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**Datasheet for the decision  
of 7 March 2007**

**Case Number:** T 0113/04 - 3.3.09

**Application Number:** 96201346.2

**Publication Number:** 0818152

**IPC:** A23J 1/06

**Language of the proceedings:** EN

**Title of invention:**

Processed globin products and methods for the production thereof

**Patentee:**

VEOS N.V.

**Opponent:**

Bernard S.A.

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 56, 83

**Keyword:**

"Admissibility of late filed document (no)"  
"Sufficiency of disclosure (yes)"  
"Inventive step (yes)"

**Decisions cited:**

T 1002/92

**Catchword:**

-



Case Number: T 0113/04 - 3.3.09

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.09  
of 7 March 2007

**Appellant:** Bernard S.A.  
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**Representative:** Maillet, Alain  
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**Respondent:** VEOS N.V.  
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**Representative:** Leherte, Georges M.L.M.  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
20 November 2003 concerning maintenance of  
European patent No. 0818152 in amended form.

**Composition of the Board:**

**Chairman:** W. Ehrenreich  
**Members:** N. Perakis  
K. Garnett

## Summary of Facts and Submissions

I. Mention of the grant of European patent No 0 818 152 in respect of European patent application No 96201346.2 in the name of VEOS N.V., which had been filed on 15 May 1996, was announced on 14 April 1999 (Bulletin 1999/15). The patent, entitled "Processed globin products and methods for the production thereof", was granted with thirteen claims. Independent product Claims 1, 12 and 13, and method Claim 8 read as follows:

"1. Protein product from a starting material selected from blood, blood-protein containing raw materials and hemoglobin, having an iso-electric point at a pH value below 5,5."

"8. A method for the production of a protein product from a starting material selected from blood, blood-protein containing raw materials and hemoglobin, comprising the steps of treating the starting material under alkaline conditions and treating the resulting product under oxidizing conditions, characterised in that

- in the alkaline treatment step the pH is brought above 12, while maintaining the temperature below 50°C,
- in the oxidizing treatment step the pH is kept below 12 and the temperature is maintained below 50°C."

"12. Edible product, characterised in that it comprises a protein product according to any one of claims 1-7."

"13. Edible product, characterised in that it comprises a protein product obtained according to any one of claims 8-11."

Claims 2 to 7 were dependent either directly or indirectly on Claim 1. Claims 9 to 11 were dependent either directly or indirectly on Claim 8.

II. A Notice of Opposition was filed against the patent by Bernard SA on 11 January 2000. The Opponent requested the revocation of the patent in its full scope, relying on Article 100(a), 100(b) and 100(c) EPC.

III. The Opposition was *inter alia* supported by the following documents:

D2: US-A-4 180 592

D3: US-A-5 151 500

D5: EP-A-0 460 219

D6: EP-A-0 397 890

D7: Perutz M F "Mechanism of denaturation of haemoglobin by alkali", Nature, 1974, 247, pp 341-344

IV. By its interlocutory decision orally announced on 6 May 2003 and issued in writing on 20 November 2003 the Opposition Division held that the grounds for opposition raised by the Opponent did not prejudice the maintenance of the patent in amended form.

This decision was based on an amended set of Claims 1 to 11 and a description adapted thereto submitted by the Patent Proprietor at the oral proceedings of 6 May 2003. Independent Claims 1 and 7 read as follows:

"1. Processed globin protein product having an iso-electric point at a pH value below 5,5 and an iron content of less than 1000 ppm, resulting from a starting material selected from blood, blood-protein containing raw materials and hemoglobin."

"7. A method for the production of a globin protein product from a starting material selected from blood, blood-protein containing raw materials and hemoglobin having an iso-electric point at a pH value below 5,5 and an iron content of less than 1000 ppm, comprising the steps of treating the starting material under alkaline conditions and treating the resulting product under oxidizing conditions, characterised in that

- in the alkaline treatment step the pH is brought above 12, while maintaining the temperature below 50°C,
- in the oxidizing treatment step the pH is kept below 12 and the temperature is maintained below 50°C,
- in a further step (an) iron containing component(s) is/are removed."

The Opposition Division held in the appealed decision that the patent fulfilled the requirements of Article 83 EPC as it disclosed the invention for which protection was sought in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

It also held that the claimed subject-matter involved an inventive step. The reason was that the claimed protein fraction with the specific solubility characteristics and the claimed method for its

production were neither envisaged nor derivable from the cited state of the art. Furthermore, the claimed protein overcame the drawback of the low solubility of the known globin protein products in the pH range of 6-7.

- V. On 20 January 2004 the Opponent (Appellant) lodged and 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 29 March 2004 the Appellant requested the revocation of the patent in its entirety on the grounds of insufficient disclosure of the claimed invention and lack of inventive step of the claimed subject-matter.

The Appellant's objections were mainly based on documents D2, D3, D6 and D7 and on the following documents cited for the first time in the appeal proceedings:

D9: WPI/DERWENT abstract of JP-A-63044599

D10: Srinivasan Damoradan "Interrelationship of Molecular and Functional Properties of Food Proteins", Food Proteins, Chapter 3, Kinsella J.E. and Soucie W.G., 1989, pp 21, 24, 25, 30, 31, 49-51

D11: Lehninger A.L., "Biochimie", Flammarion, 1972, pp 130-131.

Documents D10 and D11 constitute prior art illustrating the general technical knowledge of the skilled person as regards the relationship between the solubility of proteins and their iso-electric point.

On 5 March 2007 the Appellant informed the Board that it would not attend the oral proceedings scheduled to take place on 7 March 2007.

VI. With a letter dated 19 August 2004 the Patent Proprietor (Respondent) contested the admissibility in particular of the late filed document D9 and argued that D9 did not appear to *prima facie* constitute more convincing prior art than the documents already discussed during the opposition procedure. The Respondent requested, in the event that D9 was admitted, the necessary time to order a full translation of the document and to undertake comparative tests based on the actual disclosure of the full document. It also contested the arguments of the Appellant with respect to insufficiency of disclosure and the lack of inventive step.

VII. On 7 March 2007 oral proceedings were held before the Board.

VIII. The arguments presented by the Appellant in its written submissions may be summarized as follows:

With regard to the insufficiency of disclosure

- The subject-matter of Claim 1 covered products which were not manufactured following the method of Claim 7 and which were thus not sufficiently disclosed.
- The patent specification contained no disclosure or experimental result which proved that the products

obtained by the method of Claim 7 had an iso-electric point at a pH below 5.5.

- There was doubt whether the products obtained from the method of Claim 7 had an iso-electric point at a pH below 5.5.
- Since the claimed method was only slightly different from that of D2, which disclosed that the globin product was a coagulum, the product obtained from the claimed method should also not be different from that obtained via D2.
- Since the iso-electric point is influenced by the number of the acid residues compared to the number of the base residues in the protein (D10 and D11) and since the content of the relevant amino acids in the structures of the hemoglobin and the globin protein product of Claim 7 were practically identical (see patent in suit: table), the iso-electric point of the claimed product would not have a pH below 5.5 if that of the hemoglobin was of the order of 6.8, as was reported to be the case (D11: table 7-2).
- There was doubt whether the pH of minimum solubility of the globin protein product of Claim 7 should be considered as its iso-electric point.
- The patent in suit did not disclose any experimental protocol for the direct measurement of the iso-electric point.
- The experimental evidence filed by the Respondent in the opposition proceedings was not part of the disclosure of the impugned patent and should not be discussed at this stage of the appeal proceedings.

With regard to the lack of inventive step



- The processed globin protein product of Claim 1 lacked an inventive step in view of the obvious combination of the state of the art mentioned in the patent specification (page 1, line 40) with D3.
- The technical problem solved was to find a globin protein product which showed excellent solubility at the pH of food products, which varied between 5,5 and 9, the globin protein product being thus easily mixed with them.
- A globin protein product with an iso-electric point at a pH below 5.5 was obvious in view of D3.
- The method of Claim 7 lacked an inventive step over the obvious combination of D2, the closest state of the art, with D3 and D6/D7.
- The distinguishing features of the subject-matter of Claim 7 over D2 were the pH value of the alkali treatment and the removal of the iron-containing components.
- Each distinguishing feature solved a distinct problem. The first problem was the optimisation of the protein denaturation in order to obtain a globin protein product with an isoelectric point at a pH value of below 5.5, the second problem was the reduction of the iron content.
- The solution of the first problem was obvious in view of D6 or D7, whereas the solution of the second problem was obvious in view of D3.

IX. The arguments presented by the Respondent in its written submissions and at the oral proceedings held on 7 March 2007 may be summarized as follows:

With regard to the insufficiency of the disclosure

- The issue of insufficiency of disclosure based on the definition of the iso-electric point as a characterising feature for protein products was discussed *in extenso* before the opposition division, to which reference was made.
- The product defined in Claim 1 was properly disclosed as such, be it only through the preparation example, and this product was clearly distinguished by its claimed features from any previously known product according to the state of the art.
- The additional technical evidence submitted on 17 March 2003 should be taken into consideration since it was filed in response to specific statements from the Opponent (Appellant) and since it merely related to measurements carried out on products obtained on the basis of the disclosure of the patent in suit. It constituted information available to any skilled person in the art considering the disclosure of the patent.
- The solubility/iso-electric points of protein products were mainly determined by the three dimensional structure of the polypeptide chain (D10: page 30, second paragraph from the bottom; page 31, first paragraph) and could not be predicted on the exclusive basis of the acid/base residues in the polypeptide chain.

With regard to the lack of inventive step

- None of the cited documents involved anything other than similar processes to prepare a globin product, in which the hemoglobin underwent a denaturation step and a heme removal/oxidation step.
- D2 was the closest state of the art for both independent Claims 1 and 7.
- The product according to Claim 1 of the patent in suit was soluble at about neutral pH as its iso-electric point lay at a pH below 5.5, as distinct from the product of D2 which at that pH was a coagulum.
- The state of the art did not provide the skilled person with information enabling the reduction of the iso-electric point of globin protein to a pH below 5.5.
- The method of Claim 7 involved an inventive step. It differed from that disclosed in D2 in the conditions used for the alkali treatment and in the removal of the iron-containing components. Since the skilled person was aware that the modification of a protein was a subtle process, the distinguishing features of the alkali treatment were not obvious. The Appellant's assertion that a skilled person in the art was not led away from using a higher pH was an *a posteriori* reasoning with respect to the totally unrelated documents D6 and D7.

X. The Appellant requested that the decision under appeal be set aside and that the European patent be revoked.

XI. The Respondent requested that:

1. the appeal be dismissed and the patent be maintained in the form ordered by the Opposition Division;
2. the documents D9, D10 and D11 be not admitted into the proceedings.

### **Reasons for the Decision**

1. The appeal is admissible.
2. Admissibility of D9

The Board, following long established case law (see T 1002/92, OJ 1995, 605) with regard to the late filing of documents, decided not to admit document D9 into the procedure because it did not satisfy the criterion of *prima facie* relevance required to support the lack of inventive step objection raised against the subject-matter of independent Claims 1 and 7.

This document, which is an abstract of a Japanese patent application, relates to food additives with high solubility in water. The additives were obtained by a reforming method of globin protein which comprised an alkali treatment step of a globin protein at a pH of 11.8 followed by an oxidation treatment. However, the limited content of the abstract, relating to a patent application drafted in a non-EPO official language and for which no translation has been submitted, does not appear *prima facie* to constitute more convincing prior art against the claimed invention than the other

documents submitted by the Appellant. Even the Appellant, who cited this document, came to this conclusion in the Statement of Grounds of Appeal filed on 29 March 2004 (page 4, last paragraph of item 1.2) as it mentioned that from the analysis of documents D9, D2 and D3, the claimed invention was novel and that it was document D2 which was the closest state of the art.

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

3.1 The Board acknowledges that the patent in suit fulfils the requirements of Article 83 EPC.

3.2 The Board notices that the patent specification (example 1, paragraphs [0038] to [0040]) provides adequate information in respect of at least one method for the preparation of the claimed globin protein products. The Board accepts that on the basis of this information, which has not been contested by the Appellant, the skilled person can perform the invention within the whole range claimed, ie is able to prepare globin protein products having not only an iron content of less than 1000 ppm (example 2 discloses an iron content of less than 500 ppm) but also an iso-electric point at a pH value below 5.5.

3.3 The Board acknowledges that this has been confirmed by the additional technical evidence submitted by the Respondent with its letter dated 17 March 2003 in the course of the opposition procedure. As the Respondent explained, the experiments, the subject of this evidence, were carried out following the preferred process conditions set forth at page 3, line 49 to page 4, line 29, of the patent in suit and led to the

drawing of the solubility curve of the processed globin protein product as a function of the pH (see the letter of 17 March 2003, figures on pages 3 and 4). Since the minimum of each of the obtained curves corresponded to pH values of 4.6, 4.6 and 5, which is usually considered to be the iso-electric point of the protein (patent in suit: page, line 42), the additional technical evidence demonstrated that the information in the patent enables the preparation of processed globin protein products with an iso-electric point at a pH below 5.5.

- 3.4 The Board thus acknowledges that the patent in suit fulfils the requirements of Article 83 in that it discloses the invention for which protection is sought in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- 3.5 The Board does not concur with the Appellant when it argued that the claimed invention was also insufficiently disclosed on the ground that the scope of Claim 1 comprised globin protein products prepared by a method different from that of Claim 7. In the circumstances addressed above the non-availability of further variants of the preparation of such products is immaterial to the issue of sufficiency.
- 3.6 The Board further disagrees with the Appellant when it argued that the claimed invention was insufficiently disclosed because of the lack of experimental evidence with regard to a globin protein product having an iso-electric point at a pH below 5.5. Although it is not contested that such values are not provided in the patent specification, the additional technical evidence

submitted with letter dated 17 March 2003, which was not disputed and which comprised three experiments carried out on the basis of the information provided in the opposed patent, demonstrated that the globin protein products obtained thereby necessarily fulfilled the requirement of an iso-electric point at a pH below 5.5. In the absence of contradictory evidence, the Board considers that these values were the direct result of the implementation of the disclosed preparation method. Furthermore, the Board has not identified in the experimental protocol of this additional evidence the use of any technical feature which was not disclosed in the patent in suit nor has the Appellant raised any objection in this respect.

The Board remarks that this additional technical evidence, which was filed as a reply to the objection of insufficient disclosure raised by the Appellant, could not have been ignored, contrary to the argument of the Appellant, since it is an essential piece of proof showing that a globin protein product with an iso-electric point at a pH below 5.5 is the inevitable product of the disclosed preparation method.

- 3.7 Furthermore, the Board does not accept the argument of the Appellant that the claimed processed globin protein product having an amino acid content similar to that of the hemoglobin (patent in suit: table I) should in the light of D11 (table 7-2) have an iso-electric point at a pH of the order of 6.8. The Board remarks that the Appellant's allegations are not based on technical evidence contradicting the disclosure of the patent that the iso-electric point of the claimed product has a pH below 5.5. Furthermore, the technical evidence

filed by the Respondent with its letter dated 31 May 2001 (annex 1) shows that even if the claimed globin protein (VEOS) comprises the same amino acids as the hemoglobin (Sato), these proteins are different in respect of the amounts of these amino acids, in particular in respect of the basic/acidic amino acids such as glutamic acid, aspartic acid and lysine which have an impact on the iso-electric point. Additionally, the Board accepts the argument of the Respondent based on D10 (page 30, second paragraph from the bottom; page 31, first paragraph) that even the amino acid profile of a protein is not sufficient to allow the evaluation of its solubility or, by extension, its iso-electric point. The reason is that this depends on the amino acid groups available having regard to the conformation of the protein and of the formation of aggregates, which makes it practically impossible to calculate the solubility, and thus the iso-electric point, of a given protein exclusively from its amino-acid profile.

- 3.8 Likewise, the Board is not persuaded by the argument of the Appellant based on D10 (page 31, last paragraph) that the minimum of the solubility curve of the globin protein product as a function of pH does not correspond to its iso-electric point. The reason is that this passage of D10 refers to two proteins, different from that claimed, which are either soluble or insoluble at the pH value of their iso-electric point. This reference does not enable one to draw the conclusion that the processed globin protein product according to the invention will deviate from the usually expected situation of insolubility at the pH value of the iso-electric point, which is disclosed in the patent in



suit (page 2, line 42) and D5 (claims 8 and 9) and does not discharge the Appellant from the need to provide technical evidence in order to persuade the Board of the correctness of its assertions.

- 3.9 Finally, the Board does not agree with the Appellant's argument that the patent in suit lacks sufficiency of disclosure because it does not provide an experimental protocol for the direct measurement of the iso-electric point. The Board considers that on the basis of the content of the patent in suit, which is supported by the additional evidence filed on 17 March 2003, the skilled person is able to measure the iso-electric point of the processed globin protein products. Whether there might exist other, direct methods for the measurement of the iso-electric point is irrelevant for the issue of sufficiency as long as the Appellant has not proved that there is disagreement between the measured values.

4. Inventive step (*Article 56 EPC*)

4.1 Closest state of the art

The Board in agreement with the parties considers D2 to represent the closest state of the art of the claimed subject-matter. This document (column 1, line 68; column 2, lines 8-13 and 38-43; column 6, lines 6-12), which corresponds to the art mentioned in general terms in the patent in suit (page 1, lines 39-40), relates to processed blood protein products used as food products which are a coagulum at neutral pH. These products are prepared according to a method which includes an alkali treatment of blood up to a pH of 11.5, followed by a pH

reversal back to the range 6-8 and finally an oxidation treatment with hydrogen peroxide. The disclosed preparation method is carried out at ambient temperature.

#### 4.2 Claim 1

The subject-matter of Claim 1 of the patent in suit differs from the disclosure of D2 in that:

- (i) the processed globin protein product has an iso-electric point at a pH value below 5.5 (D2 has an iso-electric point at about neutral pH as it is a coagulum, ie not soluble, at this pH range), and
- (ii) it has an iron content of less than 1000 ppm as the result of the removal of the iron containing component(s) (although D2 does not provide for any such content, it is, however, expected to be higher than that claimed because D2 does not involve any iron containing component(s) removal step).

#### 4.3 The technical problem

The patent in suit (paragraphs [0009], [0011] and [0012]) states that the globin protein products known in the art have taste, odour and colour drawbacks due to the iron/heme fraction in the products. Moreover, they have iso-electric points in the range of pH 6 to 7, at which their solubility is very low. The low solubility at that pH affects their application possibilities in food products which usually have a pH

value ranging from 5 to 9, such as processed meat products which have a pH value ranging from 5,5 to 7.

Therefore the technical problem set out in the opposed patent is the provision of a globin protein product which is bland, colourless and has a good solubility in food products with a pH value of at least 5.5.

The various aspects of this technical problem are solved by the above mentioned distinguishing features. With regard to the first distinguishing feature, any unpleasant taste, odour and colour is removed by the reduction of the iron content. With regard to the second distinguishing feature, satisfactory solubility at the pH range above 5.5 is ensured by keeping the iso-electric point at pH values below 5.5.

The experimental part of the patent in suit (paragraph [0039]), complemented by the additional technical evidence filed on 17 March 2003, shows that the claimed processed globin protein products solve this technical problem.

The Board therefore accepts that the above technical problem has effectively been solved by the subject-matter of Claim 1.

#### 4.4 Obviousness

Furthermore, the Board notes that the Appellant has not submitted any prior art disclosure relating to processed protein products having an iso-electric point at a pH value below 5.5. Nor does the cited state of the art suggest how to lower the iso-electric point of

proteins in general, or globin proteins in particular, to pH values below 5.5. Document D2, which discloses an alkali treatment at the maximum pH of 11.5 (column 6, line 7), does not indicate that this measure leads to an iso-electric point of the processed globin protein at a pH of below 5.5.

Therefore the skilled person departing from the disclosure of D2 and facing the technical problem of providing a protein product with satisfactory solubility at a pH above 5.5 gets no help from the state of the art in this respect, since even if it is expected that a product with an iso-electric point of below 5.5 will provide a satisfactory solubility at a pH above this value, the state of the art does not provide any information as to how such products could be obtained. The Board is persuaded by the Respondent's argument that it is very difficult to predict the properties of proteins, such as their solubility/iso-electric point, since the modification of proteins is a very subtle field. On the basis of the facts submitted to the Board, it concludes that the solution of the above identified technical problem is not obvious and that the subject-matter of Claim 1 involves an inventive step.

The fact that the reduction of the iron content might be obvious in view of D3 (column 5, lines 21-27; column 8, lines 1-3) is irrelevant to the obviousness/non-obviousness of the iso-electric point of a globin protein at a pH below 5.5. As the Appellant correctly explained in its letter dated 29 March 2004, the iron content and the iso-electric point relate to two distinct issues.

4.5 Documents D3, D6 and D7 are irrelevant with regard to the issue of inventive step of the claimed product. D3, although relating to heme-free blood protein products, discloses that such products have a solubility minimum, and thus an iso-electric point, at a pH between 6 and 7 (figure 4; column 5, lines 38-49).

D6 relates to a process for purifying blood plasma, which is different from the hemoglobin fraction of blood dealt with in the claimed invention, and the skilled person would not have considered it. But even if he had done so, he would not have found any indication in it relating to the reduction of the iso-electric point of blood proteins because D6 concerns exclusively the reduction of odorous and coloured substances in plasma. The disclosure of hemoglobin modification at a pH between 9 to 13 (page 3, lines 25-28) is considered as an accidental disclosure since it is not disclosed to have any impact on the solubility of the denaturated protein.

D7 discloses the denaturation of hemoglobin by alkali at pH values from 10 to 13, without, however, disclosure of any influence on its solubility or its iso-electric point.

#### 4.6 Conclusion

In the circumstances, the processed globin protein product of Claim 1 involves an inventive step.

The same applies to the method claim according to independent Claim 7 because the method steps defined in

Claim 7 lead to a processed globin protein product falling within the scope of Claim 1.

The same applies also to the edible products according to independent Claims 10 and 11 because they comprise the processed globin protein product of Claim 1.

As a corollary, the subject-matter of dependent Claims 2 to 6, 8 and 9, which relate to specific embodiments of the subject-matter of Claims 1 and 7, also involve an inventive step.

5. Hence, the grounds of opposition under Article 100(a) and (b) EPC do not prejudice the maintenance of the patent in the amended form on the basis of Claims 1 to 11 underlying the decision of the Opposition Division.

**Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:

C. Moser

W. Ehrenreich