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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 449/90 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 5 December 1991

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

Publication in the Official Journal ~~Yes~~ / No

File Number: T 449/90 - 3.3.2

Application No.: 83 104 642.0

Publication No.: 0 094 611

Title of invention: A method for the heat treatment of plasma, of plasma fractions and compositions obtained thereby

Classification: A61K 35/16

D E C I S I O N
of 5 December 1991

Proprietor of the patent: Cedars-Sinai Medical Center

Opponent:
(02) Central Blood Laboratories Authority "The Crest"
(03) Kabi Pharmacia AB
(04) RORER GROUP, Inc.
(05) Yamada, Hideo

Headword: Treatment of plasma/CEDARS-SINAI

EPC Articles 83 and 123(2)

Keyword: "Amended claims - allowable combination of features"
"Sufficiency of disclosure - valid model tests disclosed by way of reference"

Headnote

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Decision under appeal :
Decision of Opposition Division of the European Patent Office dated 10 April 1990 revoking European patent No. 0 094 611 pursuant to Article 102(1) EPC.

Composition of the Board :

Chairman : A.J. Nuss
Members : U.M. Kinkeldey
R.L.J. Schulte

Summary of Facts and Submissions

I. The Appellants are the proprietors of patent 94611 (European patent application No. 83 104 642.0). Claim 1 as granted reads as follows:

"1. An AHF enriched composition for the manufacture of a medicament agent for the treatment of bleeding disorders; said composition comprising a human Factor VIII concentrate essentially free of blood clotting enzymes and having been treated by heating for a predetermined period of time in the lyophilized form at a temperature of at least 60°C, characterized by said human Factor VIII having both prior to and after heating an AHF purity of greater than about 300 AHF units/gram of protein, by said composition being heated to render substantially inactive a virus related to Acquired Immune Deficiency Syndrome (AIDS) and said AIDS virus being rendered substantially inactive."

Claim 2 is worded identically as Claim 1 with the exception that it is not the AIDS virus which is being rendered substantially inactive but rather a hepatitis virus. Claims 3 to 5 are dependent on Claims 1 or 2 and relate to certain preferred embodiments.

II. Notices of Opposition were filed against the European patent by five parties. Revocation of the patent was requested on the grounds of Article 100(a), and (b) and (c) EPC.

III. The Opposition Division revoked the patent on the grounds of added subject-matter under Article 123(2) EPC and insufficiency of disclosure under Article 83 EPC of the subject-matter of Claims 1 and 2.

In its decision, the Opposition Division took the view that by the feature concerning "a virus related to AIDS" the subject-matter of Claim 1 as granted extended beyond the content of the application as originally filed. The main consideration was that at the effective date, the skilled person could not find in the common general knowledge, or in the specification as originally filed, any answer to the question of whether the pathogen agent was actually a virus and whether it could be substantially inactivated by a dry-heat treatment that had preserved the Factor VIII activity, let alone the specific conditions of the treatment. Further, the original application neither disclosed a method, nor suggested the means for preparing and testing the composition of Claim 1.

Another objection of the Opposition Division was that there existed a deficiency of disclosure in respect of the reproducibility of Claims 2 to 5 as granted. It resulted from the finding that the technical teaching given in the objected claims did not lead to the desired and claimed result of inactivating the viruses mentioned there and that there was at the relevant date no possibility to provide experimental evidence to show the desired and claimed effect of virus inactivation.

Because of these deficiencies under Article 100(b) and (c) EPC of the opposed patent, the Opposition Division considered it not to be necessary to take position with regard to the objections raised by the Opponents under Article 100(a) EPC and with regard to the validity of the claim to priority.

IV. The Appellants lodged an appeal against the decision and submitted a Statement of Grounds.

V. Oral proceedings were held on 5 December 1991, during which the Appellants filed three new sets of claims. Claim 1 of the set of claims representing the main request differs from Claim 1 as granted and reads as follows (amendment underlined):

"1. An AHF enriched composition for the manufacture of a medicament agent for the treatment of bleeding disorders; said composition comprising a human Factor VIII concentrate essentially free of blood clotting enzymes and having been treated by heating for a predetermined period of time in the lyophilized form at a temperature <u>between 60°C and 125°C</u>, characterised by said human Factor VIII having both prior to and after heating an AHF purity of greater than about 300 AHF units/gram of protein, by said composition being heated to render substantially inactive a virus related to Acquired Immune Deficiency Syndrome (AIDS) and said AIDS virus being rendered substantially inactive."

Claim 2 was amended the same way i.e. the temperature range is now defined by "between 60°C and 125°C".

Claims 3 and 4 relate to Claims 3 and 4 as granted. Claim 5 as granted was omitted.

The first auxiliary request is based on Claim 1 as cited above and Claims 2 and 3 correspond to Claims 3 and 4 of the main request.

The second auxiliary request is based on Claim 2 of the main request and Claims 2 and 3 correspond to Claims 3 and 4 of the main request. Claim 5 as granted was omitted.

VI. During the appeal proceedings the Appellants argued essentially as follows:

(a) It was contested that the claims contained added matter within the meaning of Article 123(2) EPC, all features of Claims 1 and 2 having been sufficiently disclosed in the documents as originally filed with the European Patent Office. This concerned in particular with the feature that the AHF enriched composition was lyophilized, which was mentioned repeatedly and especially on page 3, lines 6 to 20. The further feature that the AHF enriched composition had been treated by heating for a predetermined period of time was clearly derivable from Table I where there were disclosed a series of periods of time for the heat treatment lying within a broad range. As far as the temperature range between 60°C and 125°C was concerned attention was drawn to originally filed Claim 15 where this range was mentioned expressis verbis.

As far as the furtheron objected feature was concerned that the human Factor VIII had "both prior to and after heating an AHF purity of greater than about 300 AHF units/gram of protein", one could find this purity degree prior to the heating from the expressis verbis disclosure of the originally filed application on page 21, lines 10 to 15. That this purity degree was to be maintained and could actually be maintained after the heating was directly and unambiguously derivable from the values of the percentage of the activity of AHF being preserved after heating compared to an unheated control sample as shown in Table I of the originally filed documents. The activity values given in Table I provided the necessary knowledge which starting activity of the AHF composition had to be taken when a certain combination of temperature and period of time for the heating was chosen to make sure that the purity of the AHF composition after heating

had to be greater than about 300 AHF units/gram of protein.

As to the feature that "said composition being heated to render substantially inactive a virus related to Acquired Immune Deficiency Syndrome (AIDS) and said AIDS virus being rendered substantially inactive", this was also expressis verbis disclosed on page 19, lines 32 to 36 of the originally filed documents.

The same arguments held true for Claim 2 of the main request which differed from the main claim only by the type of virus to be inactivated. The inactivation of hepatitis virus, however, was originally disclosed on page 18, line 34 to page 19, line 10, even if non-A, non-B hepatitis virus were concerned.

(b) The requirements of Article 83 EPC were fulfilled because at the time of the application the skilled person was able, without any inventive contribution, to prepare an AHF enriched composition by heating it for a predetermined period of time in the lyophilized form at a temperature between 60°C and 125°C which then contained human Factor VIII having the claimed activity and being rendered substantially free of the AIDS virus. The means and methods for testing the AHF purity were disclosed in detail in the originally filed documents, whereas a testing method for the presence or absence of a virus, be it a hepatitis or AIDS virus, was disclosed on page 22, lines 22 to 37 and page 23, lines 1 to 3. Of particular importance was the reference in that part of the originally filed application to a PCT international application WO 82/03871, which was published before the priority date of the present patent and incorporated into the disclosure of the present patent by reference. This

test method used so-called candidate viruses, represented, if necessary, by a known hardy virus and the inactivation of this hardy virus could be monitored and conclusions could be drawn to the AIDS or hepatitis virus. Although one could not deny that at the time of filing the application underlying the present patent no reasonable test for monitoring the inactivation of AIDS viruses as such were available, the tests by candidate viruses as disclosed in the originally filed documents and the mentioned prior art could be carried out without undue burden by the skilled person and would have provided reliable results extrapolatable to AIDS viruses. Anyone skilled in the art employing for example temperatures between 60°C and 64°C and times up to 24 hours, as disclosed preferably in Table I, with Factor VIII concentrates containing preferably as a candidate virus the sindbis virus, would have observed substantial reductions in viral titer of the sindbis virus after heat treatment of the Factor VIII concentrate. When techniques for isolating and assaying AIDS virus became available, the same heating time and temperature combination, i.e. approximately 60°C for twenty hours, was shown to effectively remove AIDS virus from Factor VIII concentrates measured in vitro. Subsequent observations from around the world had confirmed that AIDS infectivity was rendered "substantially" inactive, if not completely eradicated, in Factor VIII concentrates which had been heated utilising time and temperature combinations suggested by the range of temperatures and times disclosed in the originally filed papers of the present patent.

VII. The Respondents submitted essentially the following arguments:

(a) With the exception of the degree of purity of AHF after heating it was admitted that the respective features of Claims 1 and 2 were disclosed as such originally. However, by the combination of these features brought together during the examination proceedings in one claim they now related to each other in a way which created new subject-matter not originally disclosed. If it would have been necessary to decide whether the subject-matter of the granted claims could be regarded as novel with regard to the original disclosure this would have been accepted. Therefore, the combination of the features extended over the disclosure of the originally filed documents. As to the mentioned "novelty-test" attention was drawn to a decision of the Board of Appeal T 296/87, OJ EPO 1990, 195 Enantiomere/HOECHST where a very narrow view for answering the question of novelty was taken and the same level of narrowness had to be applied to the question of allowable amendments within the meaning of Article 123(2) EPC. In doing so one had necessarily to arrive at the conclusion that Claims 1 and 2 had been amended during the examination proceedings in an unallowable way.

As to the features as such it was in particular contested that the wording relating to the purity of the AHF prior and after heating could directly and unambiguously be derived from the values shown in Table I. Although it was agreed that the values for the AHF preserved after certain heating treatments, compared to control values showed that the reduction of activity ranged preferably within 10 to 30%, maximally of 50%, this could not be estimated as a disclosure of the wording now contained in the claim "having both prior to and after heating an AHF purity of greater than about 300 AHF units/gram of protein".

(b) Further there was a violation of the requirements of Article 83 EPC. When analysing Claims 1 and 2 as granted as to the characteristics of their features it was evident that the claims were a mixture of technical features, features which merely stated a problem and features which described an effect. In particular the feature relating to the inactivation of the AIDS virus and the hepatitis virus respectively constituted, according to the Appellant's own statements and in view of the way how the claims were worded, essential features representing the core of the invention. This necessarily meant that this inactivation had to be disclosed in a way in the documents originally filed as to enable the skilled person to do it and to test it. This requirement was not fulfilled because at the filing date there was uncontestedly no method available for testing the composition for the degree of inactivation of the AIDS virus when applying a certain heat treatment falling within the range of that claimed.

The availability of candidate viruses for carrying out the absolutely necessary tests could not be judged as being sufficient in this particular sensitive field concerning a composition for the treatment of blood clotting deficiencies as long as it was not known how heat labile or stable the newly discovered AIDS virus might be. Further, to test the compositions as to their inactivation of viruses by injecting them into chimpanzees and to observe the development of any disease symptoms would be undue burden, let alone any ethical aspects or the impossibility to measure any antibody developments. Consequently, that very feature, which was estimated as the most important one of the claims by the Appellants themselves could not

be measured at the filing date. This resulted in an insufficiency of disclosure.

(c) The right to priority, novelty and inventive step were in addition contested.

VIII. The Appellants requested that the decision under appeal be set aside and that the patent be maintained according to the main request or the first or second auxiliary request, all filed during oral proceedings.

The Respondents requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. Amendments (Article 123(2) EPC)

2.1 The three versions of the claims to be considered here were all filed during oral proceedings before the Board (see point V. above); they differ from those considered during opposition proceedings. In respect of the present version the Appellants outlined the specific and expressis verbis disclosure of all features contained in the respective claims as such and the Respondents did not contest this disclosure of these features with one exception, namely the degree of purity of AHF after heating. The Board joins this view and thus, the features in Claims 1 and 2, that heating has to be carried out for a predetermined period of time in the lyophilized form at a temperature between 60°C and 125°C and a purity of human Factor VIII prior to heating of greater than about 300 AHF

units/gram of protein and the composition being heated to render substantially inactive a virus related to Acquired Immune Deficiency Syndrome (AIDS) and said AIDS virus being rendered substantially inactive (Claim 1), or the composition being heated to render substantially inactive a hepatitis virus and said hepatitis virus being rendered substantially inactive (Claim 2), are to be considered as having been disclosed in the documents as filed in a way which ensures that incorporating these features in the claims do not add subject-matter which extends over the originally filed content of the patent.

2.2 The feature that the human Factor VIII in the enriched composition for the manufacture of a medicament agent for the treatment of bleeding disorders has also after heating an AHF purity of greater than about 300 AHF units/gram of protein is not disclosed as such expressis verbis. It has thus to be examined whether this feature can be derived from the original disclosure in a direct and unambiguous way. The specification as originally filed concerns mainly with the fact that a heating being suitable for inactivating viruses at the same time has disadvantages in that the blood clotting factors of the thus heated composition are also inactivated in an undesired way. However, in view of the teaching now provided this disadvantage can be largely avoided by heating these compositions in a lyophilized form. Thus, maintenance of the activity of, for example, human Factor VIII to a degree of at least 50% of the activity contained in the composition before heating is part of the teaching of the patent in suit. This becomes inter alia clear from the chapter "Test procedures for verifying retention of clotting factor activity" which starts at page 4, line 27 and contains results of the in vitro testing performed on Factor VIII concentrate which are summarised in Table I. As pointed out by the Appellants, the activity values

given in Table I provide the necessary knowledge which starting activity of the AHF composition must be taken when a certain combination of temperature and period of time for the heating is chosen to make sure that the purity of the AHF composition after heating will not drop below the minimum AHF value usually considered to be feasible if no heating of the commercially available starting composition would be required. The general disclosure of the patent as originally filed, including the information given in Table I, therefore, provides for the skilled person a direct and unambiguous teaching as to how to proceed with regard to a starting purity of Factor VIII to be contained in the composition to result in a Factor VIII composition which also contains **after heating** at least a purity of about 300 AHF units/gram of protein. This feature, thus, does not extend in an unallowable way over the subject-matter as originally filed.

2.3 The arguments put forward by the Respondents that the combination of features in Claims 1 and 2 extended beyond the content of the originally filed documents are not convincing, although one may agree that, even if certain features as such are clearly disclosed originally, a merely arbitrary combination of these features could possibly lead to generate subject-matter going beyond the content of the original disclosure. As already explained above, nothing the like happened here. It is certainly true, as the Respondents stated, that the combination of features now contained in Claims 1 and 2 is a result of circumstances which only became apparent during the proceedings and which made it necessary to reformulate the claims by including further technical features or effects which have not been explicitly stated in the claims as originally filed. This fact alone, however, is no indication whatsoever that the combination of features in

the present claims did not form part of the original disclosure as a whole.

2.4 The Respondents argue that the now claimed upper limit for the temperature to be applied being 125°C only could be carried out, if the composition is essentially free of of fibrinogen. That this combination of features is essential was made clear by originally filed Claims 14 and 15, the latter being referred back to Claim 14 and being the only place in the originally filed documents where a temperature range between 60°C and 125°C was claimed. By reference to Claim 14 only, however, the Appellants did not originally disclose said range of temperature in combination with the feature that the composition has to be essentially free of blood clotting enzymes in general. It was only one of the Respondents who developed the treatment of the composition such that for achieving a reasonable result when applying a temperature of 80°C the composition has to be free of fibrogen. This treatment could be considered as being an invention only made after filing of the patent in suit.

2.5 The Board cannot agree to this opinion. Firstly, it is evident that Claim 15 is referred back to Claim 14, which in turn is referred back to Claims 1 to 13. This means that any combination of Claim 15 with one of the foregoing claims is to be considered as having been disclosed originally. Originally filed Claims 1 to 13 relate very broadly to a method for treating a substantially dry composition including Factor VIII to reduce the infectivity of the micro-organisms present in the composition comprising heating the composition for a predetermined period of time at a predetermined temperature, the features of the type of heating, the temperature as such and the type of being "substantially dry" as "cryoprecipitate" are further developed in certain

sub-claims. Therefore, there is no restriction of a temperature range between 60°C and 125° as claimed in Claim 15 to a combination of this temperature range to a composition including fibrinogen as claimed in Claim 14.

2.6 Furthermore, the Board would like to draw attention to page 21, lines 16 to 36 where originally details were given about the composition being freed of other plasma proteins to varying degrees during the purification process. These other plasma-proteins may, for example, be fibrinogen (see line 23) and the ratio of AHF units to any individual enzyme unit activity in such compositions ordinarily ranges from about 10:1 to 500:1, and is preferably greater than 300:1. This is the range mentioned in Claim 3, representing a preferred embodiment of the term "essentially free of blood clotting enzymes" in Claim 1. The Board is, therefore, of the opinion that said feature does not extend over the content of the originally filed documents of the patent in suit.

2.7 In the Board's view the documents as originally filed describe AHF-enriched compositions comprising a human Factor VIII concentrate essentially free of blood clotting enzymes (see above points 2.4 to 2.6) and having been treated by heating for a predetermined period of time at a temperature between 60°C and 125°C (see whole content of the disclosure and in particular Table I and Claim 15) which is lyophilized (see whole content of the disclosure and in particular page 18, lines 13 to 18), said human Factor VIII having prior to and after heating an AHF purity of greater than about 300 AHF units/gram of protein, a feature which is literally or implicitly disclosed as already stated above (see points 2.1 and 2.2 above) said composition being heated to render substantially inactive a virus related to AIDS and said AIDS virus being rendered substantially inactive (Claim 1)

or substantially inactive a hepatitis virus and said hepatitis virus being rendered substantially inactive (Claim 2), a feature which is disclosed in connection with the composition as such having been treated as analysed above. This presentation of the features and their combination in the originally filed documents makes it abundantly clear that the amendment of the claims during the proceedings by incorporating certain technical features or effects does not create a combination of features which could not be derived directly or unambiguously from the whole content of the original disclosure. It goes without saying that it is allowed to restrict the subject-matter of an originally filed claim, for whatever reason, by incorporating single features or effects into the claim if these features, as the case is here, are directly or unambiguously correlated to the original subject-matter of the claim. This view concurs with that already expressed in the decisions T 54/82, OJ EPO 1983, 446, and T 17/86, OJ EPO 1989, 297 of the Boards of Appeal where it is stated that separate features of an originally filed document may be combined without necessarily generating new subject-matter.

2.8 This judgment of the allowability of Claims 1 and 2 with regard to Article 123(2) EPC is also not in contradiction to other established case law of the Boards of Appeal, as cited by one of the Respondents, who draw attention to the gist of the decision T 296/87 quoted above (see paragraph VII (a)). The case law to both aspects, namely the question of novelty and the question of added subject-matter, has to be in balance. Consequently, the question of added subject-matter in the present case has to be judged in the same strict and narrow way as it is done in the established case law to the question of novelty. As developed above in detail, that is, what the Board did in the present case.

3. Sufficiency of disclosure (Article 83 EPC)

3.1 All Respondents contested that Claims 1 and 2 in question enabled the skilled circles to reproduce without undue burden a composition as claimed in Claims 1 or 2 for the main reason that at the filing date of the patent in suit there were no means available for testing whether or not the composition provided the decisive effect of inactivation of viruses.

3.2 In the case of the AIDS virus (Claim 1) and non-A, non-B hepatitis virus (Claim 2) it was just around the filing date of the patent in suit that there were indications which led the scientific world to the conclusion that the pathogenic agent in question could be of a viral nature. There was no actual description of a virus nor did there exist any techniques to cultivate the virus so that consequently no means for a direct detection of the virus in a living entity or a cell culture or indirect tracing by measuring any antibodies possibly induced against the virus was at hand. Since, however, the feature of inactivated viruses in the claimed compositions was essential, it has to be ensured that the effect of being virus free must be measurable. Emphasis was put by the Respondents to the fact that in particular this feature was of importance because compositions being not free of viruses would be a threat to the life of any individual receiving them.

3.3 It is also the Board's view that the feature in question in the circumstances of the present case must be testable so that the composition as claimed fulfils the requirements of Article 83 EPC. It is the kind of functional wording of Claims 1 or 2 which connects the effect to render substantially inactive a virus as AIDS or

hepatitis virus to certain heat treatment features such that the reproduction of the claimed composition within the requirements of Article 83 EPC is only possible if the skilled person, after having taken the claimed process steps of lyophilizing, purifying and heating the composition, can be sure of the claimed effect to be achieved by the mentioned steps. This is a substantial inactivation of any viruses connected to the maintenance of a certain degree of activity of the blood clotting Factor VIII.

3.4 The Appellants do not contest that at the time of filing of the patent in suit there were no test procedures available to test the presence or absence of the AIDS virus as such or that the available tests for identifying the hepatitis virus were difficult (the situation was already discussed in the originally filed specification on page 22, lines 24 to 26). There is, however, disclosure in the originally filed documents on page 22, lines 24 to 37 and page 23, lines 1 to 5 that the necessary tests can be carried out by "candidate" viruses such as bacteriophage, sindbis, adenovirus or EHC virus. Further, reference is made to a prior art document PCT International Application WO 82/03871, which document is incorporated into the disclosure by reference. This document relates in particular to a method for the inactivation of viruses in compositions containing blood clotting factor enzymes, for example Factor VIII. On pages 19 and 20 of the published document particular examples are disclosed as to which viruses meet the criteria of being suitable as indicators. It is stated on lines 14 to 16 of page 19 that the best biological indicators for the purposes of ensuring that the inactivation conditions are effective may be viruses which are highly stable thermally. In this respect, the bacterial viruses, known as bacteriophages, are excellent choices. However, most plant and animal viruses meet the

criteria as well. Exemplary viruses include picornaviruses such as encephalomyocarditis virus (EMC), mouse encephalomyelitis virus, simian enterovirus and bovine enterovirus; togaviruses including sindbis, semliki forest virus, western equine encephalitis and yellow fever virus; retroviruses such as rous sarcoma virus; paramyxoviruses such as Newcastle disease virus; papoviruses including polyoma virus and simian virus 40; herpes viruses such as herpes simplex, pseudorabies virus and mareks disease virus; members of the adenovirus family such as infectious canine hepatitis and adeno virus; and bacteriophages such as R17, lambda, T1, T2, T4, T7 and Phi X 174. Further, mixtures of the viruses may also be used.

3.5 In the Board's opinion this disclosure has to be included into the disclosure of the patent in suit by reference; it provides the information necessary to carry out available model tests with regard to a certain desired degree of inactivation of a virus, even if the heat sensitivity of this virus might not have been known at the filing date. The Appellants convincingly emphasised that in cases of that kind the skilled person would choose a "hardy" virus, for example a bacteriophage, as described in the mentioned document, to be on the safe side in that the inactivation reaches the claimed degree of "substantially".

3.6 The Board would like to note here that the argument put forward by the Respondents that the inactivation of the viruses in the case of AIDS has to be complete because otherwise the composition might be fatal, is a question of a certainly highly desired effect; it is, however, not a question of the requirements of Article 83 EPC with regard to the fact that the claim has the wording "substantially inactivated".

These circumstances are already described in the original disclosure on page 23, lines 9 to 20 where it is made clear that the claimed composition provides a product in which the titer of viruses is reduced so low that infusion of therapeutic quantities of the product into a plurality of normal animal hosts for the virus will fail to produce clinical or serological evidence of infection in a host population, or will delay significantly the onset of infection in such population. There was, therefore, no claim that a hundred percent, i.e. complete inactivation of viruses can be ensured, whereas the claimed compositions are to be considered as a step further in the direction of the certainly desired situation of compositions being completely free of any infectious viruses which may put life at risk. There is, thus, no requirement as to the mentioned article of the EPC that the composition has to be entirely free of any viruses.

3.7 The Respondents did not contest that the steps to prepare the

- AHF-enriched composition
- being essentially free of blood clotting enzymes
- by heat treating them
- for a predetermined period of time
- in the lyophilized form
- at a temperature between 60°C and 125°C
- having both prior to and after heating an AHF purity of greater than about 300 AHF units/gram of protein

are reproducible by the skilled person without undue burden and the Board has no reason to doubt that the necessary process steps of lyophilizing, purifying and heating can be carried out while applying common skill.

3.8 Therefore, the Board comes to the conclusion that Claims 1 and 2 of the main request fulfil the requirements of Article 83 EPC.

4. Since the claims of the main request do not contravene the requirements of Articles 123(2) and 83 EPC there is no reason to deal with the first and second auxiliary requests.

5. The impugned decision of the Opposition Division does not deal with the question of valid priority, novelty and inventive step and, therefore, the Board makes exercise of its power according to Article 111 EPC to remit the case for further prosecution.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division for further prosecution on the basis of the claims submitted during oral proceedings.

The Registrar The Chairman

P. Martorana A. Nuss

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