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**Datasheet for the decision  
of 20 May 2015**

**Case Number:** T 1823/11 - 3.3.07

**Application Number:** 04004834.0

**Publication Number:** 1454618

**IPC:** A61K7/16, A61K7/26

**Language of the proceedings:** EN

**Title of invention:**

Anticaries compositions containing phaseolamin

**Applicant:**

S.I.I.T. S.r.l. Servizio Internazionale Imballaggi  
Termosaldanti

**Headword:**

**Relevant legal provisions:**

EPC Art. 123(2), 83, 111(1)

**Keyword:**

Amendments - added subject-matter (no)  
Sufficiency of disclosure - Purpose-limited product claim  
Appeal decision -  
remittal to the department of first instance (yes)

**Decisions cited:**

G 0001/03, G 0006/88, T 0906/10, T 1616/09, T 1869/11

**Catchword:**



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Case Number: T 1823/11 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 20 May 2015**

**Appellant:**  
(Applicant)

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**Decision under appeal:**

**Decision of the Examining Division of the  
European Patent Office posted on 17 February  
2011 refusing European patent application No.  
04004834.0 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman**

J. Riolo

**Members:**

A. Usuelli

D. T. Keeling

## Summary of Facts and Submissions

- I. The appeal of the applicant (appellant) lies from the decision of the examining division refusing European patent application No. 04004834.0.
- II. The documents cited during the examination proceedings include the following:
- D2: WO 01/17369  
D3: WO 02/094221  
D5: US 4,217,341  
D6: *Biochimica et Biophysica Acta*, 1343 (1997), 31-40  
D7: WO2005/094602
- III. On 11 March 2008, during the examination proceedings, the appellant submitted a set of claims comprising *inter alia* second medical use claims relating to the use of phaseolamin for the preparation of a composition for preventing teeth caries. In a communication dated 19 January 2010 the examining division objected to these claims under Article 54 EPC in view of the disclosure of document D5. The objection was based on the argument that this document implicitly disclosed a *Phaseolus vulgaris* extract containing phaseolamin and its use to inhibit adherence of cariogenic bacteria to the teeth.
- In a letter submitted on 24 May 2010 the appellant argued that since the extract disclosed in document D5 had a pH of 7.2 it could not contain phaseolamin in an active form because this enzyme exerts its activity in a pH range around pH 4.5, as disclosed in document D6.
- IV. The appellant was summoned to oral proceedings with letter of 15 October 2010. In the annex to the summons,

the examining division referred to the statement made by the appellant in its letter of 24 May 2010 according to which phaseolamin exerted its activity in a pH range around pH 4.5, and it observed that the description of the application did not contain "any indication as to the preparation and the pH of the phaseolamin". For this reason the examining division considered that the requirement of Article 83 EPC was not met.

- V. With a letter submitted on 14 December 2010, the appellant presented his arguments against the objections under Article 83 EPC and submitted a new set of claims.

Independent claims 1 and 2 read as follows:

"1. Phaseolamin for use as an anticaries agent".

"2. Compositions comprising phaseolamin for use in the prevention of teeth carie (*sic*)".

- VI. The decision of the examining division was based on the set of claims filed with letter of 14 December 2010.

In the reasons for the decision the examining division substantially repeated the arguments set out in the summons of 15 October 2010 in relation to the absence of indications as to the preparation and the pH of the phaseolamin and refused the application for non compliance with the requirements of Article 83 EPC.

- VII. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal it requested that the decision of the examining division be set aside and a patent granted on the basis of the set of claims submitted on 14 December 2010. In the

same letter the appellant requested also to be heard in oral proceedings.

In a letter dated 25 March 2015 the appellant withdrew its request for oral proceedings and asked the Board to take a decision based on the written submissions on file.

VIII. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the request submitted on 14 December 2010.

### **Reasons for the Decision**

1. *Article 123(2) EPC*

Claim 1 is a purpose-limited product claim in accordance with Article 54(5) EPC. It relates to phaseolamin for use as anticaries agent. The use of this protein as inhibitor of the conversion of starch to simple sugars, and as a consequence in the prevention of caries, finds a basis, for the purpose of Article 123(2) EPC, in paragraph [0013] of the original application.

Claim 2 has a basis in paragraph [0002] of the original application.

Claims 3 to 8 correspond to original claims 3 to 8.

In view of the above, the Board concludes that the requirements of Article 123(2) EPC are met.

2. *Article 83 EPC*

2.1 In its decision to refuse the application for non-compliance with the requirements of Article 83 EPC, the examining division pointed out two deficiencies, namely the absence of indications as to the preparation of phaseolamin and the absence of any information as to the pH conditions.

2.2 With regard to the absence of information as to the preparation of phaseolamin, the appellant explained during the examination proceedings that this protein was well known and even commercially available at the date of filing (letter of 14 December 2010).

Indeed documents D2 (see page 4, lines 8 to 25) and D3 (see example 22) indicate that phaseolamin was known before the priority date of the application. This is also confirmed in the post-published document D7 in which the protein phaseolamin is described by reference to an article published in 1992 (page 1, lines 16 to 28).

Document D2 is also evidence for the appellant's statement that phaseolamin was commercially available. This document, published nearly two years before the priority date of the present application, indicates that phaseolamin is available in two grades of purity and provides the name of a commercial source of the product (page 4, lines 18-21). From document D2 the skilled person would also derive the information that phaseolamin is a glycoprotein which inhibits alpha-amylase and can be extracted from *Phaseolus vulgaris* (page 4, lines 8 to 17). Detailed information concerning the isolation from *Phaseolus vulgaris* of proteins inhibiting alpha-amylase are furthermore disclosed in document D6 (page 32, "Material and methods").

- 2.3 From the above the Board concludes that phaseolamin was a protein sufficiently known at the filing date of the application. Thus, even in the absence of any instruction with regard to its preparation, the skilled person would have easily retrieved information with regard to its commercial availability or with regard to the methods for extracting it from *Phaseolus vulgaris*.
- 2.4 The second deficiency considered by the examining division, in relation to the assessment of sufficiency of disclosure, concerns the absence of information as to the pH of phaseolamin.

The examining division did not explain why such information would be essential to the skilled person in order to carry out the invention. In this respect the Board notes that in the submissions made during the first-instance proceedings (letter of 14 December 2010), the appellant explained that caries is caused by acid-producing bacteria which lower the pH of saliva. Phaseolamin, which exerts its activity at acidic pH, would therefore be inevitably activated by the pathogenic mechanism underlying caries formation.

The acidogenic nature of the bacteria causing caries is indeed confirmed by D5 (column 1, lines 12 to 32), while from D6 (see Figure 4) it can be seen that the alpha-amylase inhibitor extracted from *Phaseolus vulgaris* exerts its activity in acidic conditions (see also point 2.5 below). These documents support the arguments of the appellant and justify the absence of information in the application in relation to the pH at which phaseolamin is to be used.

2.5 Independently from the considerations made above, in the Board's opinion, testing phaseolamin under different conditions of acidity in order to verify in which range of pH it maintains a sufficient enzymatic activity, is an activity that would not require any undue effort. In this respect it is observed that only pH values compatible with an oral use would need to be investigated.

Moreover, documents D6 provides extensive information concerning the characterization and functional properties of the alpha-amylase inhibitor extracted from *Phaseolus vulgaris*. D6 indicates *inter alia* that the enzyme is active in a range of pH comprised between 4 and 5.5 and shows a maximum of activity at pH 4.5 (see abstract and Figure figure 4).

2.6 In the light of the considerations made in points 2.4 and 2.5 above, the Board concludes that the absence of information with regard to the pH of phaseolamin would not affect the capacity of the skilled person to carry out the invention.

2.7 Hence, the reasons adduced by the examining division to conclude that the requirements of Article 83 EPC were not met, are not tenable.

3. *Remittal of the case to the examining division (Article 111(1) EPC)*

3.1 Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of the case. The essential function of an appeal is to consider whether the



decision which has been issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is considered by the Boards in cases where a first instance department issues a decision against a party based solely upon one particular issue which is decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111(1) EPC).

The observations made above apply fully to the present case. The examining division decided that claim 1 was not patentable on the grounds of lack of sufficiency, but disregarded further essential issues concerning that grounds as well as the essential issue of inventive step, in respect of which the examining division only provided an opinion as an *obiter dictum* (see below).

Thus, the Board concludes that in the circumstances of the present case, it is necessary to remit the case to the first instance for further prosecution (Article 111(1) EPC).

- 3.2 The following observations need to be taken into consideration for the further prosecution of the examination.

- 3.2.1 In the Board's opinion to complete the assessment of the requirement of sufficiency of disclosure it is necessary in the present case to investigate also a further relevant issue.

Claim 1 is drafted as a purpose-limited product claim in accordance to Article 54(5) EPC. Hence, the technical effect of phaseolamin of being useful as an anticaries agent, is expressed in the claim.

When the technical effect is expressed in the claim, the issue as to whether this effect is indeed achieved over the whole scope of the claim is a question of sufficiency of disclosure (G0001/03, OJ 2004, 413, Reasons 2.5.2). This general approach applies in particular to claims including a therapeutic effect as a feature of the claim, such as purpose-limited product claims in accordance with Article 54(4) and 54(5) EPC or claims drafted in accordance with the "Swiss-type" format (see for instance: T906/10, Reasons 23; T1616/09, Reasons 6.2; T1869/11, Reasons 3.2.1).

Thus, in order to establish whether the requirement of sufficiency of disclosure is met it needs to be assessed whether the application discloses the potential suitability of phaseolamin to act as an anticaries agent or whether this information can be derived from the prior art.

- 3.2.2 As discussed above (see points 2.4 to 2.6), the concerns expressed by the examining division related to the question of whether the pH has an effect on the enzymatic activity of phaseolamin. However, the examining division has not addressed in its decision the issue as to whether phaseolamin is potentially suitable to be used as an anticaries agent, nor does it

appear that this question has been treated in any of the communications. Therefore, this issue will have to be considered by the examining division in the context of the assessment of the requirement of sufficiency of disclosure.

- 3.2.3 With regard to the requirement of inventive step, the examining division has expressed the opinion that the claims would not be inventive in view of the teaching of document D5. The opinion is given as an *obiter dictum*, in a paragraph with the title "Additional remarks".

In that respect, the Board wishes to make some comments in relation to the content of D5 since this document was initially considered by the examining division to affect the novelty of the claims (see III above), and in the "Additional remarks" it was considered to render them obvious.

- 3.2.4 Document D5 relates to compositions containing one or more lectins useful for inhibiting the adherence of plaque-producing bacteria to the teeth (see column 1, lines 6 to 11 and 46 to 57). The lectins are derived from the seeds of various plants including *Phaseolus vulgaris* (column 2, line 65 to column 3, line 6 and claim 1). Document D5 does not mention anywhere that the extracts of *Phaseolus vulgaris* or of any other seed may contain also phaseolamin. This protein is actually never mentioned in D5. Moreover, the document clearly identifies lectin as the active ingredient of the compositions (column 2, line 65).

Document D5 therefore does not disclose, even implicitly, the use of phaseolamin as an anticaries agent.

3.2.5 The examining division appears to have considered that an extract of *Phaseolus vulgaris* would also contain phaseolamin and that the use of this extract in accordance with the teaching of D5 would result in the use of phaseolamin in the treatment or prevention of caries.

Even assuming that the examining division was correct in concluding that an extract of *Phaseolus vulgaris* would also contain phaseolamin, none the less document D5 does not disclose the use of this protein in the treatment of caries. In this respect the Board underlines that in determining what a prior art document discloses the question to be decided is what has been made available to the public, rather than what may have been "inherent" in what has been made available (G0006/88, OJ 1990, 114, Reasons 8 to 8.2). Attaining an anticaries effect with phaseolamin is technical information which is not made available by D5, irrespective of any consideration concerning the pH. This aspect should be considered when assessing the patentability of the claims in view of this document.

**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:



S. Fabiani

J. Riolo

Decision electronically authenticated