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D E C I S I O N
of 17 October 2005

Case Number: T 0292/04 - 3.3.04

Application Number: 92301448.4

Publication Number: 0500387

IPC: A61K 38/44

Language of the proceedings: EN

Title of invention:
Methods and compositions for the treatment of infection and control of flora using haloperoxidase

Patentee:
EXOXEMIS, INC.

Opponents:
Campina Melkunie B.V.
NOVOZYMES A/S

Headword:
Haloperoxide/EXOXEMIS

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Main request - novelty (no)"
"Auxiliary request - inventive step (no)"

Decisions cited:
G 0001/83, G 0005/83, G 0006/83, G 0002/88, T 1020/03

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0292/04 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 17 October 2005

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 22 December 2003 revoking European patent No. 0500387 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chair: M. Wieser
Members: G. Alt
G. Weiss

Summary of Facts and Submissions

I. The appeal was lodged by the Patent Proprietors (Appellants) against the decision of the Opposition Division, whereby the European patent No. 0 500 387 was revoked according to Article 102(1) EPC.

The patent had been opposed by Opponents 01 and 02 (Respondents I and II) under Article 100(a) EPC on the ground of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC), under Article 100(b) EPC on the ground of lack of sufficient disclosure (Article 83 EPC) and under Article 100(c) EPC on the ground of added subject-matter (Article 123(2) EPC).

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

(10) GB 2 108 387

(18) J. Bacteriology, vol. 95, 1968, pages 2131 to 2138

(19) Biochimica et Biophysica Acta, vol. 117, 1966, pages 63 to 72

III. The Opposition Division had decided that the main request before them did not meet the requirements of Article 123(2) EPC, and that the subject-matter of claims 1 and 52 of the first auxiliary request was not novel over the disclosure in document (10).

Moreover they had decided that claim 1 of the second auxiliary request did not involve an inventive step in

the light of the disclosure in document (10) in combination with document (19).

IV. Claim 1 of the first auxiliary request before the Opposition Division read as follows:

"The use of a haloperoxidase in the manufacture of an antimicrobial Agent for selectively killing pathogenic bacteria while selectively preserving normal flora, wherein the antimicrobial agent is a liquid and comprises from 0.01 pmol to 500 pmol myeloperoxidase (MPO) or eosinophil peroxidase (EPO) per ml."

Claim 1 of the second auxiliary request read as follows:

"The use of a haloperoxidase in the manufacture of an antimicrobial Agent for selectively killing pathogenic bacteria while selectively preserving normal flora, wherein the antimicrobial agent is a liquid and comprises from 0.01 pmol to 500 pmol myeloperoxidase (MPO) or eosinophil peroxidase (EPO) per ml and an agent capable of producing a peroxide when administered to a subject."

V. The Board issued a communication on 15 April 2005. Oral proceedings were held on 17 October 2005.

The Appellants requested that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 51 of the main request, or claims 1 to 54 of the auxiliary request both filed at the oral proceedings on 17 October 2005.

The Respondents I and II requested that the appeal be dismissed.

Claim 1 of Appellants' main request was identical to claim 1 of the first auxiliary request before the Opposition Division. Claim 1 of Appellants' first auxiliary request was identical to claim 1 of the second auxiliary request before the Opposition Division (see item (3) above).

VI. The submissions made by the Appellants as far as they are relevant for the present decision may be summarised as follows:

Claim 1 of both requests was drawn up in the "Swiss type format" and referred to the use of a haloperoxidase, in the manufacture of an antimicrobial agent. Novelty and inventive step of the claim could be derived from its sole new feature that was the new use of selectively killing pathogenic bacteria while selectively preserving normal flora. The antimicrobial agent manufactured according to claim 1 had therapeutic applications as well as applications which did not fall under the exclusion from patentability according to Article 52(4) EPC. The Enlarged Board of Appeal in decision G 2/88 (OJ EPO 1990, 93), in respect to a claim to a new use of a known compound had decided that such new use might reflect a newly discovered technical effect which should be considered as functional feature of the claim from which novelty could be derived. In the light of this case law Patentees were entitled to a claim drawn up in the "Swiss type format" covering both, second medical and second non-medical use of the manufactured agent. As neither document (10) nor any

other of the cited prior art documents disclosed the newly discovered selective nature of the manufactured agent allowing its use to selectively kill pathogenic bacteria while selectively preserving normal flora, claim 1 of the main request was novel.

The same applied to claim 1 of the auxiliary request, which was further distinguished from the disclosure in document (10) by comprising an agent capable of producing peroxide when administered to a subject. The subject-matter of this claim could not be derived from in an obvious way from a combination of the disclosure in documents (10) and (19).

VII. The submissions made by the Respondents as far as they are relevant for the present decision may be summarised as follows:

In accordance with the decision of the Enlarged Board of Appeal G 5/83 (OJ EPO 1985, 64) the concept of second or further medical use could only be applied to claims to the use of substances for the manufacture of a medicament intended for use in a method referred to in Article 52(4) EPC. Claim 1 of both requests was not restricted to the use of the manufactured agent in such methods but also referred to its use in methods not excluded from patentability according to Article 52(4) EPC. Therefore, the subject-matter of claim 1 of the main request was not novel over document (10) and the subject-matter of claim 1 of the auxiliary request was obvious in the light of a combination of the disclosure in documents (10 and (19).

Reasons for the Decision

1. The question of law which was referred to the Enlarged Board in G 5/83 (OJ EPO 1985, 64) (see also G 1/83, OJ EPO 1985, 60 and G 6/83, OJ EPO 1985, 67) arose essentially because of the particular exclusion from patentability in relation to "methods for treatment of the human or animal body" set out in Article 52(4) EPC, first sentence, and the exception to the novelty requirement set out in Article 54(5)EPC. In the field of medical or veterinary inventions, the normal type of **use claim** is prohibited by Article 52(4) EPC, but Article 54(5) EPC expressly provides for an exception to the general rules governing novelty (Article 54(1) to (5) EPC) in respect of the first medical or veterinary use of a substance or composition, by allowing a claim to the substances or compositions for that use.

2. The Enlarged Board did not accept claims directed to the use of a known substance X for the treatment of disease Y, because such a claim would relate to a medical method which was not patentable under Article 52(4) EPC. However, it allowed claims of the type "use of substance X for the manufacture of a medicament for therapeutic application Y". The Enlarged Board derived the novelty of such claims from their sole new feature that is the new pharmaceutical use of that known substance. The Enlarged Board found that no intention to exclude second (and further) medical indications generally from patent protection could be deduced from the terms of the EPC. As a result, the Enlarged Board considered that it was legitimate in principle to allow claims directed to the use of a

substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even where the process of manufacture as such did not differ from known processes using the same active ingredient (cf decision G 5/83, supra, points (11) to (19) of the reasons).

3. Thus, the Enlarged Board considered for the special case where the intended purpose of the preparation of the composition was for this composition then to be used for the treatment of the human or animal body by surgery or therapy or in diagnostic methods, that then Article 54(5) EPC allowed the preparation of the composition to be treated as notionally novel, even if the medicament resulting from the preparation was not in any way different from a known medicament (see point (20) of decision G 5/83). The Enlarged Board at the end of point (21) of the reasoning held that it was to be clearly understood that the application of this special approach to the derivation of novelty could **only** be applied to claims to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC.

4. According to the normal position in patent law the fact that a composition is prepared for an intended novel use does not allow the preparation of the composition to be treated as novel, if the composition and its preparation are the same as for other, known uses. But in such other cases the novel intended use would itself be potentially patentable, which is however not the case for treatments by surgery or therapy or diagnostic methods(cf decision T 1020/03 of 29 October 2004, point (6) of the reasons).

Either a method of using a composition is not a treatment by surgery or therapy or a diagnostic method practised on the human or animal body and therefore falls outside the provision of Article 52(4) EPC first sentence, and so is patentable subject to compliance with the other provisions of the EPC, or else a method is inside the provision of Article 52(4) EPC first sentence, and so not itself patentable, but use of a composition for making a medicament for use in such treatment by surgery or therapy or in a diagnostic method is patentable for unspecified therapy as a first medical indication or for a specified indication as a further medical indication, again subject to compliance with the other provisions of the EPC, in particular novelty and inventive step (cf T 1020/03 supra, point (36)).

Main request
Novelty - Article 54 EPC

5. Claim 1 refers to the use of a haloperoxidase in the manufacture of an antimicrobial agent. The agent is intended for use in methods which are referred to in Article 52(4)EPC, but also in methods not referred to in this Article, namely methods not being intended for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. One such use of the agent manufactured according to claim 1 is its application as contact lens formulation, which is the subject-matter of dependent claim 47.

6. Thus, in accordance with the principles of decision G 5/83 (supra, see points (1) to (4) above), claim 1,

as far as it refers to the use of a haloperoxidase in the manufacture of an antimicrobial agent for use in a method falling outside the provisions of Article 52(4) EPC cannot derive novelty and inventive step from the allegedly newly discovered technical effect of selectively killing pathogenic bacteria while selectively preserving normal flora. Rather the claim, which is not restricted to a therapeutic use of the manufactured agent, has to be understood as referring to a process for the manufacture of a liquid antimicrobial agent comprising from 0.01 to 500 pmol/ml MPO or EPO.

7. The Appellants argued that neither document (10) nor any other cited prior art document disclosed the newly discovered technical effect described in the patent in suit and contained in claim 1, namely the ability of a haloperoxidase to selectively kill pathogenic bacteria while selectively preserve normal flora. In their opinion the use in the way it is claimed reflects this new technical effect which has to be considered as a functional technical feature of the claim when assessing novelty and inventive step. They referred in this respect to the decision of the Enlarged Board of Appeal G 2/88 (OJ EPO 1990, 93).

In this decision the Enlarged Board took the view that the proper interpretation of a claim whose wording clearly defined **a new use of a known compound** would normally be such that the attaining of a technical effect on which the new use was based was a technical feature of the claimed invention. Thus, where the particular technical effect underlying such use was described in the patent, the proper interpretation of

the claim would require a functional feature to be implicitly contained in the claim as a technical feature - e.g. the compound actually achieved the particular effect.

The present Board does not see that this situation applies to the present case, simply because claim 1 is not directed to the new use of a known compound, but to the use of a known compound in the manufacture of an agent. As explained in detail in point (3) above this kind of claims was considered by the Enlarged Board of Appeal in decision G 5/83 (supra) to be notionally novel for the special case only where the intended purpose of the manufacture of the agent was for this agent then to be used for the treatment of the human or animal body by surgery or therapy or in a diagnostic method.

8. Document (10) discloses MPO containing liquid pharmaceutical compositions having antimicrobial activity (claim 1). The solutions prepared according to page 3, lines 43 to 57 and listed in table 1 contain 0.01, 0.1, 1, 20 or 100 units MPO per 4 ml. As accepted by all parties (cf point (2.2) of the decision under appeal) 1 unit MPO equals 15,625 pmol. Thus, the solutions of document (10), table 1 contain from 0.039 to 390,6 pmol/ml MPO.

The subject-matter of claim 1 is anticipated by the disclosure in document (10). The claim lacks novelty and does not meet the requirements of Article 54 EPC.

Auxiliary request

9. The Respondents objected to the novelty of the subject-matter of claim 1 on the basis of the disclosure in document (10). In view of the findings on Article 56 EPC (see points (10) to (14) below) it is not deemed to be necessary to give detailed reasons with regard to Article 54 EPC.

Inventive step - Article 56 EPC

10. Claim 1 is distinguished from claim 1 of the main request in that the manufactured agent additionally contains an agent for producing a peroxide when administered to a subject.

The composition of document (10), which is considered as representing the closest state of the art for the assessment of an inventive step following the problem and solution approach, is distinguished therefrom in so far as it contains hydrogen peroxide.

The problem to be solved is considered to be the provision of an alternative antimicrobial agent containing MPO or EPO.

11. The patent in suit refers on page 6, lines 38 to 41 to document (18) and acknowledges that haloperoxidases such as MPO and EPO are known in the art to exhibit microbe killing activity in natural systems when presented with an appropriate halide as cofactor and hydrogen peroxide as substrate.

Page 11, lines 24 to 27 of the patent reads as follows:

"The presently preferred peroxide for use in the compositions of the invention is hydrogen peroxide. Hydrogen peroxide may also be made available at the site of the infection by including in the antiseptic composition an agent capable of producing hydrogen peroxide in vivo. Particularly useful agents for this purpose include, for example, oxidases, such as glucose oxidase and galactose oxidase."

12. Document (19), an earlier publication of the author of document (18), also referring to antimicrobial systems containing a peroxidase like MPO, reads in lines 3 to 5 of the summary:

"H_2O_2 may be formed endogenously (presumably by microbial metabolism), may be added, or may be generated by the addition of one of a number of H_2O_2-generating systems."

Several examples of such H_2O_2-generating systems, including glucose oxidase, are disclosed in the following lines.

13. A skilled person trying to solve the problem underlying the patent in suit would amend the composition disclosed in document (10), the document representing the closest prior art, by replacing H_2O_2 by a H_2O_2-generating system which is explicitly disclosed in document (19) as being a practicable alternative for a antimicrobial system containing MPO.

By doing so the skilled person would arrive at the subject-matter of claim 1 in an obvious way. Therefore, claim 1 does not involve an inventive step, contrary to the requirements of Article 56 EPC.

Order

For these reasons it is decided:

The appeal is dismissed.

Registrar: Chair:

P. Cremona M. Wieser