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D E C I S I O N
of 13 July 1999

Case Number: T 0532/96 - 3.3.3

Application Number: 87106784.9

Publication Number: 0245813

IPC: C08B 37/10

Language of the proceedings: EN

Title of invention:
EDTA-free heparins, heparin fractions and fragments, processes for their preparation and pharmaceutical composiitons containing them

Patentee:
Italfarmaco S.p.A., et al

Opponent:
Leo Pharmaceutical Products Ltd. A/S

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 84, 114, 123

Keyword:
"Novelty (yes) - "process" step limiting on a "use" claim"

Decisions cited:
G 0005/83, G 0002/88, T 0150/82, T 0254/93, T 0958/94

Catchword:
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Case Number: T 0532/96 - 3.3.3

D E C I S I O N
of the Technical Board of Appeal 3.3.3
of 13 July 1999

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office issued on 17 April 1999 revoking European patent No. 0 245 813 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: C. Gérardin
Members: R. Young
J. A. Stephens-Ofner

Summary of Facts and Submissions

I. The mention of the grant of European patent No. 0 245 813, in respect of European patent application No. 87 106 784.9, filed on 11 May 1987 and claiming IT priorities of 16 May 1986 and 3 October 1986 (IT 2046286 and IT 2190186, respectively) was announced on 3 November 1993 (Bulletin 93/44).

II. Notice of Opposition was filed on 3 August 1994 on the grounds of lack of novelty and lack of inventive step. The opposition was supported *inter alia* by the documents:

D5: Declaration by E. Coyne (copy filed with Notice of Opposition; original filed with a letter dated 30 October 1994);

D6: Protocol of Assay of sodium heparin (copy filed with the Notice of Opposition; no original filed);

D7: Analysis report by Niels Rastrup Andersen and Ellen Marie Tromborg (copy filed with Notice of Opposition; original filed with a letter dated 30 October 1994);

D8: Bang et al., "Haemorrhagic Effects of Unfractionated and Two Low Molecular Weight Heparins, Enoxaparin and Fragmin, in Rats", Haemostasis, 1991, 21:30-36;

D9: O'Kelly et al., "Bleeding Time: Is it a Useful Clinical Tool?", British Journal of Anaesthesia, 1992, 68:313-315;

D10: E. Lind, "The Bleeding Time Does Not Predict Surgical Bleeding", The Journal of the American Society of Hematology, 77, 1991: 2547-2252; and

D11: Pangrazzi et al., "Bleeding Effects Associated with Heparin Contaminants", Annals of the New York Academy of Sciences 556, 468-470 (1989).

III. By a decision issued on 17 April 1996, the Opposition Division revoked the patent in suit. The decision was based on a main and an auxiliary request, the former corresponding to the patent as granted, and the latter consisting of a set of two claims filed on 28 December 1994. Claim 1 of the main request, valid for the Contracting States AT, BE, CH, DE, FR, GB, IT, LI LU, NL, SE read as follows:

"The use of heparins, heparin fractions or fragments or salts thereof having an EDTA content lower than 0.1% for the preparation of an anticoagulant/antithrombotic medicament, said heparins, heparin fractions or fragments or salts thereof being further characterized in that they show a bleeding time, when administered i.v. in the rat at the dose of 0.75 mg/kg, equal or lower than 117s measured in a template lesion of the rats tail, the untreated control values being 102 $\pm$ 4 s."

Claim 1 of the auxiliary request, which was valid for all the Contracting States, differed from that of the main request by the insertion of the phrase "obtained by a process involving the use of EDTA," immediately before "having an EDTA content lower than...".

Claim 2 in each request was an independent claim directed to a process for the preparation of heparins.

According to the decision, the subject-matter of Claim 1 of the main request lacked novelty, in view of the decisions G2/88 and G 6/88 of the Enlarged Board of Appeal, since (a) the product to be used, (b) the "means of realisation", and (c) the purpose of use as claimed were the same as a heparin having an EDTA (ethylenediamine tetraacetic acid) content lower than 0.1%, which had been marketed and sold to known pharmaceutical companies as an anticoagulant/antithrombotic medicament in January 1969, as evidenced by documents D5, D6 and D7.

Similar considerations applied to the corresponding claim of the auxiliary request, since the inserted process feature was an inherent feature of any starting heparin which the skilled person would ever consider to free from EDTA.

Despite the finding of lack of novelty, the decision under appeal stated that the patent in suit had arrived at an insight into the previously unnoticed role of trace amounts of EDTA in heparins in inducing bleeding, which, if novelty could have been acknowledged, could be considered to be inventive.

IV. On 12 June 1996, a Notice of Appeal against the above decision was received, the prescribed fee being paid on 13 June 1996.

In the Statement of Grounds of Appeal, filed on 13 June 1996, the Appellant (Patentee) argued in substance as

follows:

(a) The essence of the invention lay in the purposive discrimination between heparins, eliminating thereby a risk factor, so that a new use should be seen just in the absence of this risk factor.

(b) Whilst it was true that the therapeutic results in the use of EDTA-free heparins in the case of the cited prior art and in the patent in suit were the same, this inherency had not been appreciated by anyone in clinical and medical practice. Hence, whereas before patent in suit, a patient might receive, on a statistical basis, either a EDTA-free heparin or an EDTA-contaminated heparin, after the patent the patient would always receive an EDTA-free heparin. This was a concrete technical teaching, forming a non-obvious solution to a technical problem, and therefore a technical contribution, for which it should be possible to devise a claim distinguishing from the prior art.

(c) New main and auxiliary requests had therefore been filed with a view to avoiding overlap with the prior art.

The Statement of Grounds of Appeal was accompanied by a main and a first and a second auxiliary request, each consisting of a respective single claim and being valid for all the Contracting States. The single claim of the main request reads as follows:

"The use of heparins, heparin fractions or fragments or salts thereof, having an EDTA content lower than 0.1%

whenever obtained from heparins, heparin fractions or fragments or salts thereof containing EDTA as a foreign contaminant for the preparation of an anticoagulant/antithrombotic medicament, said heparins, heparin fractions or fragments or salts thereof being further characterized in that they show a bleeding time, when administered i.v. in the rat at the dose of 0.75 mg/Kg, equal or lower than 117s measured in a template lesion of the rates [sic] tail, the untreated control values being 102 $\pm$ 4 s."

V. The Respondent (Opponent) argued, in a submission filed on 7 May 1997, substantially as follows:

(a) The additional characterising feature of Claim 1 of the main request did not provide novelty, since there was no difference from the prior art heparin containing no EDTA.

(b) The argument regarding the "risk factor" showed that the situations before and after the publication date of the patent in suit were based solely on a statistical factor. This confirmed that the technical teaching was in each case the same.

(c) The wording of the first and second auxiliary requests was in contravention of Article 123(2) and 123(3) EPC, respectively. As regards their content, the same considerations with regard to lack of novelty applied as with the main request.

VI. With communications issued on 3 March and 30 April 1999, respectively, the former accompanying a summons

to oral proceedings, the Board asked, *inter alia*, for clarification as to which claim or claims were to be regarded as making up the relevant main, and first and second auxiliary requests of the Appellant.

VII. In a letter received on 17 March 1999, the Appellant informed the EPO that he would not be attending the oral proceedings, without, however, providing any information regarding the claims making up the various requests.

VIII. In a letter received 14 June 1999, the Respondent indicated that (i) he would speak German at the oral proceedings, but (ii) an oral proceedings was not necessary, since (a) the Appellant had indicated that he would not be attending the oral proceedings, and (b) no reply to the official communication had been received, so that (c) there was no clear text on file. Consequently, (iii) a decision dismissing the appeal should be issued directly.

IX. After a telephone enquiry by the Registry of the Board, however, it emerged that the Appellant had indeed sent a reply, but that it had not been received. A copy of the reply, dated 13 May 1999 was then faxed to the EPO. This reply stated that the main request of the Appellant filed with the Statement of Grounds of Appeal consisted only of the respective single claim.

X. Oral proceedings were held on 13 July 1999, which were attended by the Respondent (Opponent) but, as previously notified, not by the Appellant. The Respondent questioned whether the Notice of Appeal, which had been filed in the Italian language, had been

supplemented by a translation into the relevant Official language. Furthermore, the Respondent expressed the view that the letter of the Appellant, dated 13 May 1999, should be interpreted as meaning that only the single claim forming the main request was relied upon by the Appellant, since the letter explicitly referred to the main request but did not mention the auxiliary requests. For the rest, the Respondent repeated, in essence, the arguments already submitted in writing, emphasising finally that it would have been standard practice, at the priority date, to ensure the removal, from any medicament prior to use, of any foreign contaminant, such as EDTA, to a threshold below that characterising the heparins claimed. In this connection, the Respondent asked for an adjournment of the oral proceedings to provide time to allow the filing of further evidence to this effect.

XI. The Appellant requested, in writing, that the decision under appeal be set aside, and the patent in suit maintained on the basis of the claim forming the main request, or the first or second auxiliary request, filed with the Statement of Grounds of Appeal (Statement of Grounds of Appeal (page 1), the main request consisting of the respective single claim filed with the Statement of Grounds of Appeal (letter dated 13 May 1999).

The Respondent requested (i) that the appeal be dismissed, or (ii) that the oral proceedings be adjourned and time allowed for the filing of further evidence by the Respondent.

Reasons for the Decision

1. *Admissibility of Appeal*

A translation in English of the Notice of Appeal, which was filed in Italian, was furnished on the same day (12 June 1996). No other objection having been raised to the formal requirements of admissibility, the appeal is admissible.

2. *Main request*

Whilst it may be disputed whether the Appellant's letter of 13 May 1999 intended to refer to the auxiliary requests or only to the main request, it was neither disputed that the Appellant did rely on the claim forming the main request filed with the Statement of Grounds of Appeal, nor that this request consisted only of that single claim. Consequently, the nature of the main request is clear. It will be dealt with first.

2.1 Admissibility of amendments

The single claim of the main request differs from the corresponding claim of the patent as granted only by the insertion of the words "whenever obtained from heparins, heparin fractions or fragments or salts thereof containing EDTA as a foreign contaminant", after "lower than 0.1%..." and before "for the preparation of an anticoagulant/antithrombotic medicament".

The basis for the amendment is in the description of the application as filed, page 3, lines 23 to 26, referring to the "presence of a foreign contaminant, in relevant amounts", in conjunction with the same page, from line 29 to page 4, line 3, stating that "said component, always present in all the industrial preparations, also those purified to the maximum obtainable grade according to the presently used methods...turned out to be ethylenediaminetetraacetic acid (EDTA)" (patent in suit, page 3, lines 45 to 47 and 49 to 51).

No objection was raised by the Respondent to this amendment, whether under Article 123(2) or Article 123(3). On the contrary, the fact that objection was raised under this head only against the first and second auxiliary requests (letter dated 7 May 1997, points 1.1, 1.2) but not against the main request, is itself an indication that the main request was regarded as complying with Article 123 EPC. Nor is the Board aware of any such objection to the claim. Consequently, the claim meets the requirements of Articles 123(2) and 123(3) EPC.

Neither was any objection under Article 84 EPC was raised against the amended claim, whether as to support or as to clarity. Nor does the Board see any lack of support or lack of clarity in the claim. Consequently, the requirements of Article 84 EPC are held to be met.

2.2 Interpretation of the claim

Whilst no objection to the clarity of the claim was

raised by the Respondent, nevertheless the question arose, during the oral proceedings, as to whether the reference to a heparin species "containing EDTA as a foreign contaminant" was properly to be construed as a feature limiting the claim or not.

2.2.1 Whilst the phrase "whenever obtained from heparins, heparin fractions, or fragments or salts thereof containing EDTA as a foreign contaminant" in the claim is reminiscent of the form of wording often adopted in a "product-by-process" claim, the product in the latter type of claim not being regarded as deriving its patentability by reason alone of the process of manufacture (T 150/82, OJ EPO 1984, 309), the claim in the present case is nevertheless directed to a "use", which is an activity, and not to a "product", which is a thing.

2.2.2 It was not contested that this form of claim corresponded to that approved for a "second medical indication" by the Enlarged Board of Appeal in G 5/83 (OJ EPO 1985, 064). It was furthermore held in that decision, in general terms (point 11, first paragraph), that an invention relating to an activity could be claimed either as the application or use of a thing for a stated purpose (eg to achieve a technical result) or as a method or process to achieve the same result using the same thing, depending on preference.

2.2.3 The significance of this general rule has been recognised, by another Board, in a similar such case, as also applying in the field of therapy (T 958/94, OJ EPO 1997, 241, Reasons, point 3.4, third

paragraph). According to the latter decision, manufacturing a medicament does indeed involve a sequence of common and obligatory steps, irrespective of the form of the claims which circumscribe its manufacture, and whether the claims are for "the application of a substance to obtain a medicament intended for a new therapeutic use" or for a "process to obtain a medicament intended for the new application, characterised in that the substance is used" (Reasons, point 3.4, fifth paragraph). Consequently, a "use" claim is to be understood as equivalent, substantively, to a "process" claim.

2.2.4 Applying these principles to the present case, the "use" claim of the patent in suit is, in substance, a claim for a process of obtaining a heparin species intended for application as an anticoagulant/antithrombotic, characterised in that a heparin, heparin fraction, fragment, etc. having an EDTA content lower than 0.1% is obtained from heparins, heparin fractions, fragments, etc. containing EDTA as a foreign contaminant.

Consequently, the requirement of starting from a heparin material containing EDTA as a foreign contaminant is a step in the "process" for obtaining the medicament. It is therefore a limiting feature of the claim. By the same token, it is also, substantively, a limiting feature of the corresponding "use" claim according to the patent in suit.

2.2.5 The argument of the Respondent at the oral proceedings, that the emphasis in such a claim was on

the provision of the medicament in a state capable of exerting its therapeutic activity, whilst certainly in line with the statement in point 11 (second paragraph) of the decision G 5/83, according to which "in both cases the active substance of composition for therapy must be in a state capable of exerting its therapeutic acitvity...", is nevertheless beside the point, since the attribution of novelty by virtue of the therapeutic indication does not itself detract from the limiting effect of the remaining features of the claim (section 2.2.3, above). This applies in particular to the sequence of manufacturing steps which are involved in the manufacture of the medicament, in the present case the use of an EDTA contaminated starting material.

2.2.6 In summary, the claim is to be interpreted, contrary to the submission of the Respondent at the oral proceedings, as being limited to the use, as starting material in obtaining the heparin medicament, of a heparin starting material containing EDTA as a foreign contaminant.

2.3 The patent in suit; the technical problem

The patent in suit addresses the problem that, when heparin is used as an anticoagulant, it has, in addition to its purely anticoagulant properties, a further, undesirable property, which is termed a "bleeding effect", namely that there is unwanted haemorrhaging in the subject. The basis of the teaching is the observation that the bleeding effect can be greatly reduced or eliminated, without

affecting the anticoagulant properties, by removing trace amounts of EDTA which, according to the patent in suit, are always present in commercial samples of heparin, even those purified to the maximum obtainable grade according to the conventionally used methods, in amounts ranging from 0.2 to 5% by weight (page 3, lines 49 to 50).

The claim of the patent in suit proposes to solve the haemorrhaging problem, starting from such a material, by ensuring that the amount of EDTA present is lower than 0.1%, so that the resulting heparin material shows a bleeding time, when administered i.v. (intravenously) in the rat at a dosage of 0.75 mg/Kg, equal to or lower than 117 s measured in a template lesion of the rat's tail, the untreated control values being 102 $\pm$ 4 s.

2.3.1 It can be seen from the large number of examples in the patent in suit, that the bleeding times, according to the template test, of rats treated with commercial samples of sodium heparin containing EDTA, were more than 100% longer, compared with those of rats treated with the heparin material after removal, by dialysis followed by lyophilisation (Examples 1 to 10) or by precipitation (Examples 11 to 13), of EDTA to a level below 0.1%. Indeed, the template bleeding times recorded are invariably between 105 s (Example 13) and 115 s (Example 8), which is within the range characterising the relevant medicaments according to the claim.

2.3.2 The argument of the Respondent, repeated at the oral proceedings, that the bleeding time was considered at

the priority date not to be a reliable or effective method of determining the bleeding disorder, which was supported by the evidence of documents D8, D9, D10 and was also dealt with in the decision under appeal, is not convincing to the Board for the same reason as that given in the decision under appeal, namely that all these documents were published after the relevant filing date of the patent in suit, and consequently, none of them formed part of the state of the art; and furthermore, that D10 in any case contained the statement that "no other tests in medical practice can claim such long-term popularity as the bleeding time (BT)". In other words, this evidence does not show that the skilled person would have had any doubts, at the relevant priority date, that the bleeding time was an effective test for the haemorrhaging disorder.

2.3.3 The above conclusion applies also to document D11, referred to more particularly by the Respondent at the oral proceedings, as containing the phrase "Since removal (by dialysis) of most of the EDTA contaminating heparin preparations was not always paralleled by a reduction of bleeding in our model, studies are in progress to investigate whether EDTA requires "co-factors" to induce bleeding." (page 468, last line). This is because D11, in common with D8 to D10, has a publication date after the relevant priority date of the patent in suit, and consequently also does not form part of the state of the art.

2.3.4 The further argument of the Respondent at the oral proceedings, that the skilled person would, at the relevant priority date, as a matter of "Good

Manufacturing Practices (GMP)", necessarily have removed any foreign contaminant such as EDTA down to below the relevant level claimed, is not convincing to the Board, since it is flatly contradicted by the statements in the patent in suit itself, according to which samples of heparin, even those purified to the maximum obtainable grade according to the contemperaneously used methods, did in fact always contain EDTA (page 3, lines 49 to 50).

2.3.4.1 The evidence of the patent in suit is itself further corroborated by additional evidence in the form of a Table of results of determination of EDTA content in sodium heparins, filed during the course of the examination procedure (submission filed on 19 July 1991, Table I). The Table shows an EDTA content in such sodium heparins, is always in excess of 0.1%.

2.3.4.2 The argument of the Respondent was, in contrast, not supported by so much as a scrap of evidence, and thus amounts to no more than a pure assertion.

2.3.4.3 Even the logic of this assertion is weakened by the closely related argument, already submitted by the Respondent during the opposition proceedings, that there would have been an obligation to report to the regulatory authorities on the alleged bleeding effect caused by EDTA. This is because such an argument pre-supposes a foreknowledge of the attributability of the bleeding effect to the presence of EDTA in the heparin sample. Since, however, this argument was equally supported only by such documents as D8 to D11, which, as stated above, were not published before the priority date of the patent in suit, such

foreknowledge has not been demonstrated. Consequently, there is no basis for assuming a perception, by the skilled person, of any need for such a report, or for further purification of a heparin sample beyond that conventionally achieved (submission filed on 30 November 1995, page 5).

2.3.4.4 The onus of proof in any case lies with the Opponent (here the Respondent). This onus has not, however, been discharged, for the reasons given.

2.3.4.5 The request of the Respondent for time to be given to provide further documentary evidence in support of the assertion was unjustifiably late considering that the relevant evidence of the patent in suit, the first publication date of which is 19 November 1987, has been available for over ten years. No reason was given, however, for the delay in furnishing such evidence.

Furthermore, the nature of the assertion, which contradicts the entire basis of the technical teaching in the patent in suit, has to be seen in the light of the obligation of good faith of an Applicant or Patentee in the presentation of his invention to the public, as well as the fact that the Respondent has already furnished a number of documents (D8 to D11) as evidence to support a closely related argument (section 2.3.4.3, above), none of which, however, was in the event found apt for this purpose. Consequently, it is, from the Board's point of view, at least somewhat improbable that more convincingly relevant evidence would be forthcoming if an adjournment had been granted.

Such an adjournment would, furthermore, vitiate one of the most important purposes of an oral proceedings, which is to enable a final decision to be taken by the Board.

In summary, there was no justification for granting such an adjournment, and the corresponding request was consequently refused.

2.3.5 In the light of the above, the Board finds it credible (a) that the problem addressed by the patent in suit was a practical reality for the skilled person at the priority date of the patent in suit, and (b) that the claimed measures evidently provide an effective solution thereof.

2.4 Novelty

The finding of lack of novelty was based on the presentation of evidence showing that EDTA-free heparin products had been marketed and used as anticoagulants/antithrombotics before the priority date (D5, D6 and D7). The essence of this evidence is the declaration in D5, that heavy metals had not been present in the relevant batch of heparin, so that the final heparin product had been isolated without the application of EDTA. Thus the freedom from EDTA was attributable to the avoidance, from the outset, of the use of any EDTA. This was confirmed by the Respondent in answer to a question of the Board at the oral proceedings.

2.4.1 It is, however, a necessary feature of the use claimed in the patent in suit, on its proper construction, that a starting material containing EDTA as a foreign contaminant is used (section 2.2.6, above). Hence, the process by which the product referred to in D5 to D8 is produced, which has been admitted to exclude the use of EDTA, cannot be novelty destroying for the claim now on file.

2.4.2 The argument of the Respondent, that the heparin medicament referred to in D5 to D8 could, in practice, be indistinguishable from that prepared according to the claim of the patent in suit, thus leading to legal uncertainty in the policing of the patent in suit, cannot affect the issue of the novelty of its use in the preparation of a medicament, and is therefore irrelevant.

2.4.3 The further argument, that the requirement for removing EDTA from an EDTA-containing starting material was a trivial feature which could only confer "formal" novelty, is not convincing, firstly since the feature is a concrete physical requirement admittedly not present in the process by which the products according to D5 were prepared, and secondly, because the presence of the EDTA was the cause of the undesirable haemorrhaging in patients which formed the basis of the technical problem. Thus the distinguishing feature is both characterising for the claimed process over the state of the art and significant in solving the technical problem addressed. It is thus neither formal nor trivial.

2.4.4 Finally, the argument, that the "non-bleeding" effect

was a mere explanation of what happened, which could not form the basis of a new technical teaching, and therefore could not confer novelty, was based on the decision T 254/93 (OJ EPO 1998, 285). According to the latter, the only question arising was held to lie in the explanation of the phenomenon underlying the treatment of patients with a preparation described in the state of the art (Reasons for the decision, point 4.4, last sentence). In the present case, however, the "explanation" is not the feature conferring novelty, but the manner of manufacture of the medicament. Consequently, the findings of the decision T 254/93 are not relevant to the question of novelty in the present case.

2.4.5 Lack of novelty was not alleged in relation to any of the other state of the art cited.

2.4.6 Consequently, the claimed subject-matter is novel.

2.5 Inventive step

It is a helpful and therefore welcome feature of the decision under appeal, that it comprises a proper discussion of inventive step an concludes that a positive finding on that issue would be appropriate, in the case that novelty could be recognised in the subject-matter claimed in the patent in suit.

Since, for the reasons given above, novelty has been recognised in the subject-matter claimed, the only remaining question is whether the Board can confirm the finding of inventive step.

2.5.1 The argument of the Respondent at the oral proceedings, that the "non-bleeding" effect of the heparin materials did not amount to a "technical teaching" as set out in G 2/88, was based on the concept that it was inherent to the use of the prior art heparins prepared without the presence of EDTA. This argument is not convincing, since the relevant criterion set out in G 2/88 is not whether a feature is inherent or not, but rather whether it was made available to the skilled person at the relevant date. The "non-bleeding effect" has not, however, been shown to have been made so available at the relevant filing date of the patent in suit.

2.5.2 Furthermore, the argument that the skilled person would in any case, in applying "Good Manufacturing Practice" ensure that the level of EDTA in an EDTA-contaminated sample of a heparin for medicament use was below that claimed, is not convincing to the Board, since the basis for such action would be a foreknowledge of the role played in the "bleeding effect" by relevant amounts of EDTA contamination, which has not been shown to have existed at the relevant priority date of the patent in suit (section 2.3.4, etc., above).

2.5.3 As to the question of the effect merely being an "explanation" in the sense of the decision T 254/93, such an explanation, whether or not it forms the basis for the recognition of novelty in an otherwise identical system, may well form the basis of an inventive insight in an otherwise novel system. In the present case, the skilled person, faced with the technical problem of the haemorrhaging disorder would

have had no hint from the state of the art, that the relevant bleeding times could be reduced by removing the trace amounts of EDTA to below the relevant threshold of 0.1%. This only becomes an obvious step when the skilled person has arrived at an insight into the cause of the observed haemorrhaging phenomenon. In this connection, the Board fully concurs with the finding, in the decision under appeal, that this was an inventive insight (Reasons for the Decision, point 4.1.1, last sentence).

2.5.4 In summary, the subject-matter of the claim of the patent in suit involves an inventive step within the meaning of Article 56 EPC.

2.6 The Board has furthermore considered the description of the patent as granted, and finds that there is a sufficient degree of conformity between the latter and the claim of the main request for the requirements of the EPC, in particular relating to clarity and support, to be regarded as fulfilled without further amendment.

2.7 Consequently, the main request, which involves the single claim as filed with the Statement of Grounds of Appeal and the description of the patent as granted, is allowable.

3. It is not, therefore, necessary, for the Board further to consider the first or second auxiliary request of the Appellant.

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 with the order to maintain the patent with the single claim submitted as main request together with the Statement of Grounds of Appeal and the description as granted.

The Registrar: The Chairman:

E. Görgmaier C. Gérardin