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**Datasheet for the decision
of 14 March 2019**

Case Number: T 2071/15 - 3.3.07

Application Number: 03075488.1

Publication Number: 1449513

IPC: A61K8/27, A61K8/66, A61Q11/00

Language of the proceedings: EN

Title of invention:
Dental care product

Patent Proprietor:
Unilever PLC
Unilever N.V.

Opponent:
Colgate-Palmolive Company

Headword:
Dental care product / UNILEVER

Relevant legal provisions:
EPC Art. 53(c), 100(b), 123(2), 111(1)

Keyword:

Exceptions to patentability - main request - (yes)
Amendments - auxiliary requests 1 to 4 - added subject-matter
(yes) - auxiliary request 5 - added subject-matter (no)
Sufficiency of disclosure - auxiliary request 5 (yes)
Appeal decision - remittal to the department of first instance
(yes)

Decisions cited:

T 1635/09



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Case Number: T 2071/15 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 14 March 2019

Appellant: Unilever PLC
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 14 October 2015
revoking European patent No. 1449513 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman A. Uselli
Members: S. Albrecht
 Y. Podbielski

Summary of Facts and Submissions

- I. European Patent No. 1 449 513 was granted on the basis of a set of eleven claims, wherein independent claims 1, 10 and 11 read as follows:

"1. The use of a dental care product comprising lactoperoxidase and zinc ions for the purpose of restoring pH in the mouth, from a lower pH to neutral pH wherein the amount of zinc ions is in the range of from 0.0025 to 0.05 wt %, preferably from 0.01 to 0.05 wt%, more preferably from 0.025 to 0.05 wt.%.

10. The use of zinc ions to enhance the effect of lactoperoxidase in a dental care product, wherein the amount of zinc ions is in the range of from 0.0025 to 0.05 wt %.

11. The use of lactoperoxidase to enhance the effect of zinc ions in a dental care product, wherein the amount of zinc ions is in the range of from 0.0025 to 0.05 wt %."

- II. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty and inventive step and was excluded from patentability pursuant to Article 53(c) EPC (Article 100(a) EPC), that its subject-matter was not sufficiently disclosed (Article 100(b) EPC) and that it extended beyond the content of the application as filed (Article 100(c) EPC).

The evidence filed during the opposition proceedings included the following:

D1: Experimental report "Synergy between lactoperoxidase and zincgluconate", filed by the patent proprietors with their telefax dated 23 June 2008 (four pages in total)

D2: Experimental report of 27 September 2010, filed by the patent proprietors with their telefax dated 21 December 2010 (three pages in total)

D3: Experimental report "The efficacy of a range zinkgluconate in combination with the lactoperoxidase system of Zendium" of 18 November 2010, filed by the patent proprietors with their telefax dated 21 December 2010 (three pages in total)

D4: Experimental report filed by the patent proprietors as third annex of their telefax dated 21 December 2010 (four pages in total)

III. The opposition division's decision to revoke the patent was based on a main request corresponding to the patent as granted and six auxiliary requests filed with the patent proprietors' letter of 21 August 2015.

IV. In the appealed decision, the opposition division came to the following conclusions:

(a) The claims of the main request satisfied the requirements of Article 123(2) EPC.

(b) The use defined in claim 1 of the main request encompassed methods of treatment of the human or animal body by therapy, as set out in paragraph

0001 of the patent in suit. Accordingly, claim 1 comprised subject-matter which was excluded from patentability under Article 53(c) EPC.

(c) Claims 10 and 11 of the main request lacked sufficiency of disclosure, in that the skilled person could not rework the claimed subject-matter without the undue burden of random experimentation. Furthermore, the claimed effects could not be achieved over the full scope of the claims.

(d) Auxiliary requests 1 to 6 contravened Article 123(3) EPC.

V. The patent proprietors (hereinafter "appellants") lodged an appeal against the decision of the opposition division. With the statement setting out the grounds of appeal the appellants refiled the six auxiliary requests forming the basis of the opposition division's decision, and requested that the decision under appeal be set aside and the patent be maintained as granted or, in the alternative, that the patent be maintained as amended on the basis of one of these six auxiliary requests.

VI. In a communication pursuant to Article 15(1) RPBA issued on 29 January 2019, the Board expressed *inter alia* its preliminary opinion that claim 1 of the main request included therapeutic methods excluded from patentability under Article 53(c) EPC.

VII. With letter dated 12 February 2019, the appellants withdrew all the existing auxiliary requests and filed six new auxiliary requests.

Claim 1 of auxiliary requests 1 and 2 read as follows:

"1. The non-therapeutic use of a dental care product comprising lactoperoxidase and zinc ions for the purpose of restoring pH in the mouth, from a lower pH to neutral pH to inhibit oral bacteria and thereby reduce halitose wherein the amount of zinc ions is in the range of from 0.0025 to 0.05 wt %, preferably from 0.01 to 0.05 wt%, more preferably from 0.025 to 0.05 wt.%."

Claim 1 of auxiliary requests 3 and 4 only differed from claim 1 of the preceding auxiliary requests in that the expression "to inhibit oral bacteria and thereby reduce halitose" was replaced by "to reduce halitose".

Auxiliary request 5 comprised two claims in total which corresponded to claims 10 and 11 of the main request respectively.

(Auxiliary request 6 is not relevant for the present decision)

VIII. Oral proceedings took place on 14 March 2019. They were attended by the appellants only.

IX. The appellants' arguments, as far as they are relevant for the present decision, can be summarised as follows:

(a) The use of claim 1 related to the beneficial effect of zinc ions and lactoperoxidase in the environment of the mouth which did not involve any therapeutic method pursuant to Article 53(c) EPC.

- (b) Claim 1 of auxiliary requests 1 to 4 met the requirements of Article 123(2) EPC, as its subject-matter found basis in the second and third paragraph of page 2 of the description of the patent application as filed.
- (c) The invention defined in the claims of the fifth auxiliary request was sufficiently disclosed. In particular, the claimed beneficial technical effects were clearly supported by the technical information in the patent and further confirmed by the experimental reports D1 to D4, whereas the opponent did not provide any evidence in support of its allegations, although it carried the burden of proof.

X. Requests of the appellants:

The appellants requested that the decision under appeal be set aside and the opposition be rejected (i.e. that the patent be maintained as granted) or, as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests 1 to 6 filed with letter dated 12 February 2019. The appellants furthermore requested that the case be remitted to the opposition division for further prosecution in the event that the Board found any of the requests to overcome the objections raised by the opposition division.

XI. The respondent did not make any submission in the appeal proceedings.

Reasons for the Decision

Main request (patent as granted)

1. Non-attendance of the respondent at the oral proceedings

Although duly summoned, the respondent did not attend the oral proceedings. It also did not submit any comments on the Board's preliminary opinion set out in its communication dated 29 January 2019.

In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the oral proceedings were held without the respondent. By deciding not to attend the oral proceedings and not to file substantive arguments in reply to the Board's communication, the respondent has chosen not to take the opportunity to comment on the Board's opinion, either in writing or orally at the oral proceedings.

2. Article 53(c) EPC - claim 1

- 2.1 Claim 1 is directed to the use of a dental care product comprising

(i) zinc ions in a certain amount, and

(ii) lactoperoxidase

for the purpose of restoring pH in the mouth, from a lower pH to neutral pH.

- 2.2 The opposition division held in point 4 of the reasons for its decision that claim 1 encompassed

non-patentable subject-matter by virtue of Article 53(c) EPC in that it covered *inter alia* the prophylaxis of a medical condition such as caries. In this context the opposition division also observed that the cosmetic and pharmaceutical uses falling within the scope of this claim were inextricably linked by the underlying therapeutic mechanism of action of inhibition of oral bacteria.

- 2.3 In their statement setting out the grounds of appeal the appellants disputed the opposition division's negative finding on patentability under Article 53(c) EPC. In their view, the use of claim 1 simply related to the beneficial effect of zinc ions and lactoperoxidase in the environment of the mouth which did not involve any therapeutic method pursuant to Article 53(c) EPC.
- 2.4 Therefore, it needs to be assessed in the present case whether the claimed use constitutes a therapeutic method in accordance with Article 53(c) EPC. In this regard, the activities carried out and/or the effects achieved in the course of that use need to be determined (T 1635/09; OJ EPO 2011, 542; catchword 2).
- 2.4.1 Paragraph 0006 of the description of the patent in suit teaches that the dental care product of the invention inhibits oral bacteria occurring in plaque. These bacteria normally cause decay of food products, leading to the formation of acids which render the pH in the mouth acidic (see paragraph 0002 of the description of the patent in suit). Hence, by inhibiting these bacteria, the dental care product causes the pH of the saliva to become less acidic which, in turn, reduces the restoration time of the pH in the mouth (see paragraph 0006 of the description of the patent in suit

as well as the experimental data contained in D1 to D4).

The Board therefore concludes that the activity carried out and/or the effect achieved in the course of the claimed use is the inhibition of growth of oral bacteria.

- 2.4.2 It remains to be assessed whether this activity underlies a therapeutic effect in terms of the prevention or treatment of a disease.

As already outlined in point 3.5 of its communication, the Board observes that paragraph 0001 of the description of the patent in suit defines the invention as relating to the use of a dental care product which has an improved capacity of preventing acid formation, e.g. in saliva, thereby preventing caries, tooth erosion and other affectations of the mouth caused by acidity. Hence, the product's capacity of preventing acid formation achieves the therapeutic effect of preventing the aforementioned diseases in the oral cavity including caries and tooth erosion. This capacity being the direct result of the product's activity of inhibiting the growth of oral bacteria (see point 2.4.1 above), it follows therefrom that this activity is inherently therapeutic, i.e. it underlies the therapeutic effect of preventing the aforementioned diseases.

- 2.4.3 The appellants did not submit any further written or oral arguments in response to the objections raised by the Board in its communication under Article 53(c) EPC.

- 2.4.4 Accordingly, the Board maintains its opinion expressed in its communication that the use of claim 1 is based

on the therapeutic mechanism of action of inhibition of growth of oral bacteria, and therefore constitutes a method of treatment of the human or animal body by therapy which is excluded from patentability under Article 53(c) EPC.

Consequently, the main request is not allowable under Article 53(c) EPC.

Auxiliary requests 1 and 2

3. Article 123(2) EPC - claim 1

3.1 Claim 1 of each of these requests concerns the non-therapeutic use of a dental care product comprising zinc ions in a specified amount and lactoperoxidase for the purpose of restoring pH in the mouth, from a lower pH to neutral pH to inhibit oral bacteria and thereby reduce halitose.

Hence, claim 1 requires a causal relationship between:

(i) the restoration of the pH in the mouth, from a lower pH to neutral pH,

(ii) the inhibition of oral bacteria, and

(iii) the reduction of halitose.

3.2 This fact has not been disputed by the appellants. In their view, the claimed subject-matter finds adequate support in the second and third paragraph of page 2 of the description of the patent application as filed.

3.3 The Board, on the other hand, considers that neither these passages nor any other passage of the patent

application as filed (hereinafter referred to as "the patent application") provides a valid basis within the meaning of Article 123(2) EPC for the aforementioned causal relationship. In this regard, the Board notes in particular the following:

3.3.1 The second paragraph of page 2 of the description of the patent application can be divided in two parts, namely

(i) a first part consisting of lines 15 to 22, and

(ii) a second part corresponding to lines 22 to 24, starting with the statement "*It has furthermore been found*".

The first part discloses the ability of the dental care product of the invention to inhibit oral bacteria and thereby reduce the restoration time of the pH in the mouth and prolong the period during which acid formation is inhibited. There is however no mention in this passage of halitose.

The second part, on the other hand, refers to the effectiveness of the dental care product of the invention in reducing halitose, but remains silent on any inhibitory effect of oral bacteria and on any pH restoring effect in the mouth.

3.3.2 Furthermore, as pointed out by the Board during the oral proceedings, the aforementioned two parts pertain to two separate, distinct findings or discoveries in respect of the invention as described in the patent application, namely

- (a) that a combination of lactoperoxidase and zinc ions significantly inhibits oral bacteria and prolongs the period during which acid formation is inhibited after use of a dental care product comprising this combination (see lines 18 to 22);
- (b) that a dental care product comprising this combination effectively reduces halitose (see lines 22 to 24).

That these two aspects of the invention are unrelated to each other is further supported by the fact that the remaining part of the patent application does not disclose any link between the reduction of halitose, on one hand, and the oral bacteria inhibiting effect and/or the pH restoring effect on the other hand either. The only further passage referring to halitose is the third paragraph of page 2 of the description of the patent application. Nevertheless, the relevant passage solely states that the combination of lactoperoxidase and zinc ions has been found to lead to more beneficial results in restoring pH in the mouth and reducing halitose than the lactoperoxidase or zinc ions alone (see lines 26 to 28), i.e. it refers to the two findings (a) and (b) disclosed in the preceding paragraph, whereas it does not provide any direct and unambiguous basis for a causal link between the restoration of the pH in the mouth and the reduction of halitose.

3.3.3 In view of the foregoing considerations, the Board concludes that auxiliary requests 1 and 2 do not comply with the requirements of Article 123(2) EPC.

Auxiliary requests 3 and 4

4. Article 123(2) EPC - claim 1
- 4.1 Claim 1 of each of these requests is directed to the non-therapeutic use of a dental care product comprising zinc ions in a specified amount and lactoperoxidase for the purpose of restoring pH in the mouth, from a lower pH to neutral pH to reduce halitose.
- 4.2 Hence, claim 1 of the present requests differs from claim 1 of the preceding auxiliary requests in that it no longer refers to the oral bacteria inhibiting effect, i.e. it merely requires a causal link between the restoration of the pH in the mouth from a lower pH to neutral pH and the reduction of halitose.
- 4.3 During the oral proceedings, the appellants identified again paragraphs 2 and 3 of page 2 of the description of the patent application as basis for the claimed subject-matter.
- 4.4 However, for the same reasons as provided in points 3.3.1 and 3.3.2 above with respect to claim 1 of auxiliary requests 1 and 2, the Board considers that neither these paragraphs nor any other part of the application as filed directly and unambiguously discloses that halitose can be reduced by restoring the pH in the mouth, from a lower pH to neutral pH.
- 4.5 Accordingly, the Board concludes that auxiliary requests 3 and 4 do not comply with the requirements of Article 123(2) EPC.

Auxiliary request 5

5. Article 123(2) EPC

According to the impugned decision, the subject-matter of the two claims of this request fulfils the requirements of Article 123(2) EPC. The Board sees no reason to deviate from this finding.

6. Sufficiency of disclosure

6.1 Claims 1 and 2 of this request pertain to the following two uses respectively:

(i) the enhancement of the effect of lactoperoxidase in a dental care product, and

(ii) the enhancement of the effect of zinc ions in a dental care product.

6.2 In point 3 of the reasons for its decision, the opposition division considered claims 10 and 11 of the main request (i.e. claims 1 and 2 of the present request) to relate to a synergistic enhancement. In its view, both of these claims were insufficiently disclosed in that the lack of indication as to the effect to be enhanced constituted an undue burden for the skilled person who had to perform random experimentation in order to reproduce the invention. Furthermore, the opposition division doubted that the enhanced effect could be achieved in the case of zinc salts which were insoluble at physiological pH.

6.3 In this respect, the Board first of all observes that claims 1 and 2 do not require that the claimed enhancements must be synergistic.

As to the nature of the effects to be enhanced, paragraph 0007 of the description of the patent in suit teaches that the combination of lactoperoxidase and zinc ions leads to more beneficial results in restoring the pH in the mouth and reducing halitose than lactoperoxidase and zinc ions alone. Particularly suitable lactoperoxidases and zinc ions in this regard are disclosed in paragraphs 0010 and 0011 and in the examples of the description of the patent in suit.

6.4 Under these circumstances, the Board considers that the burden of proof lies with the respondent to demonstrate that the claimed invention lacks sufficiency of disclosure. Nevertheless, the respondent did not submit any facts, neither in the opposition nor in the appeal proceedings, that would cast serious doubts substantiated by verifiable facts with respect to the disclosure of the claimed invention. Furthermore, the respondent did not provide any evidence that the invention could not be reproduced over the entire scope of the claims without undue burden or that the claimed enhancements could not be achieved in the case of zinc salts which were insoluble at physiological pH.

6.5 In the absence of such facts or evidence, the Board concludes that the invention underlying the claimed subject-matter is sufficiently disclosed.

7. Remittal

7.1 Under Article 111(1) EPC the Board of Appeal decides on the appeal. It may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution. There is no absolute right to have every issue decided at two

instances; it is the primary function of an appeal to give the losing party an opportunity to obtain judicial review of whether the decision appealed was correct. Factors to be taken into account when deciding on a remittal include the parties' requests, the general interest in bringing proceedings to a close within a reasonable period of time and whether or not the case was comprehensively assessed during the proceedings before the opposition division.

- 7.2 Since the opposition division decided only on the question whether the claimed subject-matter fulfils the the requirements of Article 123(2) EPC and sufficiency of disclosure and did not consider the further issues of novelty, inventive step and exclusion from patentability pursuant to Article 53(c) EPC, the Board considers it appropriate to allow the appellants' uncontested request for remittal of the case to the opposition division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Usuelli

Decision electronically authenticated