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Datasheet for the decision of 4 February 2010

Case Number: T 0352/07 - 3.3.02

Application Number: 95942318.7

Publication Number: 0800829

IPC: A61K 31/28

Language of the proceedings: EN

Title of invention:
Antitumor agent potentiator comprising IL-6 antagonist

Patentee:
Chugai Seiyaku

Opponent:
Centocor Ortho Biotech Inc.

Headword:
IL-6 Antagonist/CHUGAI SEIYAKU

Relevant legal provisions:
EPC Art. 123(2), 83

Relevant legal provisions (EPC 1973):
-

Keyword:
"Enabling disclosure (no): Functional feature - result to be achieved; research programme"
"Auxiliary request 5 Remittal (yes): fresh case"

Decisions cited:
-

Catchword:
-

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Case Number: T 0352/07 **-** 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 4 February 2010

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 27 December 2006 revoking European Patent No. 0800829 pursuant to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
J. Van Moer

Summary of Facts and Submissions

I. European patent No. 0 800 829 based on international application PCT/JP95/02769, published as WO 96/20728 and having application No. 95 942 318.7 in the EPO, was granted with 12 claims.

Independent claims 1 and 12 as granted read as follows:

"1. Use of an interleukin-6 (IL-6) antagonist, for the preparation of a medicament for enhancing the effect of an antitumor agent.

12. Use of an IL-6 antagonist and an antitumor agent for the preparation of a composition which has an enhanced antitumor effect with respect to the effect of the antitumor agent alone."

II. Opposition was filed against the granted patent under Article 100(a) EPC (novelty and inventive step) and Article 100(b) EPC (sufficiency of disclosure).

The following documents, among others, were cited during the proceedings before the opposition division and the board of appeal:

(3) EP-A-0 430 193

(5) EP-A-0 399 429

(9) Mallardo, M. et. al., "DNA damaging agents increase the stability of interleukin-1α, interleukin-1β, and interleukin-6 transcripts and the production of the

relative proteins", The journal of biological chemistry, Vol. 269 (1994), No. 21, 14899-14904

(18) Emilie, D. et. al., "Administration of an Anti-interleukin-6 monoclonal antibody to patients with acquired immunodeficiency syndrome and lymphoma: Effect on lymphoma growth and on B clinical symptoms", Blood, Vol. 84 (1994), No. 8 (15 October), 2472-2479

(19) Sachs, L. et. al., "Control of programmed cell death in normal and leukemic cells: New implications for therapy", Blood, Vol. 82 (1993), No. 1 (1 July), 15-21

(22) Hirata, Y. et al., "Characterization of IL-6 receptor expression by monoclonal and polyclonal antibodies", J. Immunol., 143 (1989), 2900-2906

(24) Matsuda, T. et al., "Establishment of an interleukin 6 (IL6)/B cell stimulatory factor 2-dependent cell line and preparation of anti-IL 6 monoclonal antibodies", Eur. J. Immunol., 18 (1988), 951-956

(32) Kakehi, Y. et. al., "Measurement of multidrug-resistance messenger RNA in urogenital cancers; elevated expression in renal cell carcinoma is associated with intrinsic drug resistance", J. Urol., 139 (1988), 862-865 (document (32) was introduced by the board during oral proceedings in view of the fact that it was cited in the description of the state of the art in the patent in suit; page 2, line 23).

III. By its decision pronounced on 16 November 2006 and posted on 27 December 2006, the opposition division revoked the patent under Article 102(1),(3) EPC 1973.

The opposition division held that the set of claims of the main request did not meet the requirements of Articles 123(2) and (3) EPC, the set of claims of the first auxiliary request did not meet the requirements of Article 83 EPC and the set of claims of auxiliary request 2 did not meet the requirements of Article 56 EPC.

It noted that the requirements of Articles 123(2), 83 and 54 EPC were fulfilled by the claims of the second auxiliary request (which is the main request in the appeal proceedings).

Closest prior art was document (9).

There, on the basis that a deregulated secretion of either interleukin-1 or interleukin-6 molecules sustained the abnormal growth of neoplastic cells and since it was shown that the production of interleukin-1β and interleukin-6 was significantly augmented by mitomycin C, it was suggested that down-regulators of interleukin-1β and interleukin-6 activity could be used to counteract these systemic effects of accidental exposures to DNA damaging agents.

In order to enhance the antitumor effect of such DNA damaging agents as mitomycin C or platinum compounds, the skilled person would have looked for means of avoiding the interleukin-6 increase and, additionally, would have been led to use an anti-interleukin-6

antibody or an anti-interleukin-6 receptor antibody in view of document (18), which makes clear that interleukin-6 can prevent malignant cell death induced by cytotoxic cancer therapeutic agents.

IV. The appellant (patentee) lodged an appeal against said decision and filed grounds of appeal, together with a request to maintain the patent according to its main or its auxiliary request (the latter referred to as auxiliary request 1 in this decision). The main request corresponds to the second auxiliary request before the opposition division.

With its letter of 30 December 2009, the appellant submitted two further sets of claims as auxiliary requests 2 and 3, together with further documents.

Claim 1 of the main request differs from claim 1 as granted, in particular with regard to the definitions of the medicament, of the active agent, of a tumor as the disease to be treated and of the interleukin-6-antagonist. It is worded as follows:

"Use of an interleukin-6 (IL-6) antagonist for the preparation of a medicament for enhancing the effect of a platinum compound having antitumor effects or mitomycin C in the treatment of a tumor, wherein the tumor in which antitumor effects are enhanced has an IL-6 receptor and exhibits growth and/or resistance to therapy by using IL-6 as a physiologically active substance and wherein said IL-6 antagonist is an anti-IL-6 antibody or an anti-IL-6 receptor antibody."

In claim 1 of auxiliary request 1, mitomycin C is left out as potential active agent; therefore, the term "or mitomycin C" is deleted.

In claim 1 of auxiliary request 2, the platinum compound as active agent is defined as "cisplatin or carboplatin".

In claim 1 of auxiliary request 3, in addition, the tumor to be treated is defined as "renal cell carcinoma"; the wording of this claim 1 is (amendments as compared to claim 1 of auxiliary request 1 in bold):

"Use of an interleukin-6 (IL-6) antagonist for the preparation of a medicament for enhancing the effect of **cisplatin or carboplatin** having antitumor effects in the treatment of a tumor, wherein the tumor in which antitumor effects are enhanced has an IL-6 receptor and exhibits growth and/or resistance to therapy by using IL-6 as a physiologically active substance, wherein said IL-6 antagonist is an anti-IL-6 antibody or an anti-IL-6 receptor antibody, **and wherein said tumor is renal cell carcinoma**."

V. On 1 February 2010, the board issued a communication, drawing the parties' attention to its opinion that the current requests had to be examined under Articles 123(2) and (3) EPC.

In particular, claims 1 of the current requests referred to "**anti** interleukin-6 antibodies" or "**anti** interleukin-6 receptor antibodies", while the claims and the description as originally filed disclosed

"interleukin-6 antibodies" or "interleukin-6 receptor antibodies" and not **anti-antibodies**.

VI. On 4 February 2010, oral proceedings took place before the board.

VII. During the oral proceedings, the appellant filed auxiliary requests 4, 5 and 6, which were admitted into the proceedings.

The wording of claim 1 of auxiliary request 4 is:

"Use of an interleukin-6 (IL-6) antagonist for the preparation of a medicament for enhancing the effect of cisplatin or carboplatin in the treatment of a tumor, wherein said IL-6 antagonist is an antibody to IL-6 or an antibody to the IL-6 receptor, and wherein said tumor is renal cell carcinoma."

In auxiliary request 5 the antibodies are specifically defined as follows (amendments of claim 1 as compared to claim 1 of auxiliary request 3 in bold):

1. "Use of an interleukin-6 (IL-6) antagonist for the preparation of a medicament for enhancing the effect of cisplatin or carboplatin in the treatment of a tumor, wherein said IL-6 antagonist is **the PM-1 antibody or MH166 antibody**, and wherein said tumor is renal cell carcinoma.

2. The use as set forth in claim 1 wherein said antibody is a PM-1 antibody.

3. The use as set forth in claim 2 wherein said antibody is a humanized PM-1 antibody.

4. Use of an IL-6 antagonist and an antitumor agent selected from cisplatin and carboplatin for the preparation of a composition for the treatment of a tumor, wherein the composition has an enhanced antitumor effect with respect to the effect of the antitumor agent alone and wherein said IL-6 antagonist is the PM-1 antibody or the MH166 antibody to the IL-6 receptor, and wherein said tumor is renal cell carcinoma."

Auxiliary request 6 is restricted to the PM-1 antibody alone.

VIII. The appellant's submissions can be summarised as follows:

The terms "**anti** interleukin-6 antibodies" and "interleukin-6 antibodies" were used synonymously and the skilled person was fully aware of this. He would not have been in danger of doubt whether the "anti interleukin-6 antibody" could be an anti-antibody with an "interleukin-6 antibody" as the antigen.

As far as the decision of the opposition division was concerned, its conclusions with respect to inventive step were incorrect since the basis in document (18) was merely speculative without any sound scientific background.

With respect to new auxiliary request 3 before the board, it was incorrect to regard the treatment of

renal cell cancer with cisplatin as a basis for including the use of this active agent in the problem to be solved. In the time before the priority date, almost every chemotherapeutic agent had been tested as a means of treating this kind of cancer, most of them with little success.

In addition, the arguments of the respondent concerning Article 83 EPC were irrelevant:

As far as the treatment of tumor cells was concerned, it was clear from the state of the art and from post-published documents that all known tumors with the claimed feature, i.e. which "have an interleukin-6 receptor and exhibit growth and/or resistance to therapy by using interleukin-6 as physiologically active substance", were receptive to the claimed therapy.

In addition, most of the platinum compounds being used as a medicament and most of the antibodies as defined worked according to the features of claim 1 as requested. Frequent failures were no reason to doubt sufficiency of disclosure.

Suitable interleukin-6 antibodies were, as a first step, identifiable on the basis of the stipulation in the description that they had to block signal transmission by interleukin-6 and inhibit the biological activity of interleukin-6 and, in the second step, a majority of them proved to exhibit enhancing abilities as set out in the claims of the current requests.

In particular, it was clear from the patent in suit that the antibodies PM-1 and MH166 had been used in the examples. Each of the two documents cited in the two examples to define the antibodies used disclosed the selection of two stable antibodies, but both documents clearly showed that only one of them had proved to be active in blocking signal transmission within the meaning of the patent. The methods used for this assessment were exactly the same methods as a skilled person would have adopted, based on his common general knowledge, as the relevant tests for the blocking of the interleukin-6 signal and inhibition of the biological activity of interleukin-6 required in the patent.

Moreover, the preferred antibodies PM-1 and MH166, as well as various other suitable antibodies, were already known at the date of priority and some were even commercially available. They could easily be used to carry out the invention. Knowing these antibodies and their structure enabled the person skilled in the art to develop various other antibodies in accordance with the claimed invention by repeating their binding regions and varying the other regions of these protein bodies in any suitable way.

Finally, the subject-matter of the auxiliary requests was restricted step by step to particular active substances, to a particular kind of tumor and to particular antibodies and, therefore, at least in this way any objections under Article 83 EPC were overcome.

IX. The respondent's arguments can be summarised as follows:

The arguments of the appellant with respect to Article 123(2) EPC and admissibility of the requests submitted during the oral proceedings before the board were not contested.

As far as Article 83 was concerned, the respondent pointed out that claim 1 of the main request and auxiliary requests 1 to 4 contained one or more of three results to be achieved: the skilled person could not find the active substance having antitumor effects, the tumor to be treated or the antibodies that would enhance the antitumor effects without undue burden.

In particular, the patent contained no purposive teaching as to how to find the antibodies falling within the scope of these claims. Interleukin-6 fulfilled many functions in an organism. Moreover, it exhibited more than one binding site (epitope) active to antibodies. Based on the features set out in the claims, which did not take into account all the different functionalities following from these facts, all antibodies to interleukin-6 or interleukin-6 receptor were potential candidates which might exhibit the functional feature of enhancing antitumor effects of (certain) active agents; in order to find the enhancing ones, the person skilled in the art had to test one after the other for the enhancement according to the principle of trial and error without any conclusive guidance in direction of successive experiments.

Even the definition in the description, i.e. that antibodies had to block interleukin-6 signalling or inhibit the biological activity of interleukin-6 and could therefore be preselected, was no real guidance for the skilled person. He could not even find definite disclosure in the claims and description as to which test had to be applied to find the antibodies exhibiting exactly this feature, not qualitatively and even less so quantitatively.

In addition, the examples in the patent were of no use, because it was not even clear which antibodies had been used by the inventor. In the patent in suit, the appellant had tried to characterise the antibodies used by citing two scientific articles (documents (22) and (24)), but there was no unambiguous link between any of the antibodies prepared according to the cited documents and the antibody ultimately used. It was even far less justified to infer from these citations that the specific tests used in the cited documents were exactly the tests to be carried out according to the invention to find the antibodies blocking interleukin-6 signalling in order to preselect antibodies suitable as an enhancer. One of the tests was a simple test for activity in DNA production and the other one a competitive test; each of them represented only one of several possibilities arbitrarily applied by the authors with no link to the selection test to be suggested in the description as a means of carrying out the teaching of the current claims.

In addition, the subject-matter of the requests was obvious in the light of documents (9), (18), (19) or (32), whether considered in isolation or in combination

(document (32) was introduced by the board as potential closest prior art).

There were no additional or specific objections to the appellant's auxiliary requests 4 to 6 submitted during the oral proceedings.

X. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the sets of claims filed as main request or auxiliary request 1 with letter of 7 May 2007 or on the basis of auxiliary request 2 or 3 filed with letter of 30 December 2009 or on the basis of auxiliary request 4, 5 or 6 submitted during the oral proceedings.

XI. The respondent (opponent) requested that the appeal be dismissed.

Reasons for the decision

1. The appeal is admissible.

2. Since the amended claims filed by the appellant as auxiliary requests 4 to 6 are a response to the arguments set out during the oral proceedings and because the respondent did not raise any objections in this regard, they are admitted into the proceedings.

3. *Main request and auxiliary requests 1 to 3; Article 123(2) EPC*

In the light of the state of the art on file, the board is convinced that the amended terms "**anti** interleukin-6 antibody" and "**anti** interleukin-6 receptor antibody" are synonymous with the originally filed terms "interleukin-6 antibody" and "interleukin-6 receptor antibody" and that on this basis there is no doubt for the skilled person that the amended claim does not include "**anti**-antibodies", which would constitute different subject-matter. Therefore, the board accepts the claims of the main request and auxiliary requests 1 to 3 as not extending beyond the content of the application as filed.

The question whether reversing these amendments by reintroducing the originally filed terms "interleukin-6 antibody" and "interleukin-6 receptor antibody", as the appellant tried to do by submitting auxiliary requests 4 to 6 during the proceedings, was allowed under the provisions of the EPC did not have to be decided, as can be seen from point 5 of this decision.

4. *Main request and auxiliary requests 1 to 3; requirements of Article 83 EPC*

4.1 Article 83 EPC requires that the invention be disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. For this requirement to be fulfilled, the skilled person must, *inter alia,* be in a position not only to reproduce the examples as disclosed in the patent in suit, but also

to largely reproduce the claimed teaching successfully beyond the examples but within the scope of the claims.

In the present case, claim 1 of all requests corresponds to the second medical use format containing as predominant features

- at least two active components,
- the medicament,
- and the illness to be cured.

4.2 *Main request and auxiliary request 1; the active substance the effect of which is to be enhanced*

Concerning the active substance, these claims correspond to the use of a platinum compound having antitumor effects.

Platinum chemistry has already produced well-known anticancer agents and, for years, has been the subject of ongoing research to find new embodiments exhibiting therapeutic effects in tumors. Thus, there is no scientifically closed list of known substances of this kind.

Consequently, the functional feature "platinum compound having antitumor effects" characterises a full research programme in itself and, therefore, cannot constitute a feature characterising a teaching which is sufficiently disclosed for the skilled person to carry it out.

In addition, there are the other functional features concerning the tumor to be treated and the antibodies to be used, which are dealt with in the context of auxiliary requests 2 and 3.

4.3 *Auxiliary request 2; the tumor to be treated*

With respect to the disease to be treated, the use of an enhanced active agent for the preparation of a medicament is claimed, wherein the tumor in which antitumor effects are enhanced has an IL-6 receptor and exhibits growth and/or resistance to therapy by using IL-6 as a physiologically active substance.

Again, it is the subject of ongoing scientific research to investigate conditions favouring the growth of tumor cells as a target for treating correlated diseases. Sustained proliferation of cancer cells on the basis of interleukin-6 is a well-known phenomenon in this context (see for instance document (3), page 2, lines 30 to 31, page 2, line 48, to page 3, line 3; or document (5), page 2, lines 17 to 19). However, scientific research in this field has not yet come close to producing a closed list of kinds of tumors involved in this mechanism.

Once again, this functional feature characterises a full research programme in itself and, therefore, cannot constitute a feature characterising a teaching which is sufficiently disclosed for the skilled person to carry it out.

In addition, there is the other functional feature concerning the antibodies, which is dealt with in the context of auxiliary request 3.

4.4 *Auxiliary request 3; the antibodies to be used*

4.4.1 The claim is directed to the use of an anti-IL-6 antibody or an anti-IL-6 receptor antibody for the preparation of a medicament for enhancing the antitumor effect of cisplatin or carboplatin wherein the tumor in which antitumor effects are enhanced is renal cell carcinoma.

4.4.2 The skilled person, when carrying out the claimed teaching, has to use antibodies to interleukin-6 or interleukin-6 receptor functionally defined by their intended result, i.e. the enhancement of antitumor activity (see, for instance, text of claim 1 and examples in the description of the patent in suit).

With various biological functions (see, for instance, document (5), page 2, lines 14 to 16; or document (22), page 2900, left hand column, first paragraph after the abstract) and at least two different epitopes to bind antibodies (see document (22), page 2900, abstract, lines 10 and 11), there is an indefinite pool of substances which - as antibodies as defined in claim 1 - can act as such an enhancer. In the absence of a teaching which could point the skilled person in the direction of success in case of failure to find enhancement in a particular antibody, he has to test one after the other according to the principle of trial and error.

In these circumstances, the teaching of the patent in suit exhaustively defines a problem but not its solution.

This amounts to a research programme in itself and cannot be the basis of a teaching which can be carried out by the skilled person.

4.5 In these circumstances, the further arguments of the appellant cannot succeed either:

4.5.1 The appellant argued that preferred embodiments of the claimed invention as set out in the claims (use of antibody PM-1) and in the description (e.g. use of antibody MH166) according to the cited documents (22) and (24) and even other anti interleukin-6 antibodies or anti interleukin-6 receptor antibodies were well known at the priority date of the application. In addition, the person skilled in the art could derive from these multiple other antibodies. Therefore, he could carry out the claimed invention.

However, the subject-matter of the claims is much broader and these broad claims ultimately comprise the use of antibodies not yet invented.

In contrast to these broad claims, variations of the known antibodies using their structural information can only result in the use of a limited group of similar antibodies. Guidance on how to derive from this information knowledge leading to purposive experiments to find the large range of unknown antibodies within the meaning of the claimed teaching is not given and, thus, the information on the known antibodies is of no use in answering the question whether this teaching can be carried out as required under Article 83 EPC with respect to the claimed but as yet unknown antibodies.

4.5.2 The appellant submitted that there was guidance on how to select candidates which might be useful antibodies in the description.

The teaching was that, in a first step, the skilled person had to find an antagonist to interleukin-6 or interleukin-6 receptor which "may be of any origin provided it blocks signal transmission by IL-6, and inhibits the biological activity of IL-6" (page 12, lines 32 to 34 of the translation of the international application filed on 29 July 1997); then, in a second step, he had to test whether such an antibody enhanced the effect of a chemotherapeutic agent on a tumor as defined in the claims.

(a) On the one hand, there is a contradiction between the claims and this teaching. While, according to the claims, any antibody to interleukin-6 or interleukin-6 receptor can be used, the description appears to restrict the useful antibodies rigorously to those blocking signal transmission by interleukin-6 and inhibiting the biological activity of interleukin-6.

In such cases, the board usually accepts the broader teaching as taking precedence, while regarding the narrower teaching in the description as an alternative or mere embodiment defined in a restricted way.

Therefore, the finding under point 4.4 of this decision remains conclusive and decisive.

(b) On the other hand, even additional assessment of the teaching restrictively defined by the disclosure in the description leads to the following arguments and conclusions:

There is no dissent that the person skilled in the art, albeit laboriously, can produce antibodies to interleukin-6 or interleukin-6 receptor. On this basis, the problem is how to select those "inhibiting the biological activity of interleukin-6 and inhibiting the biological activity of interleukin-6" within the meaning of the claimed teaching.

The first question is what kind of biological activity is meant (for possible selections, see for instance document (5), page 2, lines 14 to 16; or, as an alternative, document (22), page 2900, left hand column, first paragraph after the abstract). The second question arises when looking for a means of testing for either of the activities, while the third question concerns the extent to which the activity has to be blocked - for instance 90%, 95% or 99% - for an antibody to be a candidate within the meaning of the claimed invention.

However, no general teaching can be found in the description as to how to test whether any antibodies selected from well-known procedures would have this feature. In addition, the appellant has not claimed that the skilled person would be sure what to do from his common general knowledge and, in particular, has not produced any

evidence in support of such a claim. Nor is there any general statement that any method disclosed in the examples has to be used. Finally, not even in the examples is a particular method explicitly described.

(c) In the opinion of the appellant, the citation of documents (22) and (24) in the examples made clear by itself, what tests were to be used to select antibodies blocking interleukin-6 signalling within the meaning of the patent in suit.

Closer investigation, however, reveals that there is no evidence in these documents that the tests used were of general importance in the art or, clearly and unambiguously, the only or by far decisive ones.

From the wording in document (24) under paragraph 3.3, bridging pages 953 and 954, or document (22) in the discussion of the results starting on page 2901, it must be concluded that the tests used there are just those chosen arbitrarily from a whole range of suitable experiments. In addition, in document (5) is disclosed that merely one possible test has been used and that there are also others (see page 4, lines 45 to 48).

(d) Thus, even when reading documents (22) and (24), the skilled person has no idea how to test for the feature set out in the very wording of the teaching that an antagonist to interleukin-6 or interleukin-6 receptor should be selected that

"may be of any origin provided it blocks signal transmission by interleukin-6, and inhibits the biological activity of interleukin-6".

That any method arbitrarily used in the referenced documents (22) and (24) was the method of ensuring that an antibody would block signal transmission by interleukin-6 and inhibit the biological activity of interleukin-6 within the meaning of the claimed invention could not be recognised by the skilled person and thus, with respect to the claimed invention, cannot serve as a basis for a clear and complete teaching under Article 83 EPC.

(e) The attempt of the appellant to define the test on the basis of the assumption that all the activity of interleukin-6 and not a particular one should be blocked by the antibody to be selected does not help either. On the contrary, the documents on file set out a plurality of tests directed to the measurement of specific activities but not even one for measuring the blocking of all activities of interleukin-6 at once.

5. *Auxiliary request 4; requirements of Article 83 EPC*

As follows from the findings set out under point 3 of this decision, and since only general formulations commenting on some features were replaced by other definitions which nevertheless include these general formulations, the wording of claim 1 of auxiliary request 4 is synonymous with that of auxiliary request 3 and thus cannot be allowed under Article 83 EPC for the same reasons.

6. *Auxiliary request 5*

6.1 The respondent raised no further objections to auxiliary request 5, neither with respect to its introduction during the oral proceedings, nor on its merits.

6.2 Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered at two instances, it is recognised that any party may be given an opportunity for two readings of the important elements of a case.

In the present case, the features of auxiliary request 5 as now amended are found to constitute a new situation in the form of the new claims, which should now be examined on their own merits and under all aspects of the EPC.

7. Accordingly, the invention as based on the description as filed in its translation on 29 July 1997 and as claimed in the main request and auxiliary requests 1 to 4 of the appellant is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

Since subject-matter of auxiliary request 5 constitutes a fresh case as compared with the subject-matter discussed in the oral proceedings before the opposition division, the board exercises its discretion under Article 111 EPC and remits the case to the first instance.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution on the basis of auxiliary request 5 submitted during oral proceedings.

The Registrar: The Chairman:

N. Maslin U. Oswald