

Internal distribution code:

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

D E C I S I O N
of 4 May 2005

Case Number: T 1401/04 - 3.3.7

Application Number: 98942969.1

Publication Number: 1021158

IPC: A61K 7/22

Language of the proceedings: EN

Title of invention:

Mouth hygienic composition for the treatment of halitosis

Applicant:

Pedersen, Ejvind Jersie

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 123(2), 111(1)

Keyword:

"Amendments - allowable (yes)"

"Decision re appeals - remittal (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 1401/04 - 3.3.7

D E C I S I O N
of the Technical Board of Appeal 3.3.7
of 4 May 2005

Appellant: Pedersen, Ejvind Jersie
Ulvshalevej 70
DK-4780 Stege (DK)

Representative: Kjerrumgaard, Bent
Budde, Schou & Ostenfeld A/S
Vester Soegade 10
DK-1601 Copenhagen V (DK)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 30 July 2004
refusing European application No. 98942969.1
pursuant to Article 97(1) EPC.

Composition of the Board:

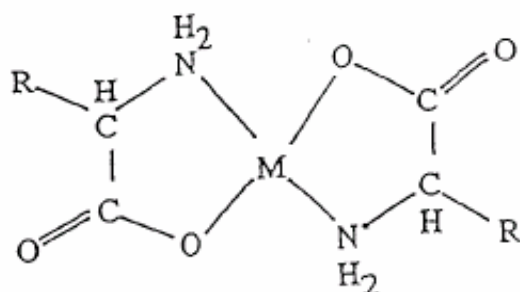
Chairman: R. E. Teschemacher
Members: B. L. ter Laan
G. Santavicca

Summary of Facts and Submissions

I. European patent application No. 98 942 969.1, filed as international application PCT/IB98/01503 and published as WO 99/17735, was refused by a decision of the Examining Division of the European Patent Office dated 30 July 2004. That decision was based on a set of ten claims submitted by letter dated 30 August 2001, the independent claims reading:

"1. A composition in the form of a preparation effective in the treatment of halitosis, said preparation comprising

- i) a chelate comprising a metal ion and an amino acid and having the general formula



wherein M is a metal ion and R is H or a side chain of a biologically acceptable amino acid, said chelate being controllably releasable into the oral cavity of a subject,

- ii) a saliva-inducing agent, said saliva-inducing agent being effective in producing saliva in said oral cavity, said saliva-inducing agent being further effective in stimulating a controlled release of said chelate into said oral cavity,

iii) a flavouring agent, said flavouring agent being effective in reducing and/or eliminating any trace of an astringent taste associated with said chelate, and

iv) a pharmaceutically acceptable carrier."

"9. Use of a chelate comprising a metal ion moiety and an amino acid moiety as a component of a composition for treatment of halitosis."

II. The Examining Division held that the claimed subject-matter did not satisfy the requirements of Article 54 EPC in view of the following documents:

D1 US-A-4 425 325

D2 WO-94/26243

D3 WO-86/00004

D4 US-A-4 830 716.

D1 disclosed oral compositions containing a "zinc-glycine combination". Although the chemical structure was not disclosed, from the reaction conditions described in D1, in view of the information given in D4, it could be concluded that the compositions of D1 contained the same chelates as present in the compositions now being claimed. The Applicant had not shown that the chelates as claimed were not present in the compositions of the prior art. The same was valid for D2 and D3.

III. On 30 September 2004, a notice of appeal was lodged against that decision, together with the payment of the prescribed fee. With the statement of grounds of appeal filed on 25 November 2004, the Appellant (Applicant) filed a set of eight claims as the sole request, requesting the grant of a patent on the basis of the claims as amended or, alternatively, the remittal of the application to the first instance for further prosecution. The appellant also cited the following documents:

D5 EP-B-0 202 936

D5' US-A-4 599 152

D6 US-A-4 216 143

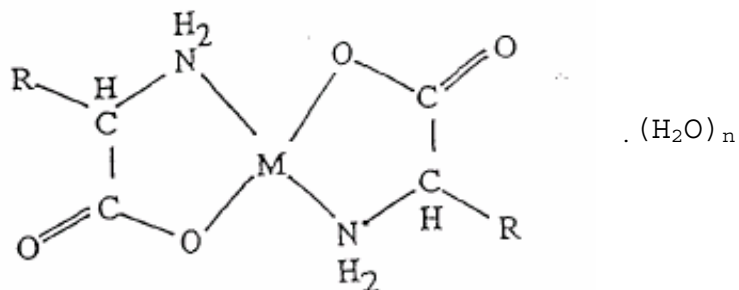
In reaction to a communication by the board, the appellant filed (letter of 4 April 2005), a set of five claims replacing the claims then on file, and two additional documents:

D7 Albion^(R) Research Notes, Vol. 9, No. 2,
August 2000,

D8 A copy of Albion Brazil's website entitled
"AlbionTM Nutrition" (17 pages).

IV. Oral Proceedings were held on 4 May 2005. After discussion of the novelty of claim 1 of the request then on file, the appellant submitted a new set of claims as the sole request, the only independent claim reading as follows:

"1. Use of a chelate having the general formula



wherein M is a metal ion selected from the group consisting of Zn^{2+} , Sn^{2+} and Cu^{2+} and R is H or a side chain of a biologically acceptable amino acid, said chelate being controllably releasable into the oral cavity of a subject, as the metal source for the preparation of a composition for the treatment of halitosis, said preparation further comprising

- i) a saliva-inducing agent, said saliva-inducing agent being effective in producing saliva in said oral cavity, said saliva-inducing agent being further effective in stimulating a controlled release of said chelate into said oral cavity,
- ii) a flavouring agent, said flavouring agent being effective in reducing and/or eliminating any trace of an astringent taste associated with said chelate, and
- iii) a pharmaceutically acceptable carrier."

V. The Appellant's arguments can be summarized as follows:

- (a) The amendments had a basis in the original application.
- (b) A preferred feature of the chelates used according to the claimed subject-matter was the presence of two rings. In fact, it was intended to use two-ring chelates as the only metal source in the composition because they gave better results than chelates with one or three rings. The claims were now indeed restricted to the use of such chelates; in conformity with that, the product of Albion Lab. specified in the description and used in the examples, was a more or less pure two-ring chelate. Adaptation of the description was offered to avoid any discrepancy with the claims.
- (c) None of the cited documents mentioned the chelates used as claimed, but even if such chelates were present in the compositions of the prior art, which was denied, none of the documents mentioned the specific use of the chelate as the only metal source now being claimed, or the technical effect of those chelates.

As regards D1 in particular, the molar ratios of the components were not in the range where chelates would form. Even if chelates formed, that would be in the form of a mixture of various kinds of chelates and not as the pure two-ring chelates that were used according to the claimed subject-matter, so that the use of the present specific two-ring would amount to a selection from D1. The two-ring structure provided a desired

combination of good reduction of bad breath with low astringency, which properties were not derivable from D1.

Halitosis could, but must not be the consequence of an underlying illness. The treatment of halitosis with the two-ring chelates now being used was also not known from the prior art, in particular D3, nor could it be derived from the prior art.

Therefore, the claimed subject-matter complied with the formal requirements and it was novel and inventive.

- VI. The Appellant requested that the decision of the first instance be set aside and that a patent be granted on the basis of the set of amended claims 1 to 4 submitted as the sole request during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

Amendments

2. Claim 1 finds its basis in claims 7 and 12 of the original application (the use of the chelates), in claim 2 and page 17, lines 18 to 32 (definition of the metal ions of the two-ring chelates) and in claim 7 and page 4, line 31 to page 5, line 2 (treatment of halitosis).

The use of the metal chelate as "the" metal source for the preparation of a composition for the treatment of

halitosis - which implies that no other metal source is present - is supported by the description, where the difference between chelates and other compounds (e.g. page 6, lines 5 to 27) and the use of the latter for halitosis reduction are described (page 14, line 28 to page 17, line 8). Further support can be found in the examples. In each example, the comparative ones as well as the one according to the claimed subject-matter, only one zinc containing compound is present in the composition (Table 1). The last compound in Table 1 is a product named "Zinc amino acid chelate TF (tastefree)" by Albion Laboratories, which contains 10% Zn and is identified by the number 3463, and which was used to illustrate the invention. According to D8, product No. 3463 is a zinc bis-glycine chelate and in D7 (Figures 1 and 2) the structure of the Albion product is disclosed as being a two-ring chelate in accordance with the claimed subject-matter. In this light, the board finds that the description contains sufficient support for use of the two-ring zinc-glycine chelate as the only metal source for the preparation of a composition for the treatment of halitosis.

Claim 2 is based on claims 3 and 18 of the original application; claim 3 on claims 5 and 19 of the original application; claim 4 on claims 6 and 20 of the original application.

The requirements of Article 123(2) are therefore fulfilled.

Novelty

3. Claim 1 is restricted to the use of the chelate with the indicated structure as "the" metal source in the preparation of a composition for the treatment of halitosis. The use of the definite article indicates that the chelate is the only source of metal in the preparation of the halitosis-reducing composition.

The decision under appeal was based upon claims in which the use of the word "comprising" indicated the possible presence of other metal sources than the chelate. According to the decision, those claims lacked novelty since compositions disclosed in the documents on file contained metal sources that, under the conditions given, could lead to the formation of the chelates defined in the application in suit. As the present claims now exclude the possible presence of further metal sources apart from the chelate, the novelty objection raised by the examining division is not applicable anymore. Therefore, the present claims provide a new situation that has not yet been examined by the first instance.

For that reason, and since the question of inventive step has not been dealt with in the decision under appeal, the board finds it appropriate to remit the case to the first instance for further prosecution, in compliance with Article 111(1) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:

C. Eickhoff

R. Teschemacher