

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

**Datasheet for the decision
of 21 October 2008**

Case Number: T 0936/06 - 3.3.08

Application Number: 97916278.1

Publication Number: 0895534

IPC: C12N 7/00

Language of the proceedings: EN

Title of invention:

Compositions containing bacteriophages and methods of using bacteriophages to treat infections

Applicant:

NYMOX CORPORATION

Opponent:

-

Headword:

Bacteriophage preparations/NYMOX

Relevant legal provisions:

EPC Art. 84

Relevant legal provisions (EPC 1973):

-

Keyword:

"Main request and auxiliary request - clarity (no)"

Decisions cited:

G 0002/88, G 0010/93, T 0094/82, T 0068/85, T 0437/98,
T 0728/98, T 1020/03

Catchword:

-



Case Number: T 0936/06 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 21 October 2008

Appellant: NYMOX CORPORATION
9900 Boulevard Cavendish, Nr. 306
Saint-Laurent
Quebec H4M 2V2 (CA)

Representative: Pohlman, Sandra M.
df-mp
Fünf Höfe
Theatinerstrasse 16
D-80333 München (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 20 January 2006
refusing European application No. 97916278.1
pursuant to Article 97(1) EPC 1973.

Composition of the Board:

Chairman: L. Galligani
Members: M. R. Vega Laso
C. Rennie-Smith

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division posted on 20 January 2006, by which the European patent application No. 97 916 278.1 published as WO 97/39111 with the title "Compositions containing bacteriophages and methods of using bacteriophages to treat infections", was refused under Article 97(1) EPC 1973. The refusal was based on the finding that the subject-matter of claims 1, 2, 5, 7, 9, 12, 15, 17 and 19 as then on file lacked novelty (Article 54(1) and (2) EPC 1973), and that the subject-matter of claims 21 and 22 did not involve an inventive step within the meaning of Article 56 EPC 1973.

II. The appellant (applicant) filed a notice of appeal against the decision of the examining division. Together with the statement of grounds of appeal, the appellant submitted two sets of claims as its main request and auxiliary request, respectively. As a subsidiary request, oral proceedings under Article 116 EPC were requested.

III. Claim 1 of the set of claims according to the **main request** reads:

"1. A purified, bacterial microorganism host-specific, non-toxic, wide host range and virulent bacteriophage preparation consisting essentially of a bacteriophage, whereby said bacterial microorganism is selected from the group consisting of staphylococci, hemophilii, helicobacter, mycobacterium, mycoplasmi, streptococci, neisserii, klebsiella, enterobacter, proteus, bacteriodes[sic], pseudomonas, borrelii, citrobacter,

escherichia, salmonella, propionibacterium, treponema, shigella, enterococci and leptospirex, and wherein the bacteriophage preparation is capable of killing, *in vitro*, bacteria from at least 50% of host samples for use as a medicament."

Dependent claims 2 to 8 are directed to specific embodiments of the preparation of claim 1. Independent claim 9 relates to a pharmaceutical composition comprising a bacteriophage preparation and a pharmaceutically acceptable carrier, the bacteriophage preparation being defined as in claim 1; dependent claims 10 and 11 concern particular embodiments of the pharmaceutical composition. Claims 12 to 20 relate to the use of a bacteriophage preparation as defined in claim 1 for the manufacture of a medicament for treating a mammal suffering from infection by a bacterial microorganism. Independent claims 21 and 22 are directed to alternative methods of preparing a bacteriophage preparation defined as in claim 1.

- IV. Amended claim 1 of the set of claims according to the **auxiliary request** differs from the corresponding claim of the main request in that the bacterial microorganism is selected from a group of microorganisms consisting of "*helicobacter, mycobacterium, mycoplasmi, neisserii, klebsiella, borrelii, salmonella, treponema, shigella, enterococci, leptospirex, Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus oralis, Streptococcus parasanguis, Streptococcus pyogenes, Streptococcus viridans, Group A streptococcus and anaerobic streptococcus, Hemophilus influenzae, and Pseudomonas aeruginosa*".

Moreover, dependent claim 2 is limited to particular embodiments among those specified in claim 2 of the main request. Finally, claims 5, 7 and 13 to 18 have been deleted, and the remaining claims have been renumbered and their dependencies amended accordingly.

V. The examining division did not rectify its decision and the appeal was remitted to the boards of appeal (Article 109 EPC 1973).

VI. The appellant was summoned to oral proceedings. In a communication under Rule 11(1) of the Rules of Procedure of the Boards of Appeal (RPBA) attached to the summons, the board provided observations on some of the issues to be discussed at oral proceedings. In particular, the board expressed the provisional view that the feature "*the bacteriophage preparation is capable of killing, in vitro, bacteria from at least 50% of host samples*" in, *inter alia*, claim 1 was vague. The board observed that different meanings were given in the application to the term "*host*", and that not only the kind of samples, but also the number to be taken as reference was not defined in the application. It was also indicated that, in view of the fact that the appellant relied on the feature in question to establish novelty and inventive step of the claimed bacteriophage preparations, the issues raised in the communication had to be thoroughly discussed at oral proceedings. The appellant was given the opportunity to submit comments and/or file amended requests in response to the board's observations.

VII. No comments or new requests were received within the time limit set by the board.

VIII. Oral proceedings were held in the absence of the appellant on 21 October 2008, its representative having informed the board by a fax letter dated 17 October 2008 of her likely non-attendance.

IX. The arguments put forward by the appellant in the statement of grounds of appeal, as far as they are relevant to this decision, were as follows:

The limitation "*wherein the bacteriophage preparation is capable of killing, in vitro, bacteria from at least 50% of host samples*" introduced into claim 1 was supported by the statements on page 8, lines 17 to 18 of the application as filed, as well as on page 5, lines 23 to 24. It was clear to a skilled person reading the claims in the light of the description that the term "*host sample*" referred to a sample of the specific bacterial microorganism which the bacteriophage was able to kill. This understanding was further emphasized by the requirement in claim 1 that the bacteriophage preparation is bacterial microorganism host-specific. The ability to kill 50% of the host samples *in vitro* gave meaning to the term "*wide host range*" and "*virulent*", which was defined in terms of being able to kill bacteria of a wide host range (see page 8, lines 5 to 10).

The application provided ample explanation of the method of obtaining a bacteriophage preparation as claimed in claim 1. For each feature of the claim, an explanation was given with regard to tests that could be carried out with a bacterial preparation obtained by the described methods in order to select the bacterial

preparations having the desired properties. Both *in vivo* and *in vitro* tests were described.

Example 9 disclosed that the method of the invention resulted in a bacteriophage preparation effective in killing 56% of the host samples of *S. aureus*. Thus, at least one example with supporting *in vitro* data was given. Reasonable generalizations from a single example were permissible. In the absence of well-founded reasons an objection of lack of support should not have been raised by the examining division. According to decision T 1020/03 (OJ EPO 2007, 204), there was no substantive support requirement under Article 84 EPC.

- X. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, the auxiliary request filed with the statement of grounds of appeal.

Reasons for the Decision

Procedural issues

1. During examination proceedings, the examining division raised several formal objections under Article 84 EPC in respect of some features in the claims then on file, among others the feature "*wherein the bacteriophage preparation is capable of killing, in vitro, bacteria from at least 50% of host samples*", which was also present in the set of claims on the basis of which the application was refused. However, no formal issues were addressed in the decision under appeal. Rather, the

refusal of the application was based on the finding that the claimed subject-matter lacked novelty or did not involve an inventive step. Thus, no decision has been taken by the examining division in respect of Article 84 EPC.

2. According to decision G 10/93 (OJ EPO 1995, 172, see Order), *"In an appeal from a decision of an examining division in which a European patent application was refused, the board of appeal has the power to examine whether the application or the invention to which it relates meets the requirements of the EPC. The same is true for requirements which the examining division did not take into consideration in the examination proceedings or which it regarded as having been met. If there is reason to believe that such a requirement has not been met, the board shall include this ground in the proceedings."* In line with this decision, the board is thus empowered to examine issues that were not discussed in the decision under appeal, in particular clarity issues.

Main request and auxiliary request - Article 84 EPC

3. Pursuant to Article 84 EPC, the claims shall define the matter for which protection is sought, be clear and concise, and be supported by the description. The guiding principle of Article 84 EPC is the principle of legal certainty. As the purpose of claims under the EPC is to enable the protection conferred by the patent (or patent application) to be determined (see G 2/88, OJ EPO 1990, 93), Article 84 EPC is aimed at *"ensuring that the public is not left in any doubt as to which*

subject-matter is covered by a particular claim and which is not" (T 728/98, OJ EPO 2001, 319).

4. Adhering to the principle of legal certainty, it has been established in the jurisprudence of the boards of appeal that, when a product for which protection is sought is defined in the claims using particular parameters, a person skilled in the art must be able to determine those parameters clearly and reliably, either using technical information provided in the application or by objective procedures which are usual in the art (see, *inter alia*, T 94/82, OJ EPO 1984, 75). The same applies to functional features defining a product in terms of the result to be achieved. These features must provide instructions which are sufficiently clear for the skilled person to reduce them to practice (T 68/85, OJ EPO 1987, 228; T 437/98 of 29 January 2003).

5. In the present case, a decisive question is, *inter alia*, whether or not the feature "*wherein the bacteriophage preparation is capable of killing, in vitro, bacteria from at least 50% of host samples*", which is present in claim 1 of both the main request and the auxiliary request, defines the claimed bacteriophage preparations in a manner sufficiently clear to allow the public to ascertain whether a particular preparation is covered by the claim or not.

6. In the board's communication under Rule 11(1) RPBA, it was not questioned that this particular feature may have a formal basis in the passage on page 8, lines 17 and 18 of the application as filed. Rather, the board expressed the view that, due to the presence of the feature in question, the claims offended against

Article 84 EPC, as neither this passage nor any of the further passages indicated by the appellant in its statement of grounds of appeal provide technical information that allows a person skilled in the art to determine **clearly, reliably and in an objective, standardized manner** whether or not a particular bacteriophage preparation is capable of killing, *in vitro*, bacteria from at least 50% of host samples. Thus, the said feature is open to any subjective technical interpretation.

7. In support of its line of argument on Article 84 EPC (see Section IX above), the appellant pointed to further passages of the application as filed, in particular the passages on page 5, lines 23 and 24, and on page 8, lines 5 to 10. However, the first passage, which must be read in connection with lines 15 to 20 of the same page, does not provide any technical information, but expresses only a *desideratum*, namely that bacteriophages which can be selected by a method of screening described in the application should be "*capable of killing a wider range of host bacteria from a wider range of different isolated cultures of a given bacteria, i.e., a wide host range.*" The second passage describes Figures 4 to 6 showing a DNA fingerprinting (Figures 4 and 5) and an electron micrograph (Figure 6) of specific bacteriophages. Hence, neither passage cited by the appellant provides the required technical information.
8. In its statement of grounds of appeal, the appellant also alleged that the application described both *in vitro* and *in vivo* tests which could be carried out with a bacteriophage preparation obtained by the described

(and claimed) methods in order to select bacteriophage preparations having the desired properties. However, the appellant failed to indicate any passage of the application in which such *in vitro* tests are described, and the board has not been able to find in the application any detailed technical information in this respect.

9. Example 9, which was mentioned by the appellant as support for the claimed subject-matter, does not provide any details on how the bacteriophage preparations, and in particular bacteriophage 83A which is said to be particularly virulent and effective in killing 5 out of 9 different samples of *S. aureus* (ie. 56%), were tested *in vitro*. Example 6, to which Example 9 refers, describes two bacteriophage preparations (146A and 173A) which are said to be particularly virulent and have been selected on the basis of concentration and isolate sensitivity (see second full paragraph on page 24 of the application). It is described in Example 9 that purified preparations of these two bacteriophage preparations were tested against 52 *E. coli* isolates, and that phage preparation 146A was effective against 22 isolates (42%) and 173A against 20 isolates (38%). However, the experimental conditions under which the *in vitro* tests were carried out are not apparent from the Example.

10. Nor has any evidence been submitted by the appellant for objective procedures usual in the art which could be applied by the skilled person to determine clearly and reliably whether or not a specific bacteriophage preparation is capable of killing, *in vitro*, bacteria from at least 50% of host samples. It is also doubtful

whether such procedures exist, because the extent of bacterial lysis caused by different bacteriophages may be strongly affected by specific experimental conditions such as the composition of the culture media, temperature, incubation time and bacteriophage:bacteria ratio, the results obtained under different experimental conditions differing considerably.

11. The legal considerations in point 10 of decision T 1020/03 (*supra*), which was cited by the appellant in its statement of grounds of appeal, are not considered to be relevant to the present case, as the breath of the claims compared to the disclosure of the application is not the decisive issue in the present case.

12. In sum: having considered the arguments submitted by the appellant in writing, the board is not convinced that, with regard to the feature "*wherein the bacteriophage preparation is capable of killing, in vitro, bacteria from at least 50% of host samples*", the subject-matter of claim 1 of either the main request or the auxiliary request can be determined without doubt. Consequently, neither request complies with Article 84 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

A. Wolinski

L. Galligani