly encompasses the embodiment "overall sequence identity". To the contrary, the application defines "sequence identity" on page 13, first paragraph as being "calculated as the percentage of nucleotides present in the smaller of the two sequences to be compared that may also be found in the larger of the two sequences, the nucleotides preferably being arranged in the same order in both sequences". It is clear from this definition that it is not an assessment of sequence identity over the whole length of the sequences, i.e. an "overall sequence identity". The board hence fails to see a basis in the application as filed for the expression "overall sequence identity" in the context of the claimed subject-matter.

2.2 The board disagrees with the respondent's arguments that it would be implicit to the skilled person that a reference to sequence identity in relation to a genome would necessarily mean overall sequence identity. While of course the sequences encompassed by the claim should comprise a whole functional genome, as is required in the claim, this does not allow coming to any conclusion on how the sequence identity is to be assessed. It is

also apparent from claim 26 that the argument does not hold, since claim 26 has the same amendment but is not directed to polynucleotides encompassing the genome but instead only ORFs.

2.3 Claim 1 of the main request is thus considered to contravene Article 123(2) EPC. The same applies to claims 18 and 26, which have the same amendment.

3. Auxiliary request 1, admission

3.1 Auxiliary request 1 was filed at oral proceedings after the board announced its conclusions regarding the main request. The appellant requested that it not be admitted into the proceedings.

3.2 Pursuant to Article 13(2) RPBA, any amendment to a party's appeal case made after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances which have been justified with cogent reasons by the party concerned.

3.3 The board fails to see that the allegedly surprising decision of the board according to which the expression "overall sequence identity" in claims 1, 18 and 26 of the main request had no basis in the application as filed could be considered as exceptional circumstances justifying the late-filing of this request. In fact, these objections had been discussed during opposition proceedings, and the appellant had maintained them in the appeal. Moreover, in its communication pursuant to Article 15(1) RPBA, the board had already provided a negative preliminary opinion in this respect.

3.4 In addition, the board notes that *prima facie* the new claims give rise to new objections. As noted by the appellant, the amendment inserted into claim 26 of the main request (claim 6 in auxiliary request 1) renders the claim unclear since the claimed subject-matter, which is simply directed to "An isolated polynucleotide comprising the nucleotide sequence...", is now further characterised by the feature "..., wherein a bacteriophage comprising the polynucleotide is a bacteriophage according to claim 1 - 4".

3.5 Hence, the board exercises its discretion under Article 13 RPBA not to admit auxiliary request 1 into the proceedings.

4. Auxiliary request 2

Article 83 EPC

4.1 Claim 1 is directed to a bacteriophage defined both by functional features, namely that it is "capable of lysing a *P. acnes* bacterium and incapable of lysing any bacterium which is not *P. acnes*, and which is incapable of sustaining lysogeny in a bacterium", and by reference to the accession numbers given to the bacteriophages as deposited with a recognised depositary institution under the Budapest treaty.

4.2 Rule 31(1) (a) EPC states that if an invention involves the use of or concerns biological material not available to the public and which cannot be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed as prescribed in Article 83 EPC if (a) a sample of the biological material has been

deposited with a recognised depositary institution on the same terms as those laid down in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977 not later than the date of filing of the application; (b) the application as filed gives such relevant information as is available to the applicant on the characteristics of the biological material; (c) the depositary institution and the accession number of the deposited biological material are stated in the application; and (d) where the biological material has been deposited by a person other than the applicant, the name and address of the depositor are stated in the application and a document is submitted to the European Patent Office providing evidence that the depositor has authorised the applicant to refer to the deposited biological material in the application and has given their unreserved and irrevocable consent to the deposited material being made available to the public in accordance with Rule 33.

4.3 The appellant has not argued that any of these requirements of Rule 31 EPC has not been fulfilled, nor is this in any way apparent from the file. As to requirement (b) that the application as filed must give such relevant information as is available to the applicant on the characteristics of the biological material, the board notes that there is plenty of information concerning the functional properties of the deposited bacteriophages (e.g. page 28, last paragraph to page 30, last paragraph; page 31, last paragraph; and Table 4 on page 32) and even their structural properties, such as reference to the DNA sequences of their genomes (page 9, first paragraph and page 32,

last paragraph). The board thus considers that the requirements of Rule 31 EPC are fulfilled.

4.4 The appellant argued that it was not plausibly disclosed in the application that the claimed bacteriophages possessed the functional property required by the claim of being "incapable of lysing any bacterium which is not *P. acnes*", i.e. species specificity. The board agrees that the application indeed only tested the ability of the bacteriophages to infect four bacteria species other than *P. acnes* (page 30, last paragraph) and that this may not allow concluding that the same results would be expected with any other bacteria. Nevertheless, the board considers that this is not relevant for sufficiency of disclosure of the claimed subject-matter because none of the functional features of the claim imposes any limitations on the claimed subject-matter, which simply consists of the bacteriophages as defined by the reference to the deposit.

4.5 No objections under Article 83 EPC have been raised in appeal on the remaining independent claims, such as claim 5 ("a composition comprising at least one bacteriophage according to claims 1 - 4...") and the second medical use claims 10 and 11, directed to use in the prevention or treatment of acne.

4.6 The board thus comes to the conclusion that auxiliary request 2 fulfils the requirements of Article 83 EPC.

#### Article 56 EPC

4.7 The patent relates to bacteriophages and their uses, in particular to their use in compositions for the treatment of acne (patent, paragraph [0001]). The

bacteriophages according to the invention are capable of lysing a *P. acnes* bacterium, incapable of lysing any bacterium which is not *P. acnes* and incapable of sustaining lysogeny in a bacterium (paragraph [0023]). For use in therapy, it is important that the bacteriophages according to the invention are purely lytic, i.e. incapable of entering the lysogenic phase of the bacteriophage life-cycle, a quiescent stage which is undesirable in the creation of an effective therapy and is also unacceptable from a regulatory point of view (paragraph [0024]).

- 4.8 The opposition division considered document D8 the closest prior art, and no other documents have been put forward in the appeal proceedings. The board agrees that document D8, a meeting abstract disclosing the use of bacteriophages for treatment of acne, is a suitable starting point for the discussion of inventive step. Although D8 does not disclose any particular bacteriophage, it teaches that "Unlike antibiotics, phage are specific for one species of bacteria" and furthermore states that they have isolated several strains of phage which kill subsets of the strain bank comprising a large number of strains of *P. acnes* and that they "are currently isolating mutants of these phages with exclusively lytic capabilities and broad spectrum of virulence". D8 thus identifies the functional features as claimed, namely species specificity with a broad spectrum of virulence and exclusively lytic capabilities (i.e. no lysogenic capability) as being desirable properties for bacteriophages to be used in the treatment of acne.
- 4.9 The difference between D8 and the subject-matter claimed in claim 1 is that specific bacteriophages, identified by reference to their deposit numbers or by



structural features, are not provided in D8. The technical problem can thus be formulated as the provision of bacteriophages which possess the desired characteristics as listed in D8 and are therefore suitable for use in the prevention and treatment of acne. The solution consists of the bacteriophages as claimed, and the board is satisfied that the problem has been solved.

- 4.10 In addition, the board considers that the solution involves an inventive step because there is no teaching in the prior art rendering obvious the provision of the three claimed bacteriophages, which are not merely further bacteriophages as they do have properties that render them particularly suitable for the aim of the patent, namely prevention and treatment of acne. Indeed, the patent application shows that the claimed bacteriophages are capable of lysing a *P. acnes* bacterium (page 28, last paragraph to page 30); incapable of lysing other bacteria such as *P. granulosum*, *P. avidum*, *S. epidermidis* and *C. bovis* species (page 30, last paragraph); and incapable of sustaining lysogeny in a bacterium (page 31, last paragraph and Table 4 on page 32).
- 4.11 The board disagrees with the appellant's arguments that the patent did not plausibly show that the problem as stated in the patent application, namely the provision of bacteriophages with the functional properties as in the claim, in particular the species specificity, had been solved. As discussed above in the context of Article 83 EPC, even if the data in the patent do not allow concluding that there is absolute species specificity, they nevertheless show that the claimed bacteriophages do not infect four other bacterial species commonly present in the skin. As explained in

the patent (paragraph [0025]) and argued by the respondent, in the context of acne therapy, it is important that the bacteriophage leaves other bacteria of the skin flora unaffected, thus reducing the opportunity for the overgrowth of potentially harmful flora and also eliminating the possibility of drug resistance emerging in other members of the microflora. Whether the bacteriophage is able to infect other bacteria not part of the skin microflora is not relevant in the context of the invention.

- 4.12 The board thus comes to the conclusion that claim 1 of auxiliary request 2 involves an inventive step. The same applies to the remaining claims.

## **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 with the following claims and a description to be adapted thereto:

Claims 1 to 15 of auxiliary request 2, filed as auxiliary request 5 with the letter of reply dated 2 February 2017.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated