PATENTAMTS

OFFICE

BESCHWERDEKAMMERN BOARDS OF APPEAL OF CHAMBRES DE RECOURS DES EUROPÄISCHEN THE EUROPEAN PATENT DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:

(A) [] Publication in OJ

(B) [] To Chairmen and Members

(C) [X] To Chairmen

(D) [] No distribution

Datasheet for the decision of 6 June 2013

T 0360/09 - 3.3.04 Case Number:

Application Number: 03767649.1

Publication Number: 1565207

IPC: A61K 38/38

Language of the proceedings: EN

Title of invention:

Prekallikrein depleted plasma derived albumin fraction

Patent Proprietor:

Octapharma AG

Opponents:

NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) CSL Behring GmbH Baxter Aktiengesellschaft Stichting Sanquin Bloedvoorziening Biotest AG

Headword:

Albumin fraction/OCTAPHARMA

Relevant legal provisions:

EPC Art. 108, third sentence EPC R. 99(2)

Keyword:

"Admissibility of the appeal (no) - insufficient substantiation"

Decisions cited:

T 0150/82, T 0717/01, T 0934/02, T 1045/02

Catchword:

See points 1.1-10.2



Europäisches Patentamt

European Patent Office

Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 0360/09 - 3.3.04

DECISION

of the Technical Board of Appeal 3.3.04 of 6 June 2013

Appellant: Octapharma AG (Patent Proprietor) Seidenstraße 2

CH-8853 Lachen (CH)

Representative: Meyers, Hans-Wilhelm

von Kreisler Selting Werner

Deichmannhaus am Dom Bahnhofsvorplatz 1 D-50667 Köln (DE)

Respondent I: NHS Blood and Transplant (Gwaed a

(Opponent 1) Thrawsblaniadau'r GIG)

Oak House Reeds Crescent

Watford WD24 4QN (GB)

Representative: Beacham, Annabel Rose and Rigby, Barbara

Nicole Dehns

St Bride's House 10 Salisbury Square London EC4Y 8JD (GB)

Respondent II: CSL Behring GmbH

(Opponent 2) Emil-von-Behring-Straße 76

D-35041 Marburg (DE)

Representative: Hauser, Hans-Peter

ZLB Behring GmbH

Intellectual Property/Legal Emil-von-Behring-Straße 76 D-35041 Marburg (DE)

Respondent III: Baxter Aktiengesellschaft

(Opponent 3) Industriestraße 67

A-1221 Wien (AT)

Representative: Alge, Daniel

Sonn & Partner Patentanwälte

Riemergasse 14 A-1010 Wien (AT) Respondent IV: Stichting Sanquin Bloedvoorziening

(Opponent 4) Plesmanlaan 125

NL-1066 CX Amsterdam (NL)

Representative: Tepper, Annemiek Delina

Vereenigde

Johan de Wittlaan 7

NL-2517 JR Den Haag (NL)

Respondent V: Biotest AG

(Opponent 5) Landsteinerstraße 5

D-63303 Dreieich (DE)

Representative: Kalhammer, Georg

Lederer & Keller Patentanwälte Unsöldstraße 2

D-80538 München (DE)

Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted 15 December 2008 revoking European patent No. 1565207 pursuant

to Article 102(3)(b) EPC.

Composition of the Board:

Chairman: C. Rennie-Smith

Members: G. Alt

R. Morawetz

- 1 - T 0360/09

Summary of facts and submissions

- I. This is an appeal by the patent proprietor (hereinafter "appellant") against the decision of the opposition division to revoke the European patent No. 1 565 207.

 The patent has the title "Prekallikrein depleted plasma derived albumin fraction".
- II. The following documents are cited in the present decision:
 - El British Journal of Anaesthesia, vol. 86, no. 5 (2000), pages 887-895, Matejschuk, P. et al.
 - E7 Transfusion, vol. 21, no. 3 (1991), pages 320-324, Marley, P.B. and Gilbo, C.M.
 - E9 Brazilian Journal of Medical and Biological Research, vol. 31 (1998), pages 1383-1388, Tanaka, K. et al.
- III. The decision under appeal dealt with a main request corresponding to the five claims as granted and with two auxiliary requests comprising four and two claims, respectively. Claims 1 to 3 of the main request and claims 1 and 2 of the two auxiliary requests were directed to a "Method of manufacturing an albumin enriched fraction having a reduced prekallikrein activator (PKA) content". Claims 4 and 5 of the main request and claims 3 and 4 of auxiliary request I were directed to products. Auxiliary request II had no product claims.

- 2 - T 0360/09

- IV. Claims 1 to 5 of the main request read:
 - "1. A method of manufacturing an albumin enriched fraction having a reduced prekallikrein activator (PKA) content comprising the steps of:
 - (a) reconstitution of paste V (Cohn fraction)
 - (b) performing a concentration step of the fraction obtained in step (a),
 - (c) heating the fraction obtained in step (b) in a range of from 50°C to 70°C for a sufficient time to pasteurise the fraction,
 - (d) filling of the obtained fraction for use, and
 - (e) performing an incubation step under the following conditions for 10 days at 30-32°C or 4 weeks at 20-25°C.
 - 2. The method of claim 1 wherein after filling a second pasteurization step is performed.
 - 3. The method of any one of the claims 1 to 2 wherein the pasteurization is performed for a time period of from at least 9 h at a temperature of 58 to 65°C.
 - 4. An albumin containing fraction having a reduced prekallikrein activator (PKA) [sic] obtainable according to the method of at least one of the claims 1 to 3.
 - 5. The albumin of claim 4 having a PKA content of less than 12 IU/ml, preferably 10 IU/ml, wherein the PKA is determined according to European Pharmacopeia, Fourth Edition."

- 3 - T 0360/09

- V. Claims 1 to 4 of auxiliary request I read:
 - "1. A method of manufacturing an albumin enriched fraction having a reduced prekallikrein activator (PKA) content consisting of the steps:
 - (a) reconstitution of paste V (Cohn fraction),
 - (b) performing a concentration step of the fraction obtained in step (a),
 - (c) heating the fraction obtained in step (b) in a range of from 50°C to 70°C for a sufficient time to pasteurise the fraction,
 - (d) filling of the obtained fraction for use, and
 - (e) a second pasteurization step is performed,
 - (f) performing an incubation step under the following conditions for 10 days at $30-32^{\circ}\text{C}$ or 4 weeks at $20-25^{\circ}\text{C}$.
 - 2. The method of any one of the claims 1 to 2 wherein the pasteurisation is performed for a time period of from at least 9 h at a temperature of 58 to 65°C.
 - 3. An albumin containing fraction having a reduced prekallikrein activator (PKA) [sic] obtainable according to the method of claim 1 and wherein the pasteurisation of step (e) of claim 1 is performed for a time period of from at least 9 h at a temperature of 58 to 65°C.
 - 4. The albumin of claim 3 having a PKA content of less than 12 IU/ml, preferably 10 IU/ml, wherein the PKA is determined according to European Pharmacopeia, Fourth Edition."

- 4 - T 0360/09

Auxiliary request II was identical to
Auxiliary request I with the exception that product
claims 3 and 4 were deleted.

- VI. The opposition division refused the main request because its claim 1 contained subject-matter extending beyond the content of the application as filed (Article 100(c) EPC) and because the subject-matter of its claim 4 lacked novelty in view of the disclosure in documents E7 or E9 (Article 100(a) EPC in combination with Article 54 EPC). The two auxiliary requests were rejected because they comprised claims containing subject-matter extending beyond the application as filed thus violating the requirements of Article 123(2) EPC.
- VII. As to the finding of lack of novelty of claim 4 of the main request, the opposition division reasoned as follows in point 2.2 of the decision under appeal:

"Concerning the product claim of the main request it should be kept in mind that a product characterized by a process has to be novel and inventive on its own regardless on how it is produced. Subject-matter of claim 4 as a product is only characterised to be an albumin composition with reduced PKA content. Any albumin product with a PKA lower then normal will be pertinent for novelty. Thus it is first necessary to know what is a normal PKA content for the skilled person. E2 and E3 (European pharmacopoeia) which are not cited to be combined with other documents but as evidence for the general knowledge of the skilled person disclose that albumin solutions for pharmaceutical use seem to be acceptable up to a PKA

- 5 - T 0360/09

value of 35 I.U./ml. The albumins produced by the methods taught in E7 or in E9 obviously lead to a PKA activity even less then 10 I.U./ml, the preferred value in the contested patent. Thus subject-matter of claim 4 is not novel over the prior art. Consequently, the patent cannot be maintained unamended."

VIII. In its notice of appeal the appellant requested:

"Es wird beantragt, die Entscheidung der Einspruchsabteilung vom 15. Dezember 2008 aufzuheben und die Einsprüche zurückzuweisen."

IX. With its statement of grounds of appeal the appellant filed a new main and auxiliary request both containing one - amended - claim to a method and two - amended claims to products.

Claims 1 to 3 of the main request read:

- "1. A method of manufacturing an albumin enriched fraction having a reduced prekallikrein activator (PKA) content consisting of the steps:
- (a) reconstitution of paste V (Cohn fraction),
- (b) performing a concentration step of the fraction obtained in step (a),
- (c) addition of stabilizers to the concentrate obtained in step (b) and adjustment of pH and sodium content,
- (d) heating the fraction obtained in step (c) for a time period of from at least 9 h at a temperature of 58 to 65°C to pasteurise the fraction,
- (e) filling of the obtained fraction for use, and
- (f) a second pasteurisation step is performed,

- 6 - T 0360/09

- (g) performing an incubation step under the following conditions for 10 days at $30-32^{\circ}\text{C}$ or 4 weeks at $20-25^{\circ}\text{C}$.
- 2. An albumin containing fraction having a reduced prekallikrein activator (PKA) [sic] obtainable according to the method of claim 1.
- 3. The albumin of claim 2 having a PKA content of less than 12 IU/ml, preferably 10 IU/ml, wherein the PKA is determined according to European Pharmacopeia, Fourth Edition."
- X. Claims 1 to 3 of the auxiliary request read:
 - "1. A method of manufacturing an albumin enriched fraction having a reduced prekallikrein activator (PKA) content consisting of the steps:
 - (a) reconstitution of paste V (Cohn fraction),
 - (b) if necessary, a pH adjustment has to be performed, the pH should be in the range of 7.2-7.6,
 - (c) an ultrafiltration is performed followed by diafiltration and another ultrafiltration for concentration of the protein,
 - (d) stabilizers are added which is followed by a further pH adjustment in a range of 6.7 to 7.3 and an adjustment of sodium content,
 - (e) heating the fraction obtained in step (d) for a time period of from at least 9h at a temperature of 58 to 65°C to pasteurize the fraction,
 - (f) this step is followed by a sterile filtration,
 - (g) filling of the obtained fraction for use, and
 - (h) a second pasteurisation step is performed,

- 7 - T 0360/09

- (i) performing an incubation step under the following conditions for 10 days at $30-32^{\circ}\text{C}$ or 4 weeks at $20-25^{\circ}\text{C}$.
- 2. An albumin containing fraction having a reduced prekallikrein activator (PKA) [sic] obtainable according to the method of claim 1.
- 3. The albumin of claim 2 having a PKA content of less than 12 IU/ml, preferably 10 IU/ml, wherein the PKA is determined according to European Pharmacopeia, Fourth Edition."
- XI. In its statement of grounds of appeal the appellant discussed the reasons in the decision under appeal for rejecting the method claims as unallowable pursuant to Article 123(2) EPC and explained in detail where the basis in the application as filed was found for the amended method claims.

This section of the statement ends with the sentence:

"Der Gegenstand des Haupt- und Hilfsantrages I ist ursprünglich offenbart und verstößt nicht gegen Art. 123(2) EPÜ."

XII. The above-mentioned section is directly followed by two sections, one with the title "Neuheit" and the other with the title "Erfinderische Tätigkeit". The entire reasoning on novelty and inventive step reads as follows:

- 8 - T 0360/09

"Neuheit

Der Gegenstand des Hauptantrages ist auch neu, da die in El genannten Verfahren entweder chromatographische Schritte ausüben, die nicht Gegenstand des erfindungsgemäßen Verfahrens sind, oder es werden nicht zwei Pasteurisierungen durchgeführt. Auch die anderen Entgegenhaltungen nehmen den Gegenstand der Ansprüche des Hauptantrages nicht vorweg.

Erfinderische Tätigkeit

Der Gegenstand des Hauptantrages beruht auch auf einer erfinderischen Tätigkeit. Es ist jedenfalls nicht ersichtlich, warum der Fachmann, ausgehend von irgendeinem Dokument des Standes der Technik, die erfindungsgemäß beanspruchten Merkmale wie im Anspruch 1 geschehen ausgewählt und zusammengestellt hätte um die vorteilhaften Eigenschaften des durch das erfindungsgemäße Verfahren erzielbaren Produktes zu erreichen.

Auch das Produkt, das sich aus dem erfindungsgemäßen Verfahren ergibt ist neu und erfinderisch, da es nicht nahegelegen hat."

Then in the following last section of the statement of grounds of appeal the appellant requests the remittal of the case to the opposition division:

"Da die Einspruchsabteilung keine Gelegenheit hatte, zur Frage der Artikel 54 und 56 EPÜ Stellung zu nehmen und einen Instanzenverlust zu vermeiden, wird beantragt - 9 - T 0360/09

zur Feststellung dieser Frage die Angelegenheit and die Einspruchsabteilung zurück zu verweisen."

- XIII. Opponents 01, 03, 04 and 05 (hereinafter "respondents") filed replies to the appellant's statement of grounds of appeal.
- XIV. In a communication dated 7 February 2013 the parties were summoned to oral proceedings to take place on 6 June 2013.
- XV. In a communication dated 8 May 2013 the board informed the parties of its preliminary view on some issues, inter alia in points 6 to 13 of the communication that the appeal was likely to be held inadmissible due to insufficient substantiation. The board announced that the parties would be heard at the oral proceedings on this issue.
- XVI. In reply the appellant commented *inter alia* on the board's view on the admissibility of the appeal.

In a further letter the appellant informed the board inter alia that it would not attend the oral proceedings.

XVII. Oral proceedings took place on 6 June 2013. All parties were represented except - as announced - the appellant.

The parties were heard *inter alia* on the issue of the admissibility of the appeal.

- 10 - T 0360/09

The parties' requests at the end of the oral proceedings were as follows:

The appellant requested in writing that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of the main request filed with the statement of grounds of appeal or one of the auxiliary requests 1 to 3 filed with its letter of 28 May 2013.

The respondents I to V requested that the appeal be dismissed.

At the end of the oral proceedings the board gave its decision that the appeal was rejected as inadmissible.

XVIII. The appellant's arguments submitted in writing and regarding the admissibility of the appeal may be summarized as follows:

The two requests filed with the statement of grounds of appeal were based on auxiliary request I before the opposition division. This request had been rejected only for containing subject-matter extending beyond the content of the application as filed, i.e. the novelty of the product claims had not been considered by the opposition division. The main request before the opposition division, which was refused for lack of novelty, was not maintained on appeal, so it was not necessary to discuss novelty in relation to the requests now filed.

- 11 - T 0360/09

It went against the fundamental principle of procedural economy if an appellant had to argue on an issue which had not been considered by the opposition division with regard to the claims at stake, see for example decision T 934/02.

Moreover, for the same reason it would be premature for the board of appeal to discuss the novelty of the product claims.

Thus, the only issue of the appeal procedure was Article 123(2) EPC and this issue had been sufficiently substantiated in the statement of grounds of appeal.

XIX. The respondent's arguments submitted at the oral proceedings regarding the admissibility of the appeal may be summarized as follows:

It was the appellant's intention in this case to file an appeal against the entire decision of the opposition division. This could be seen firstly, from its request in the notice of appeal - it was requested "die Entscheidung der Einspruchsabteilung vom 15. Dezember 2008 aufzuheben" (emphasis added) - and secondly, by the inclusion of product claims in both of the requests filed with the statement of the grounds of appeal. Thus, added-matter of the method claims and the novelty of the product claims were issues in the appeal.

The argumentation of the opposition division regarding lack of novelty of the product claims was detailed and comprehensible. The opposition division found that the subject-matter of the product claims lacked novelty

- 12 - T 0360/09

over the disclosure in documents E7 and E9. Therefore the appellant should have addressed these documents. However, they were not mentioned at all in the whole statement of grounds of appeal. Instead the appellant made only vague comments relating to document E1 and these were not even in keeping with the well-known EPO case law on product-by-process claims.

It was also not prima facie apparent that the product claimed in the two requests filed with the statement of grounds of appeal differed from the product claimed in the main request dealt with in the decision under appeal. Thus, on that basis also it was impossible to understand why the appellant asserted that the contested decision was not correct.

In the light of established case law as reflected for example by decision T 1045/02 it was neither sufficient for the admissibility of an appeal if the statement of grounds of appeal did not deal with all of the main grounds considered in the decision under appeal, nor if the statement dealt with one of the main grounds in an insufficient manner. Hence, the present appeal should be held inadmissible.

Reasons for the decision

1. According to Article 108 EPC one requirement for the admissibility of an appeal is that "a statement setting out the grounds of appeal shall be filed in accordance with the Implementing Regulations". Rule 99(2) EPC stipulates that "[i]n the statement of grounds of appeal the appellant shall indicate the reasons for setting aside the decision impugned [...]".

- 13 - T 0360/09

1.1 In cases where the appeal is against the whole decision of the first instance the requirement to "indicate the reasons for setting aside the decision impugned" has been interpreted by the Boards of Appeal to mean that the statement of the grounds of appeal should analyse (a) the main reasons given in the contested decision and this (b) in sufficient detail, the latter requirement serving the purpose that the board and the other parties be put in a position to understand the reasons why the decision is alleged to be incorrect (Case Law of the Boards of Appeal, 6th edition 2010, VII.E.7.6.1, first and second paragraph). Thus where, as in the present case, the claims filed on appeal are different from those dealt with in the contested decision, it has to be derivable from the statement of grounds of appeal and the requests relied on, why the reasons in the contested decision for rejecting the claims then on file do not apply to the claims filed on appeal.

There may be cases where this is understandable merely on the face of the amended claims. However, if this is not so, it is necessary that the statement of grounds of appeal provides an analysis of the reasoning in the impugned decision with respect to the amended claims, it being the presence and not the persuasiveness of such an analysis which is required.

In the present case the opposition division gave a detailed reasoning in the decision under appeal why it had decided to reject the main request because (i) its method claim 1 contained subject-matter extending beyond the content of the application as filed and (ii) - 14 - T 0360/09

the subject-matter of its product claim 4 lacked novelty in view of the disclosure in documents E7 or E9 and also (iii) why it had decided to reject the two auxiliary requests because their method claims contained subject-matter extending beyond the application as filed. Hence, in the board's view, both added matter with regard to the method claims and novelty with regard to the product claims must be considered as the two "main" reasons relied on in the decision under appeal.

- 2.1 In its notice of appeal the appellant requested the board to set aside the decision of the opposition division and to reject the oppositions. The statement of appeal further contained a request for remittal to the first instance for examination of the issues of Article 54 and 56 EPC.
- 2.2 The amended main and auxiliary requests filed with the statement of grounds of appeal each contain three claims, namely, one amended claim to a method and two by reference to the amended method - amended claims to products.
- 2.3 It thus follows that, as regards the extent to which the decision under appeal is appealed, the appellant, both of whose requests filed with the statement of grounds contain amended product claims, appeals not only against the decision of the opposition division to reject the main and the auxiliary requests for added matter, but also against the decision to reject claim 4 of the main request for lack of novelty. Hence, in the light of the observations in points 1.1 and 2 above, for the appeal to be admissible not only the issue of

- 15 - T 0360/09

added matter with regard to the method claims, but also the issue of novelty of the amended product claims has to be addressed in a sufficient manner vis-à-vis the reasons set out in the decision under appeal, namely here lack of novelty with regard to the disclosure in documents E7 and E9.

3. In the statement of grounds of appeal detailed explanations are given where the basis in the application as filed is found for the amended method claims. Thus, one of the main reasons for revocation in the decision under appeal (see point 2 above), added matter, is sufficiently substantiated in the statement of grounds of appeal.

With regard to the issue of novelty it is stated in the statement that the subject-matter of the main request (which includes product claims) is new and also that the product is new (see section XII above). Thus, in contradiction to its argumentation (see sections XVI and XVII above), at the time of filing of the appeal the appellant itself had apparently considered novelty of the product claims to be an issue that needed to be dealt with.

The question in the present case is however the sufficient substantiation of this issue, i.e. whether or not it is understandable from the statement of grounds of appeal why the subject-matter of the amended product claims is novel over the disclosure in documents E7 or E9 (see point 2.3 above).

4. Claim 4 refused by the opposition division for lack of novelty read: "An albumin containing fraction having a

- 16 - T 0360/09

reduced prekallikrein activator (PKA) content obtainable according to the method of claim 1 to 3." Thus, this claim is a so-called product-by-process claim, i.e. a claim which is directed to a product and which relies on process features for the definition of the product - here by reference back to the method defined in claims 1 to 3, a method which is according to the preamble of the claims for "manufacturing an albumin enriched fraction having a reduced prekallikrein activator (PKA) content".

- 4.1 With respect to the novelty of this claim 4 the opposition division reasoned that (see section VII above):
 - it should be kept in mind that a product characterized by a process has to be novel and inventive on its own regardless on how it is produced;
 - the subject-matter of claim 4 as a product is only characterised to be an albumin composition with reduced PKA content;
 - any albumin product with a PKA lower then normal is pertinent for novelty;
 - albumin solutions for pharmaceutical use seem to be acceptable up to a PKA value of 35 IU/ml;
 - the albumins produced by the methods taught in documents E7 or in E9 lead to a PKA activity even less then 10 IU/ml which is the preferred value in the contested patent;
 - the subject-matter of claim 4 is therefore not novel over the disclosure in documents E7 and E9.

- 17 - T 0360/09

- 5. Claims 2 and 3 of the main and auxiliary request filed with the statement of grounds of appeal read:
 - "2. An albumin containing fraction having a reduced prekallikrein activator (PKA) [sic] obtainable according to the method of claim 1.
 - 3. The albumin of claim 2 having a PKA content of less than 12 IU/ml, preferably 10 IU/ml, wherein the PKA is determined according to European Pharmacopeia, Fourth Edition."
- 5.1 Apart from the amended claim reference the only difference between claim 2 of both the main and auxiliary requests and claim 4 of the previous main request is that, by reference back to claim 1, claim 2 of the pending request characterizes the product by methods which are different from those characterizing the product of claim 4 of the previous main request. Essentially, the difference between the methods is that the methods according to claim 1 of the present main and auxiliary requests include more and even more precise steps, respectively. Present claim 3 is dependent on claim 2. Its wording is identical to that of claim 5 of the main request before the opposition division. Thus, these two claims only differ in respect of the method feature (see sections IV, IX and X above).
- 6. When considering the amended claims per se, it is not self-explanatory why the amendment characterization by a different method overcomes the reasons for finding that the subject-matter of claim 4 of the main request before the opposition division lacks novelty

- 18 - T 0360/09

over the disclosure in documents E7 or E9. This is particularly so in the light of the opposition division's statement that it should be kept in mind that a product characterized by a process has to be novel and inventive on its own regardless on how it is produced. The board notes in this respect that the opposition division's view reflects established and consistently applied case law since the decision in case T 150/82 was issued in 1984 (see also Case Law of the Boards of Appeal, 10th edition, II.B.6.1 and 6.2). Further it is not prima facie apparent whether or not the additional method steps have an influence on the PKA content, and if they do, if the PKA level is reduced to such an extent that the claimed subjectmatter differs from and is therefore novel over that disclosed in documents E7 and E9.

- 7. In its statement of grounds of appeal the appellant submits in support of the novelty of the product claims that:
 - the subject-matter of the main request is new because the process characterized in the claims is different from the process disclosed in document E1;
 - the product is new because it is the result of a new and inventive process;
 - none of the other documents anticipates the subject-matter of the main request.
- 7.1 The first two arguments thus explain the novelty of the product merely by referring to the novelty (and inventiveness) of the process referred to in the product claim generally and in relation to a process

- 19 - T 0360/09

disclosed in document E1. However, the opposition division had expressly stated in the decision under appeal that this is per se not a sufficient reason. Thus, for the appellant's argument to be understood in the light of the reasoning in the decision under appeal, it should have explained why the product becomes new over the disclosures in documents E7 and E9 in view of the new process features.

- 7.2 The appellant's third argument mentioned in point 7 above neither takes account of documents E7 and E9 nor of the opposition division's reasoning that these documents disclose albumin-containing fractions with a PKA content of "even less than 10 IU/ml" and thus also does not elucidate why the amended product claims overcome the reasons in the decision under appeal for refusing the main request for lack of novelty of its product claim 4.
- 8. In summary, it is not understandable either when considering the claims per se or when considering them in the light of the written submissions in the statement of grounds of appeal why the subject-matter of the amended product claims is novel over the disclosures in documents E7 or E9. For this reason the statement of grounds of appeal is considered to insufficiently substantiate one of the two main reasons in the decision under appeal, i.e. the reason of lack of novelty (see points 2 and 2.3 above).
- 9. The appellant argued, that since it did not pursue the main request rejected for lack of novelty by the opposition division, but rather based its new main request on the first auxiliary request which was only

- 20 - T 0360/09

rejected for added matter, the board could not deal with the novelty of the product claims of the new requests because the opposition division had not considered the novelty of the product claims of the this auxiliary request. It would therefore be premature and against the fundamental principle of procedural economy, if the appellant had to argue in the statement of grounds of appeal the issue of lack of novelty in relation to the product claims. The appellant referred to decision T 934/02 of 29 April 2004 to support its case.

- 10. Which of the reasons of the impugned decision have to be dealt with in the statement of the grounds of appeal is determined by considering an appellant's procedural and claim requests filed with the notice and the statement of grounds of appeal in the light of the contested decision as a whole. It is therefore not relevant which of the requests rejected at the first instance form the basis of the requests filed on appeal. In the present case the circumstances are such that it was necessary for the appellant to substantiate the issue of novelty in a sufficient manner in order for the appeal to be admissible (see point 2.3 above).
 - 10.1 Proceedings before the Boards of Appeal of the EPO are not of a purely cassative nature, i.e. the contested decision can be challenged by filing of amended claims (Case Law of the Boards of Appeal, 6th edition 2010, VII.E.16). Article 111(2) EPC gives the Boards the discretion either to deal with these amended claims itself or to remit the case to the first instance. However, a decision pursuant to Article 111(2) EPC is only taken after the appeal has been held to be

admissible which requires sufficient substantiation. Thus, sufficient substantiation is a prerequisite for the admissibility of an appeal and cannot, as the appellant's argument suggests, be premature nor can it, for reasons of procedural efficiency, be postponed to a later point in time.

10.2 In the case cited by the appellant, decision T 934/02 (supra), the opposition division had rejected the main request on the grounds that the subject-matter of claim 1 was not inventive over the combination of documents D1 and D6. With its statement of grounds of appeal the appellant-patent proprietor filed amended claims and explained in detail the reasons why their subject-matter should be considered inventive over the combination of documents D1 and D6.

The appellant-opponent challenged the admissibility of the appeal for the reason that it was based on new amended claims. In its view the purpose of the appeal was to review the decision on the rejected request and not to examine an entirely different request raising issues never considered by the opposition division.

The board did not agree with the appellant-opponent's view. It stated that there is nothing in the provisions of the EPC concerning the admissibility of an appeal "supporting the idea that the task of a Board should be strictly limited to considering the claims contained in the requests rejected by the opposition division." (see point 2 or the Reasons). Furthermore the board quoted from decision T 717/01 of 14 January 2003 which holds that an appeal of the patent proprietor is to be considered sufficiently substantiated if (i) there is a

- 22 - T 0360/09

change in the subject of the proceedings due to the filing of new claims and (ii) the statement of grounds sets out in detail why the grounds of opposition do not prejudice the maintenance of the patent as amended on the basis of these new claims.

In the case under consideration in decision T 934/02, (supra) the statement of grounds gave detailed reasons why the subject-matter of claim 1 of the main request should be considered novel over documents D1 or D6 as well as inventive over the combination of these two citations. Therefore the appeal was held admissible.

Decision T 934/02 (supra) rather than helping the appellant's case, supports the opposite view, namely that amended claims may be filed in appeal proceedings (see point 10.1 above) and that for an appeal to be considered as sufficiently substantiated an explanation of why these amended claims overcome the decision under appeal is necessary (see point 1.1 above).

11. The board concludes in view of the observations in points 2 to 8 above that the statement of grounds of appeal cannot be considered as sufficiently substantiated within the meaning of Article 108 EPC in combination with Rule 99(2) EPC.

Order

For these reasons it is decided that:

The appeal is rejected as inadmissible.

The Registrar:

The Chairman:

P. Cremona

C. Rennie-Smith