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**Datasheet for the decision
of 12 May 2010**

Case Number: T 0568/05 - 3.3.07

Application Number: 94304078.2

Publication Number: 0637446

IPC: A61K 7/16

Language of the proceedings: EN

Title of invention:

Dental floss provided with chemotherapy agents

Patentee:

JOHNSON & JOHNSON CONSUMER PRODUCTS, INC.

Opponent:

Barz, Peter

Headword:

-

Relevant legal provisions:

EPC Art. 123(2)(3), 84, 83, 54, 56

Relevant legal provisions (EPC 1973):

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Keyword:

"Amendments - added subject-matter (no)"
"Claims - clarity (yes) - not a ground for opposition"
"Disclosure - enabling"
"Novelty - yes"
"Inventive step - yes"

Decisions cited:

-

Catchword:

-



Case Number: T 0568/05 - 3.3.07

D E C I S I O N
of the Technical Board of Appeal 3.3.07
of 12 May 2010

Appellants: Barz, Peter
(Opponents) Kaiserplatz 2
D-80803 München (DE)

Representative: -

Respondents: JOHNSON & JOHNSON CONSUMER COMPANIES, INC.
(Patent Proprietors) Grandview Road
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New Jersey 08558-9418 (US)

Representative: Mercer, Christopher Paul
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
1 March 2005 concerning maintenance of European
patent No. 0637446 in amended form.

Composition of the Board:

Chairman: S. Perryman
Members: B. ter Laan
F. Rousseau

Summary of Facts and Submissions

I. The appeal by the opponents (hereinafter "appellants") lies against the decision of the opposition division to maintain European patent No. 0 637 446 (based on European application No. 94 304 078.2) in amended form. This decision was posted on 1 March 2005.

II. The patent was granted on the basis of ten claims, independent claim 1 reading:

"1. Dental floss provided with at least one chemotherapy agent, characterized in that said floss further includes a wax that is emulsible upon contact with saliva, the wax including at a (sic) least one surfactant capable of emulsifying said wax upon contact with saliva."

III. The opposition as filed asked for revocation of the patent in its entirety on the grounds of Article 100(a) EPC (lack of novelty as well as lack of an inventive step), and Article 100(b) (lack of disclosure). The opposition was based *inter alia* on the following documents:

D1 US-A-4 029 113
D2 US-A-2 772 205
D5 WO-A-93/02633.

IV. The decision under appeal was based on a main and two auxiliary requests filed during the oral proceedings before the opposition division. The new requests were objected to under Articles 123(2) (added subject-matter) and 123(3) (extension beyond the

granted claims) by the opponents. Claim 1 of the main request read:

"1. Dental floss provided with at least one chemotherapy agent, characterized in that said floss further includes an **insoluble** wax that is emulsible upon contact with saliva, the **insoluble** wax including at least one surfactant capable of emulsifying said wax upon contact with saliva."

(the additions compared to claim 1 as granted are indicated in bold).

V. The opposition division held that

(a) The main request fulfilled the requirements of Article 123(2) and 123(3) EPC since it was based on claims as granted. For that reason, also Article 84 EPC was complied with.

(b) Based on the guidance and recipes given in the description which showed that a relatively large amount of surfactant was needed to arrive at a wax-emulsion upon contact with saliva at body temperature, the skilled person starting from the recipes given was able, without undue burden, to carry out the invention in the whole range claimed. The opponents had not given any evidence in support of the contrary position. So the Opposition division was of the opinion that the teaching was sufficiently disclosed for a skilled person to carry out the invention so that the requirements of Article 83 EPC were met.

- (c) As none of the cited documents clearly and unambiguously disclosed all the claimed features, the claimed subject-matter was novel. In particular "an insoluble wax that is emulsifiable upon contact with saliva" was not disclosed in any of the documents either because in these the amount of surfactant was too low for the wax to be emulsifiable in saliva, or because no (insoluble) wax was disclosed.
- (d) The subject-matter of the patent according to the main request also involved an inventive step since it was not obvious to arrive at the dental floss as claimed when considering the closest document D1 or when combining one or more of the documents cited. D1 was considered to lead rather away from the present teaching and the other documents cited were more remote and by no means rendered the present teaching according to the main request obvious. The patent and its claims as amended were therefore considered to meet the requirements of the EPC.
- (e) Since the main request fulfilled the requirements of the EPC, the auxiliary requests needed not be dealt with.

VI. A notice of appeal was filed on 29 April 2005, and the prescribed fee paid on the same date. A statement of grounds of appeal was filed on 11 July 2005 together with a new document and an experimental report, to which no further reference was made during the proceedings. In response to a communication by the Board dated 27 October 2009 outlining various potential

problems seen, the appellants gave additional arguments in a letter dated 24 December 2009.

VII. By letter dated 25 November 2005 the patent proprietors (respondents) filed comments on the grounds for the appeal as well as two test reports and a main and two auxiliary requests. By letter dated 18 December 2009 a new main and three auxiliary requests were submitted, as well as four further documents. No further reference was made during the proceedings to these test reports and the additional documents.

VIII. Oral proceedings before the Board were held on 12 May 2010. After a preliminary round of submissions by the parties and comments by the Board, the respondents filed a new main request, replacing all other previous requests, claim 1 reading:

"1. Dental floss provided with at least one chemotherapy agent, wherein said floss further includes a wax that is emulsible upon contact with saliva, the wax including at a least one surfactant capable of emulsifying said wax upon contact with saliva, characterized in that said emulsible wax includes:
25% to 40% by weight of refined beeswax;
4% to 10% by weight of microcrystalline wax;
23% to 35% by weight of ethoxylated sorbitan monostearate;
3% to 10% by weight of glyceryl monostearate; and
22% to 38% of ethoxylated glyceryl monostearate."

Claims 2 to 4 were directed to preferred embodiments of the dental floss according to claim 1.

IX. The appellants' arguments can be summarised as follows:

- (a) The new request should not be admitted into the proceedings. As the respondents had been aware of the problems indicated in the communication of the board, new requests could and should have been filed at an earlier stage. Also, the claims were not clearly allowable because they would result in a *reformatio in peius* for the appellants due to the deletion of the requirement that the wax should be insoluble, which had been introduced during the opposition proceedings. Furthermore, the restricted subject-matter of the new claims had not been the subject of examination.
- (b) The claimed composition was not emulsible upon contact with saliva, as shown by tests provided by the respondents and also because the waxes were not liquid at 37°C, so that no emulsion could be formed at body temperature. Also, there was no definition of what "emulsible" exactly meant. The same applied to the surfactant which should be capable of emulsifying. In addition, it was not clear if the substances used in the example fell under the claims. Therefore, Article 83 EPC was not complied with.
- (c) The novelty objections raised against the claims as maintained by the opposition division were not maintained against the new request.
- (d) Regarding inventive step, D1 was the closest prior art document, in particular example II. No technical effect at all over D1 had been

established so that the problem to be solved should be formulated so as to provide an alternative dental floss. According to standard jurisprudence of the Boards, merely providing an alternative was never inventive. Therefore, the requirements of Article 56 EPC were not met.

X. The arguments of the respondents can be summarized as follows:

- (a) The new claims found their basis in original claims 1, 2 and 7 and were essentially the same as those of auxiliary request 3 filed on 18 December 2009. Therefore, they were not late filed and also complied with Article 123(2) EPC.
- (b) The respondents' tests, which were more relevant than those of the appellants, showed that an emulsion was formed so that Article 83 EPC was met.
- (c) D1 solved a different technical problem than the patent in suit, in particular as regards the release qualities of the floss, so that it could not render the present composition obvious. In D1 the amount of surfactant was much lower than now being claimed and D1 contained no hint to raise that amount. Also, the respondents did not rely on any advantage over D1, but on those indicated in paragraph [0039] of the patent in suit. Therefore, the claimed subject-matter was inventive.

XI. The appellants (opponents) requested that the decision under appeal be set aside and the patent be revoked.

The respondents (patent proprietors) requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request submitted at the oral proceedings on 12 May 2010.

Reasons for the Decision

1. The notice of appeal, payment of the appeal fee, and the statement of grounds meet the relevant requirements of the EPC so that the appeal is admissible.

Amendments

2. The new main request filed during the oral proceedings before the Board corresponds in essence with auxiliary request 3 as filed by letter dated 18 December 2009. The only difference is the deletion of the word "insoluble" before "wax", which, in view of the present precise definition of the waxes used, i.e. refined beeswax and microcrystalline wax - both insoluble waxes - has become redundant so that its omission does not extend the scope of the claim. Hence, no question of *reformatio in peius* arises from the deletion of the word "insoluble". Moreover, the request was filed as a direct reaction to the points raised during the oral proceedings.

Furthermore, since there is in general no reason to assume that granted claims have not been the subject of examination before grant, and since there is no indication in the file that in the present particular case the dependent claims would not have been examined (nor did the appellants point to any such indication),

the argument of the appellants that the restricted subject-matter of the new claims had not been the subject of examination, cannot be followed.

Since the amended claims avoid the objections raised by the board to the previous claims, the claims of the main request are admitted into the proceedings in the exercise of the discretion of the board.

- 2.1 Claim 1 of the main request is a combination of claims 1, 2 and 7 as originally filed, so that the requirements of Article 123(2) EPC are met.

Claim 1 of the main request is further also a combination of claims 1 and 7 as granted. The other claims have, apart from editorial adaptations, remained unchanged. Therefore, the scope of protection has not been extended and Article 123(3) is complied with.

Clarity

3. Any lack of clarity in a granted claim cannot be objected to under Article 84 EPC, as an objection under this article is not a ground for opposition. Rather a meaning must be attributed to the claim, if necessary by reference to the description. In the present case, the unclear functional definition "a wax that is emulsible upon contact with saliva" has been supplemented by a precise definition in the form of the specific combination of compounds and their amounts as appearing in granted claim 7. This combination according to paragraph [0033] of the patent specification results in an "emusible wax" in the sense

meant in the patent, so that for the present claim 1 interpretation is superfluous.

Sufficiency of disclosure

4. It has not been contested that the skilled person is capable of preparing a composition falling within the specific requirements of claim 1 and to produce a dental floss including that composition. It follows from paragraph [0033] of the patent specification that the composition as specified in claim 1 is emulsible upon contact with saliva. Therefore, the requirements of Article 83 EPC are fulfilled.

Novelty

5. The appellants did not raise any objections as to lack of novelty regarding the main request and the board sees no reason itself to raise any such objection. The requirements of Article 54 EPC can be regarded as fulfilled.

Inventive step

6. The patent in suit concerns a dental floss provided with chemotherapy agents. It aims at a dental floss providing an improved chemotherapy product release as well as comfort in use (paragraph [0023]). Such dental flosses are described in D1, D2 and D5. The appellants started from D1 as the closest prior art document. The respondents argued that D1 concerned a completely different problem than the patent in suit but did not indicate any other document that could or should serve

as a starting point for the assessment of inventive step.

- 6.1 D1 discloses a method of preparing waxed dental textile material comprising applying a coating of wax to the textile material that is water insoluble and solid at room temperature and has a fluorine-containing compound distributed therein which provides fluoride ion in a therapeutic amount when the waxed textile material is intimately contacted with the teeth and gingiva to remove the food deposits, wax particles being deposited on the teeth and fluoride ion being slowly released therefrom (claim 1).

The wax is deposited on the textile by means of a wax containing liquid (figure; column 2, lines 13 to 18). The wax content in the liquid may be varied from 5 to 75% by weight, preferably from 20 to 50% by weight (column 4, lines 49 to 53). The liquid may be a molten wax, an aqueous emulsion, a gel-like or a solution (column 3, lines 27 to 29; column 4, lines 37 to 38). In case of aqueous emulsions, suitable emulsifying agents are alkali metal salts of fatty acids, synthetic nonionic surfactants and anionic surfactants (column 4, lines 1 to 11). As suitable kinds of wax microcrystalline wax and beeswax, amongst others, are mentioned (column 3, lines 42 to 52). In Example II the preparation of an aqueous emulsion is described containing 25 parts by weight of microcrystalline wax, 5 parts by weight of a nonionic synthetic detergent and the remainder water, to which stannous fluoride is added.

The object of D1 is to provide dental floss inhibiting the formation of caries by providing a wax coating that slowly releases fluoride ions in a sufficient amount (column 1, lines 46 to 56).

- 6.2 D2 describes a dental floss comprising a substantially saturated aliphatic acyl amide of a saturated aliphatic monoaminocarboxylic acid, the aliphatic acyl group having 12 to 16 carbon atoms, and less than 15% by weight based on the acyl amide of higher fatty acid material (claim 1). Suitable acyl amides of water-soluble salts of e.g. N-lauroyl sarcoside, N-myristoyl sarcoside, N-palmitoyl sarcoside are mentioned (column 2, lines 11 to 14). In Example II a dental floss is prepared by intimately mixing sodium N-lauroyl sarcoside with molten beeswax to form a homogeneous mixture containing about 5% sarcoside. A nylon yarn is then coated with that wax composition.

D2 aims at providing a dental floss that inhibits the acid production in the mouth for a prolonged period of time (column 1, lines 30 to 35).

- 6.3 D5 describes a flavoured dental floss coated with an inner wax coating having a melting temperature of at least 60°C, which inner coating is at least partially covered by an outer wax coating having a melting temperature below that of the inner wax coating and containing volatile flavouring oil (claim 9). The first wax composition may be a microcrystalline wax (claim 11), the second wax composition may comprise polyethylene glycol (claims 10, 13). The outer coating may contain emulsifying waxes such as PEG-40 sorbitan diisostearate (page 7, lines 4 to 9).

In Example 1 the second coating is prepared by mixing peppermint and spearmint flavours and menthol, adding PEG 40 Sorbitan diisostearate, then adding a heated mixture of sorbitol and sodium saccharin, which combination of compounds is then mixed with heated polyethylene glycol (65°C). The mixture is kept at 50 to 65°C and applied to the threads to be coated.

D5 aims at preparing a flavoured dental floss at lower temperatures in order to prevent the rapid vaporization and oxidization of the flavouring oils (page 2, lines 2 to 12).

- 6.4 Since D1, D2 as well as D5 aim at a dental floss providing chemotherapy product release, any of them may be considered as a proper starting point for assessing the presence of an inventive step.
7. In the patent in suit two dental flosses are described by way of example, one impregnated with an unidentified wax said to be according to the invention, one with polyethylene glycol, both containing sodium fluoride. According to the patent in suit, both flosses release an equivalent amount of fluorine, but the floss with the polyethylene glycol is less comfortable to use than the other one (paragraph [0039]).
- 7.1 The comparative example does not reflect any of the documents D1, D2 or D5, so that there is no suitable comparison with the closest prior art. No conclusions can therefore be drawn regarding any improvement or advantage in relation to any one of D1, D2 or D5, representing the actual knowledge at the filing

(priority) date of the patent in suit. The advantages to which the respondent referred, comparing the present composition with unknown prior art, cannot be taken as a basis for the definition of the problem to be solved.

- 7.2 Also, according to the problem-solution approach, if an improvement is used as the basis of a definition of the problem to be solved by the claimed subject-matter, then even if that problem cannot be regarded as effectively solved by the claimed measures, this merely means that the problem to be solved has to be reformulated: it does not automatically mean that there is no invention.

As the alleged improvement cannot be regarded as established, the problem to be solved in the present case has to be reformulated less ambitiously, and here can be seen as being to provide a further dental floss, irrespective of which document is taken as the starting point. From the patent specification it is clear that that problem of providing an alternative has been effectively solved by the subject-matter of claim 1.

8. Therefore, the question remains to be answered whether or not the claimed solution to the problem as above defined, i.e. to provide a further dental floss, can be derived in an obvious manner from the cited prior art.

- 8.1 As can be seen from the above analysis of documents D1, D2 and D5, none of those discloses a composition that comes even close to what is now claimed. Nowhere in D1, D2 or D5, nor in any of the other documents on file, is there any hint at the specific combination of waxes and surfactants in the specific amounts now being claimed,

- in particular the high amounts of surfactants, so that those documents cannot render the subject-matter of claim 1 obvious.
- 8.2 The appellants' argument that, according to standard jurisprudence of the boards, merely providing an alternative solution to a known problem automatically leads to the conclusion that the claimed subject-matter is obvious, cannot be followed (See Case Law of the Boards of Appeal of the European Patent Office, 5th edition 2006, I.D.4.5). Providing a further dental floss to those already existing can be regarded as an invention if the solution claimed would not be arrived at in an obvious manner. From point 8.1 above it can be seen that the very specific composition now being claimed was not suggested by the cited documents, taken singly or combined, so that it cannot be regarded as obvious over those documents.
- 8.3 In view of the above, the Board comes to the conclusion that the subject-matter of claim 1 of the main and only request, as well as that of claims 2, 3 and 4 depending on claim 1, is inventive, so that the requirements of Article 56 EPC are fulfilled.
9. During the oral proceedings the respondents also filed a new page 3 of the patent specification as published which had been adapted to the amended claims. The appellants did not raise any objections against the adaptations and the Board sees no reason to take a different view.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for maintenance of the patent on the basis of claims 1 to 4 and amended page 3 of the granted patent specification as published filed at the oral proceedings on 12 May 2010 together with page 2 of the granted patent specification as published.

The Registrar

The Chairman

S. Fabiani

S. Perryman