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**Datasheet for the decision  
of 10 November 2011**

**Case Number:** T 1818/09 - 3.3.07

**Application Number:** 03741093.3

**Publication Number:** 1641427

**IPC:** A61K 8/18

**Language of the proceedings:** EN

**Title of invention:**  
Antibacterial mouthwash

**Applicant:**  
Betafarma S.p.A.

**Opponent:**  
-

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 54

**Relevant legal provisions (EPC 1973):**  
-

**Keyword:**  
"Novelty (no)"

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 1818/09 - 3.3.07

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.07  
of 10 November 2011

**Appellant:** Betafarma S.p.A.  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 17 March 2009  
refusing European patent application  
No. 03741093.3 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman:** J. Riolo  
**Members:** F. Rousseau  
P. Schmitz

## Summary of Facts and Submissions

I. The appeal lies from the decision of the Examining Division, posted on 17 March 2009, refusing European patent application No. 03 741 093.3, filed as international application No. PCT/IT2003/000419 on 3 July 2003 and published as WO 2005/002535. The decision was based on a set of claims 1 to 4 filed with letter of 19 September 2008, claim 1 reading as follows:

"1. A mouthwash antibacteric composition for sanitizing the buccal cavity, said antibacteric composition comprising an oil phase and an aqueous phase, characterized in that said oil phase comprises vegetable oils, mineral oils, aliphatic esters, aliphatic ethers, aliphatic alcohols, triglycerides and aliphatic hydrocarbons, that said composition further comprises, dissolved in said oil phase, antiseptic substances exclusively soluble in said oil phase, and dissolved in said aqueous phase, water soluble antibacteric substances, in that that said aqueous phase and oil phase are present in synergistic amounts from about 60% w/w to about 95% w/w for said aqueous phase and from about 5% w/w to about 40% w/w, thereby said oil phase in said mouthwash composition provides, as said mouthwash composition contacts the teeth of a user, an oil film on said teeth resisting against water rinsings."

II. By reference to the International Preliminary Examination Report drawn up for the present application in the international phase, examination had been based *inter alia* on the following documents :

D5: US-A-5 401 496  
D6: WO-A-99/22703  
D7: EP-A-0 528 457 and  
D8: US-A-5 416 075.

III. According to the impugned decision, amended claim 1 was based on a combination of originally filed claims 1 to 3, 6 and 7 and the paragraph bridging original pages 2 and 3. Amended claims 2 to 4 corresponded to originally filed claims 4, 8 and 9, respectively. As regards the meaning of amended claim 1, the expression "exclusively soluble in said oil phase" had no limiting effect, because antiseptic substances would always be present in both the oil and the aqueous phases. Support for this point of view could be found in example 6 of document D6 and in documents D7 and D8, that stated that lipophilic substances had, albeit limited, solubility in water. Novelty was acknowledged. As regards inventive step, the closest state of the art was represented by D8, in particular its example 9, which demonstrated that the incorporation of the antimicrobial agent thymol in the oil phase led to an improved antimicrobial effect. In the absence of any evidence for a technical effect arising from the features distinguishing the claimed subject-matter from D8, the objective problem solved over D8 was the provision of an alternative composition. In particular, the Applicant had not gone beyond alleging a synergistic effect in forming a durable film on a user's teeth for the very broad ranges for the amounts of oil and aqueous phases contemplated by claim 1. The use of the oil-in-water emulsion according to D8 as a mouthwash, the selection of concentration ranges of 60 to 96% w/w and 5 to 40% w/w for the aqueous and oil

phases, respectively, the selection of an oil phase comprising vegetable oils, mineral oils, aliphatic esters, aliphatic ethers, aliphatic alcohols, triglycerides and aliphatic hydrocarbons and the use of a second antimicrobial agent dissolved in the aqueous phase, insofar thymol was not considered as present in that phase, were measures contemplated by D8 itself. It followed therefore that the subject-matter of claim 1 lacked an inventive step over D8.

- IV. In the statement setting out the grounds of appeal dated 15 July 2009, the Appellant agreed with the Examining Division that the expression "exclusively soluble in said oil phase" had no limiting effect, but disputed that the claimed subject-matter lacked an inventive step over D8.
- V. The Appellant was summoned to attend oral proceedings to be held on 10 November 2011. In a communication dated 27 September 2011, sent in preparation of the oral proceedings, the Board indicated that the expression "*said oil phase comprises vegetable oils, mineral oils, aliphatic esters, aliphatic ethers, aliphatic alcohols, triglycerides and aliphatic hydrocarbons*" in claim 1 of the application was understood to mean that the oil phase comprised at least one of those substances, but not necessarily all in combination. The Board *inter alia* gave a reasoned preliminary negative opinion in respect of lack of novelty over example 2 of D5, in which it was pointed out that hexadecyltrimethylammonium chloride (a water soluble antibacterial substance) and menthol (an antiseptic substance) were considered to be contained in the aqueous phase and in the oil phase, respectively.

It was also indicated that any argument by the Appellant that the composition according to example 2 of D5 would not fulfil the functional feature defined in present claim 1, i.e. "*said oil phase in said mouthwash composition provides, as said mouthwash composition contacts the teeth of a user, an oil film on said teeth resisting against water rinsings*", would require attention when assessing sufficiency of disclosure (Article 83 EPC) and support from the description (Article 84 EPC) in respect of that feature.

- VI. The Appellant neither responded to the Board's communication, nor attended the oral proceedings which took place as scheduled and were held in the absence of the Appellant according to Rule 115(2) EPC.
  
- VII. The Appellant requested in the statement setting out the grounds of appeal dated 15 July 2009 that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 4 filed with letter dated 19 September 2008 before the Examining Division.
  
- VIII. The decision was announced at the oral proceedings.

## Reasons for the Decision

1. The appeal is admissible.

### *Subject-matter of claim 1*

2. It was not disputed by the Appellant, that the expression "*said oil phase comprises vegetable oils, mineral oils, aliphatic esters, aliphatic ethers, aliphatic alcohols, triglycerides and aliphatic hydrocarbons*" in claim 1 is intended to define an oil phase which comprises at least one of those substances, but not necessarily all in combination. It was also acknowledged in the statement setting out the grounds of appeal, that the expression "exclusively soluble in said oil phase" had no limiting effect, because antiseptic substances would always be present in both the oil and aqueous phases. Finally, the term "*synergistic amounts*" used in the definition of the amounts of aqueous and oil phases is not deemed, in the absence of any indication to the contrary in the application as filed or by the Appellant, to impose any limitation on the amounts already quantified in claim 1 by the ranges of from 60 to 95 wt.-% for the aqueous phase and of from 5 to 40 wt.-% for the oil phase.

### *Novelty*

3. D5 discloses in example 2 the preparation of a mouthwash in the form of an emulsion comprising about 65 weight% of an aqueous phase (water and xylitol), about 31 weight% of an oil phase (ESTOL-3604, a caprylic / capric triglyceride), hexadecyltrimethylammonium chloride (a water soluble antibacterial

substance) and menthol which is a lipophilic antiseptic substance (see in particular D8, claim 10, column 8, lines 27-53). Due to their respective affinities with oil and water, it follows that some menthol is present in the oil phase and some hexadecyltrimethylammonium chloride is contained in the aqueous phase. Thus, all structural features defined in present claim 1 are disclosed in example 2 of D5.

4. There is no indication, neither in the application as filed, nor in light of the skilled person's common general knowledge, that in addition to the amounts and chemical substances defined in claim 1 further measures are needed for obtaining the technical result defined in present claim 1, i.e. for achieving that the "*oil phase in said mouthwash composition provides, as said mouthwash composition contacts the teeth of a user, an oil film on said teeth resisting against water rinsings*". It must therefore be concluded that said technical result is automatically obtained for any composition meeting the structural definition given in claim 1. Hence, the composition disclosed in example 2 of D5, which meets the structural definition of present claim 1, is also considered to fulfil the functional requirement defined in that claim, with the consequence, that the subject-matter of claim 1 lacks novelty, contrary to the requirements of Article 54 EPC.
  
5. Should one have nevertheless considered that the expression "*synergistic amounts*" imposed a functional restriction on the amounts of aqueous and oil phases, or that the resistance of the oil film on the teeth against water rinsings were not inherent to the compositions of claim 1 as otherwise defined in terms



of their structural features, this could only have signified that additional steps were required in order to obtain the sought effect(s). In the absence of any information in the application in this respect or any indication by the Appellant as to which information would be available to the skilled person at the date of filing of the application in order to complete the teaching which is missing in the application, the subject-matter of claim 1 would have been found to lack sufficiency of disclosure (Article 83 EPC) and support from the description (Article 84 EPC).

6. Consequently, the subject-matter of present claim 1 is not patentable and the Appellant's request is therefore rejected.

## **Order**

### **For these reasons it is decided that:**

The appeal is dismissed.

The Registrar

The Chairman

S. Fabiani

J. Riolo