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Datasheet for the decision of 19 March 2008

Case Number: T 0034/06 - 3.3.09

Application Number: 99946084.3

Publication Number: 1112003

IPC: A23L 1/05

Language of the proceedings: EN

Title of invention:
Use of a viscosity modulating polymer material for reducing tooth erosion

Patentee:
SMITHKLINE BEECHAM PLC

Opponent:
Friesland Brands B.V.

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56
RPBA Art. 12, 13(1),(3)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request - novelty - no"
"Amended main request - not admitted"
"First auxiliary request - inventive step - yes"

Decisions cited:
-

Catchword:
see 3.2.5, 4-4.1.3

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0034/06 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 19 March 2008

Appellant: (Patent Proprietor)
SMITHKLINE BEECHAM PLC
980 Great West Road
Brentford,
Middlesex TW8 9GS (GB)

Representative:
White, Susan Mary
GlaxoSmithKline
Corporate Intellectual Property (CN9.25.1)
980 Great West Road
Brentford, Middlesex TW8 9GS (GB)

Respondent: (Opponent)
Friesland Brands B.V.
Blankenstein 142
NL-7943 PE Meppel (NL)

Representative:
Prins, Adrianus Willem
Vereenigde,
P.O. Box 87930
NL-2508 DH Den Haag (NL)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 15 November 2005 revoking European Patent No. 1112003 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: P. Kitzmantel
Members: J. Jardón Álvarez
M-B. Tardo-Dino

Summary of Facts and Submissions

I. The grant of European patent No. 1 112 003 in respect of European patent application No. 99946084.3 in the name of SmithKline Beecham plc which had been filed on 31 August 1999 as International application PCT/EP99/06423 (WO - 00/13531), was announced on April 2003 (Bulletin 2003/16) on the basis of 13 claims. Independent Claims 1 and 13 read as follows:

"1. The use of a viscosity modulating polymer material for the manufacture of an orally administered acidic composition having an effective pH less than or equal to 4.5, for the reduction of tooth erosion caused by acid.

13. A process for reducing the tooth erosion potential of an acidic composition for oral use comprising adding a viscosity modulating polymer material, and optionally calcium in the range 0 to 0.8 mol per mol of acid, to an acidic oral composition and controlling the effective pH, if necessary or desired, to provide a composition with an effective pH less than or equal to 4.5."

Claims 2 to 12 were dependent claims.

II. A Notice of Opposition, requesting the revocation of the patent in its entirety on the grounds of Articles 100(a) and (b) EPC was filed against the patent by Friesland Brands B.V. on 16 January 2004.

During the opposition proceedings *inter alia* the following documents were cited:

D1: "The adsorption of two polyphosphonates on hydroxyapatite and their influence on the acid solubility of whole bovine enamel", T. Bartels *et al.* in Journal of Dentistry, 7 (3), 1979, pages 221 - 229,

D2: WO - A - 97/30601,

D3: "Ion Displacement Following the Adsorption of Anionic Macromolecules on Hydroxyapatite", E.I.F. Pearce in Calcif. Tissue Int. 33, 1981, pages 395-402,

D4: "Influence of polymers for use in saliva substitutes on de- and remineralization of enamel *in vitro*", W.A. van der Reijden *et al*. Caries Res. 31(3), 1997, pages 216 - 223, and

D5: "Adsorption of Neutral and Anionic Polyacrylamides on Hydroxyapatite and Human Enamel: Influence on the Dissolution Kinetics" P. Schaad *et al.* Journal of Colloid and Interface Science 164, 1994, pages 291 - 295.

III. By its decision announced orally on 22 September 2005 and issued in writing on 15 November 2005, the Opposition Division revoked the patent.

The Opposition Division held that the patent disclosed the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person, essentially because the Opponent did not demonstrate that the reworking of the patent in suit was not

possible. The Opposition Division further pointed out that the objections of the Opponent concerning Article 83 EPC related in fact to the clarity of the claims, which did not constitute a ground for opposition. In any case the Opposition Division stated that the claims were clear.

However, the Opposition Division revoked the patent because in its opinion the subject-matter of Claim 13 of the then pending main and first auxiliary requests lacked novelty having regard to the disclosure of D1, and the subject-matter of the claims according to the second auxiliary request lacked inventive step in view of D1 taken alone. In the Opposition Division's opinion the only feature that was not disclosed in D1, namely the intention to use the composition of D1 in a medical or prophylactic treatment was trivial for the skilled person, essentially because the tests in D1 were designed to monitor tooth erosion caused by acid, irrespective of the origin of the acid.

IV. On 9 January 2006 the Patent Proprietor (Appellant) lodged an appeal against the decision of the Opposition Division and paid the appeal fee on the same day.

In the Statement of Grounds of Appeal filed on 17 March 2006, the Appellant requested that the decision of the Opposition Division be set aside and that the patent be maintained with the claims of the newly filed main request (corresponding to the second auxiliary request before the Opposition Division) or of one of the newly filed auxiliary requests 1 to 5.

V. The Opponent (Respondent) filed a reply with its letter dated 2 August 2006 and requested that the appeal be dismissed.

VI. On 25 October 2007 the Board dispatched the summons to attend oral proceedings. In the annexed communication pursuant to Article 11(1) of the Rules of Procedure of the Boards of Appeal (RPBA), version EPC 1973, the Board asked the Appellant to correct a mistake in the numbering of the requests. The Board also gave a preliminary opinion on the issue of sufficiency of disclosure and drew the attention of the parties to the points to be discussed during the oral proceedings.

VII. By letter dated 19 February 2008, the Appellant filed an amended set of claim requests to correct the error in the numbering of the previously filed requests.

The Appellant also referred in its letter to the web page of a further document:

D12: "Statutory Instrument 1995 No. 3187: The Miscellaneous Food Additives and Regulations 1995".

Independent Claims 1 and 13 of the main request as filed with this letter read as follows:

"1. The use of a viscosity modulating polymer material for the manufacture of an orally administered acidic composition having an effective pH less than or equal to 4.5, for the reduction of tooth erosion caused by acid.

13. A process for reducing the tooth erosion potential of an acidic composition for oral use comprising adding a viscosity modulating polymer material, and calcium in the range 0.01 to 0.75 mol per mol of acid, to an acidic oral composition and controlling the effective pH, if necessary or desired, to provide a composition with an effective pH less than or equal to 4.5."

The claims of the first auxiliary request were amended to limit the acidic composition to a foodstuff. Independent Claims 1 and 12 of this request read as follows:

"1. The use of a viscosity modulating polymer material for the manufacture of an orally administered acidic composition which is a foodstuff having an effective pH less than or equal to 4.5, for the reduction of tooth erosion caused by acid.

12. A process for reducing the tooth erosion potential of an acidic foodstuff composition for oral use comprising adding a viscosity modulating polymer material, and calcium in the range 0.01 to 0.75 mol per mol of acid, to an acidic oral foodstuff composition and controlling the effective pH, if necessary or desired, to provide a composition with an effective pH less than or equal to 4.5."

VIII. The arguments presented by the Appellant in writing and at the oral proceedings held on 19 March 2008 may be summarized as follows:

– The subject-matter of Claim 1 of the main request was novel essentially because D1 was directed to the

field of dental caries which is not the same as the field of dental erosion, and because D1 was accordingly concerned with the prophylactic protection of teeth against subsequent attack by acid (generated by the transformation of carbohydrates into acid by mouth bacteria), while the patent was concerned with the modification of an acidic composition so that the composition itself did not damage the teeth. The Appellant admitted that the expression "tooth erosion caused by acid" in Claim 1 could also be interpreted in a broader way but argued that in the present case it was clear by reference to paragraphs [0001], [0002] and [0006] of the description of the patent in suit that the claims were only directed to the dental erosion caused by the acidic compositions themselves.

– To clarify this in Claim 1 itself, the Appellant suggested during the oral proceedings an amended main request whose Claim 1 differed from that of the previous main request by insertion of the word "the" before "acid", so that it read as follows:

"1. The use of a viscosity modulating polymer material for the manufacture of an orally administered acidic composition having an effective pH less than or equal to 4.5, for the reduction of tooth erosion caused by the acid."

– Concerning the first auxiliary request, the Appellant considered D2 as the closest prior art document as it was in the same technical field as the patent in suit and it concerned the same objective, namely to reduce the tooth erosion

potential of acidic compositions. The Appellant saw the technical problem to be solved by the patent in suit as to provide alternative means to protect the teeth from the erosion caused by acidic foodstuffs. The solution to this problem according to Claim 1, namely the use of a viscosity modulating polymer, was not obvious in view of the cited prior art. In particular D1 did not give any hint to this solution because it did not make any reference to dental erosion. The polymers in D1 were adsorbed on the teeth to protect them when acid was produced in the mouth. Moreover the concentration of the polymers in the compositions used according to D1 was too high to be usable as foodstuff and it was by no means clear to the skilled person that foodstuff-compatible lower concentrations would provide the desired acid protecting effect.

IX. The arguments presented by the Respondent may be summarized as follows:

– The requirements of Article 83 EPC were not fulfilled because: (i) the term "complex polysaccharide" used in Claim 2 was not defined in the patent in suit and the skilled person would not be able to determine whether a given polysaccharide was a complex polysaccharide or not, and (ii) an essential feature, i.e. the concentration of the polymer in the acidic composition, was missing from the claims.

– The Respondent further argued that D1 was novelty destroying for the subject-matter of Claim 1 of the main request because it disclosed the use of

polyphosphonates to reduce the etching away of tooth enamel by acid without bacterial involvement, that is to say, it disclosed the use of acidic compositions containing a viscosity modulating polymer material for the reduction of tooth erosion caused by acid. Although D1 did not use the wording "tooth erosion" it made reference to exactly the same phenomenon for use in exactly the same environment. The solubility experiments of D1 showed that polyphosphonates reduced the solubility of hydroxyapatite in an acidic solution. Hence the subject-matter of Claim 1 of the main request lacked novelty.

– Concerning the amended main request, the Respondent pointed out that it should be considered as filed too late and that moreover it was not appropriate to render the subject-matter of Claim 1 clearly distinguishable from the disclosure of D1. It therefore opposed the admittance of this request into the appeal proceedings at this late stage.

– Concerning the first auxiliary request the Respondent acknowledged the novelty of the subject-matter of Claims 1 and 12 but argued that it did not involve an inventive step having regard to the teaching of D1 alone or in combination with D2. The Respondent regarded D1 as the closest prior art document and argued that taking into account that the compositions of D1 were suitable to protect against tooth erosion without bacterial involvement, it would have been obvious for the skilled person to use these solutions also for the reduction of tooth erosion caused by acidic compositions. The addition

of the polymers to foodstuff was merely an alternative way of introduction of the polymers into the mouth. In any case it would be a matter of routine adaptation to find out the effective amount of polymer that should be added to the acidic compositions of D2.

X. The **Appellant** requested:

– That the decision under appeal be set aside and that the patent be maintained on the basis of Claims 1 to 13 of the main request or, alternatively, on the basis of the claims of any of the five auxiliary requests, all as submitted with the letter of 19 February 2008.

– It also orally requested that the amended main request be admitted into the proceedings.

The **Respondent** requested:

– that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

MAIN REQUEST.

2. *Sufficiency of disclosure (Article 83 EPC).*

2.1 The Board agrees with the finding in the appealed decision that the patent discloses the invention in a

manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

2.2 The Respondent has not disputed that at least one way is clearly indicated in the patent specification enabling the skilled person to carry out the invention nor has it shown that reworking of the patent was not possible.

2.3 The objections raised by the Respondent concerning the term "complex polysaccharide" and the (possible) absence of an essential feature from the claims relate to the question whether the claims clearly define the matter for which protection is sought and whether the claims are supported by the description, that is to say, issues not governed by Article 83 EPC but by Article 84 EPC. These objections do not belong to the grounds of opposition under Article 100 EPC and since they concern the granted claims, they cannot be raised in opposition.

2.4 There is thus no valid attack under Article 83 EPC and moreover the Board sees no reason to doubt the fulfilment of the requirements of this article.

3. *Novelty (Article 54 EPC).*

3.1 Claim 1 of the main request is drafted in the form of a second medical use claim and directed to the use of
(a) a viscosity modulating polymer material,
(b) for the manufacture of an acidic composition having an effective pH of 4.5 or less,
(c) intended for oral administration,

(d) wherein the effect to be achieved by the viscosity modulating polymer is the reduction of tooth erosion caused by acid.

3.2 The novelty of the subject-matter of this claim has been contested by the Respondent having regard to the disclosure of D1.

3.2.1 D1 describes at page 223 under the heading "Solubility experiments" the treatment of bovine enamel with an aqueous composition comprising polyphosphonates, the polyphosphonate being a viscosity modulating polymer (feature (a)). As indicated in Figure 3, the experiments involve pre-treatment with acidic compositions having a pH of 4.0 (curves C and E) (feature (b)). The results show that polyphosphonates reduce the acid solubility of bovine enamel (page 226; see also last three lines of "Conclusions" on page 228), that is to say, they reduce tooth erosion (feature (d)).

Although not explicitly disclosed it is within the disclosure of D1 that the compositions are intended to be used orally because D1 aims to study the caries-reducing effect of polyphosponates on tooth enamel, which is naturally only found in the oral cavity. Thus feature (c) is also implicitly disclosed in D1.

3.2.2 The Appellant does not dispute that feature (c) is implicitly disclosed in D1 but argued that feature (d) was not disclosed in D1 because the teaching of D1 was directed to the protection of the teeth against the acids produced by the bacteria on the tooth surface while the subject-matter of Claim 1 was directed to the reduction of dental erosion by modification of the

acidic composition itself. Thus while in D1 the teeth were treated during a certain period of time with an acidic solution of the polymer to adsorb the polymer onto the teeth, the objective of the patent in suit was to modify the acidic composition to reduce the erosive effect of the acid in the composition.

3.2.3 The Board cannot accept this argument of the Appellant. The intended use of the polymer material in Claim 1 is clearly stated as "the reduction of tooth erosion caused by acid" in general terms, without any limitation to the origin of the acid.

3.2.4 The Appellant conceded during the oral proceedings that the claim could be understood as referring generally to tooth erosion caused by any acid but argued that the claim should be interpreted in the light of the description and that it was clear from paragraphs [0001], [0002] and [0006] of the specification that the acid referred to in Claim 1 was the acid present in the acidic compositions itself.

3.2.5 This argument is unconvincing. The Board notes that there is no need to refer to the description for the interpretation of Claim 1, which is in itself entirely clear. The subject-matter of Claim 1 is not directed to foodstuffs or oral health care compositions and the acid is not limited to the acid present in acidic foods or drinks. The Appellant has chosen to define the claimed subject-matter by using the broad terms "acidic composition" and "acid" without any limitation to specific compositions (for instance, foodstuff) or to specific acids (for instance, acid not produced by bacteria on the tooth surface). Both terms used in the

claims are entirely clear and determine the subject-matter covered by the claim. Consequently, there is no need to interpret Claim 1 in a more restrictive manner in the light of the description because the claim is in itself completely clear. It is noted in this context that it is not unusual for a main claim to stretch the invention to its furthest possible limits i.e. going beyond its real core and in doing so there is the risk of anticipation/obviousness. It remains the responsibility of the Patentee/Appellant throughout the proceedings before the EPO to draft the claims and would be contrary to this concept to permit an interpretation of *per se* clearly formulated subject-matter which deviated from its unambiguous meaning.

3.3 For these reasons the subject-matter of Claim 1 lacks novelty (Art. 54 EPC).

AMENDED MAIN REQUEST

4. The Appellant filed this request during the oral proceedings, after the Board had decided against the novelty of the main request, that is to say, at an extremely late stage of the proceedings. According to Article 13(1) and (3) RPBA, version EPC 2000, admittance of an amendment of a party's case submitted after the first stage of the appeal proceedings (cf. Article 12(2) RPBA, version EPC 2000) is at the Board's discretion taking into consideration *inter alia* the need for procedural economy. Such amendment shall not be admitted if it raises issues with which the Board or the other party cannot reasonably expected to deal without adjournment of the oral proceedings.

4.1 The Appellant justified the late filing of this request as resulting from the discussion of novelty during the oral proceedings and relied in particular on the argument that the interpretation of the claims by the Respondent/Board as not being limited to the dental erosion caused by the acidic composition was surprising. The proposed amendment, namely the introduction of the word "the" before "acid" would clarify this point.

4.1.1 The Board cannot agree with the Appellant. The argument concerning the interpretation of the claim had already been brought up by the Respondent in its letter dated 2 August 2006 (see page 12, first paragraph). Moreover, the Board had also pointed out in its communication in preparation for the oral proceedings (see points 3.4 and 3.5) that it should be clarified during the oral proceedings if the expression "for reduction of tooth erosion caused by acid" was adequate to exclude the disclosure of D1. The argument of the Appellant that the late filing arose from the discussion during the oral proceedings cannot therefore be accepted.

4.1.2 Moreover, due to the absence of an antecedent for "**the** acid" in the first part of the claim, it still cannot be ruled out that the tooth erosion could be caused by the acid produced by the bacteria on the tooth surface.

4.1.3 Consequently, in the interests of procedural economy the Board exercises its discretion not to admit the amended main request of the Appellant because it was filed without proper excuse at an extremely late stage and does not overcome in an unambiguous way the objection it is intended to meet.

FIRST AUXILIARY REQUEST.

5. *Novelty (Article 54 EPC).*

5.1 The subject-matter of Claim 1 of this request has been limited to acidic compositions which are a foodstuff in accordance with a preferred embodiment disclosed, for instance, on page 4, lines 25-26 of the application as originally filed.

5.2 The disclosure of D1 does not deal with foodstuffs. The subject-matter of the claims is therefore clearly novel.

5.3 As the novelty of the subject-matter of the claims of the first auxiliary request was also acknowledged by the Respondent no further comments are needed.

6. *Inventive step (Article 56 EPC).*

6.1 Closest prior art.

6.1.1 The subject-matter of Claim 1 of this request is directed to the use of a viscosity modulating polymer in a foodstuff having a pH equal to or less than 4.5 for the reduction of tooth erosion.

6.1.2 As stated in the specification of the patent in suit it is known that the consumption of acidic foods and drinks plays a role in dental erosion. In document D2, which in the Board's judgement represents the closest prior art document, the tooth erosion potential of acidic compositions is reduced by the addition of calcium. In the acidic compositions of D2 calcium is present in the range of 0.3 to 0.8 mol per mol of acid

and the pH is 3.5 to 4.5 (see Claim 1). Acidic compositions according to D2 are useful in reducing tooth erosion (see D2 examples and comparative examples).

6.1.3 The Board disagrees with the Respondent that document D1 represents the closest prior art. As already discussed above in relation to novelty, D1 is directed to the study of the adsorption of two polyphosphonates on hydroxyapatite and the influence of said polymers on the acid solubility of whole bovine enamel (see page 222, third paragraph). Acidic aqueous solutions of the polyphosphonates are used in order to adsorb the polyphosphonate on the hydroxyapatite. The adsorption of the polyphosphonate aims to modify the tooth structure in order to protect teeth against subsequent attack by acid. This treatment is carried out with acidic compositions including relatively high amounts of polymer in order to ensure protection of the teeth but there is no mention in D1 of a possible use of the polymers as additives to foodstuffs. Consequently the disclosure of D1 is remote from the disclosure of the patent in suit and D1 cannot qualify as the closest prior art document.

6.2 The objective problem to be solved and its solution.

6.2.1 The technical problem to be solved by the patent in relation to D2 can be formulated as the provision of alternative means to reduce the tooth-erosion potential of acidic compositions.

6.2.2 This problem is solved according to Claim 1 by the addition to the foodstuff of a viscosity modulating polymer material.

6.2.3 The addition of this polymer material is said to reduce the erosion of teeth. The examples in the patent in suit show that the enamel loss caused by acidic foodstuffs is reduced if the foodstuff contains a polymer. Thus, according to example 1, the enamel loss of a tooth when exposed for 4 hours to a ready-to-drink beverage having a pH of 3.5 was drastically reduced if xanthan gum (a viscosity modulating polymer) was added to the beverage. Similar results were obtained with other polymers (see examples 2 to 11).

6.2.4 Having regard to the fact that the tests in the examples were carried out over four hours whereas foodstuffs normally remain in the mouth for a considerably shorter period of time, the Appellant pointed out during the oral proceedings that measurement of the erosion during the very short period of time that the foodstuff remains in the mouth would be difficult because the amount of erosion would be very small. In any case it was well known that acidic foodstuffs damaged teeth and if the protective effect of the polymer acted over long periods of time, a proportionate benefit from the use of polymers would logically also be obtained even if the acidic foodstuff remained for only a short period of time in contact with the teeth.

6.2.5 This finding was not contested by the Respondent. The Board has no reason to question it, it is thus

satisfied that the technical problem defined above has been credibly solved.

6.3 Obviousness.

6.3.1 It remains to be decided whether, in view of the available prior art documents, it would have been obvious for the skilled person to solve this technical problem by the means claimed, namely by adding a viscosity modulating polymer to the foodstuff.

6.3.2 There is no hint to this solution in D2 as it suggests the addition of calcium to the acidic compositions and it is completely silent about the possible use of any polymer material.

6.3.3 There is also no suggestion of this solution in the other documents cited by the Respondent. Although in these documents the protective effect of some polymers against acidic attacks is mentioned, such protective effect is always achieved by adsorption of the polymer on the teeth (see D3, Abstract, D4 abstract and D5 Abstract), not by addition to a foodstuff.

In particular D1, on which the Respondent mainly relied, gives no hint to the possible use of the two polyphosphonates therein tested in foodstuffs. There is no motivation for the skilled person to use these polymers in foodstuffs merely because of the fact that the acid solubility of tooth enamel is reduced when pre-treated with the polymers. Rather, the whole thrust of D1 is the prophylactic treatment of teeth with two very specific polymers to render them more resistant against caries (see second paragraph of the abstract).

6.3.4 The Board can also not accept the argument of the Respondent that the skilled person would add the polymers of D1 to the acidic compositions of D2 and thus arrive at the claimed subject-matter, because this approach starts from the wrong assumption that D1 contains a pointer towards a beneficial effect to be expected from this combination. D1 however gives no hint at all to the possible use of the polyphosponates tested in the formulation of foodstuffs.

The assertion of the Respondent that it would anyway have been obvious to try out the polymers of D1 in foodstuffs can only be justified with the knowledge of the invention.

6.3.5 Hence, the Board considers that, in the light of the cited prior art, it would not have been obvious to a person skilled in the art to use a viscosity modulating polymer material in an acidic foodstuff having a pH less than or equal to 4.5 in order to reduce its tooth erosion potential. The subject-matter of Claim 1 of the first auxiliary request thus involves an inventive step within the meaning of Article 56 EPC.

6.3.6 Claim 12 is directed to a process for reducing the tooth erosion potential of an acidic foodstuff by adding a viscosity modulating polymer material and calcium. As explained above for Claim 1, the use of viscosity modulating polymer in order to reduce the tooth erosion potential of an acidic composition cannot be derived in an obvious manner from the available prior art.

Consequently, the reasoning above for the subject-matter of Claim 1 applies *mutatis mutandis* for the subject-matter of Claim 12, which thus also satisfies the requirements of Article 56 EPC.

7. As the claims of the first auxiliary request of the Appellant fulfil the requirements of the EPC, there is no need for the Board to deal with the auxiliary requests 2 to 5.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The amended main request submitted during the oral proceedings is not admitted.

3. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of Claims 1 to 12 of the first auxiliary request as filed with the letter of 19 February 2008, after any necessary consequential amendment of the description.

The Registrar: The Chairman:

D. Sauter P. Kitzmantel