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Datasheet for the decision of 18 June 2007

Case Number: T 0188/05 - 3.2.05

Application Number: 95937462.0

Publication Number: 0787020

IPC: A61M 29/00

Language of the proceedings: EN

Title of invention:
Stent and method of manufacture

Patentee:
Medtronic AVE, Inc.

Opponent:
Boston Scientific Scimed, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 84, 123(2)
RPBA Art. 10a, 10b, 18

Keyword:
"Admissibility of late filed submissions (no)"
"Clarity (yes)"
"Extension beyond the content of the application as filed (no)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0188/05 - 3.2.05

D E C I S I O N
of the Technical Board of Appeal 3.2.05
of 18 June 2007

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 3 December 2004 concerning maintenance of the European Patent No. 0787020 in amended form.**

Composition of the Board:

Chairman: W. Zellhuber
Members: W. Widmeier
C. Rennie-Smith

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the interlocutory decision of the Opposition Division maintaining European patent No. 0 787 020 in amended form.

II. Oral proceedings before the Board of Appeal were held on 18 June 2007.

III. The appellant requested that the decision under appeal be set aside and that the European patent No.0 787 020 be revoked or that either the proceedings be continued in writing or the case be remitted to the first instance.

IV. The respondent (patent proprietor) requested, as main request, that the appeal be dismissed or, as auxiliary measure, that the decision under appeal be set aside and that the patent be maintained on the basis of the sets of claims according to auxiliary requests 1 to 9 filed on 18 May 2007.

V. Independent claims 1 and 8 of the main request read as follows:

"1. A stent delivery system comprising:
a balloon catheter (30) having a catheter body, a balloon (36) positioned upon said catheter body and a portion defining an inflation lumen (34) for selectively inflating and deflating said balloon;
a stent (20) having a generally tubular shape and a first diameter for intraluminal delivery, said stent

being expandable to a second diameter for deployment in a vessel;
wherein said stent (20) is mounted on said balloon (36) of said balloon catheter for implantation in a vessel within the human body, said balloon at least partially conforming to the generally tubular shape of said stent; and characterised in that
said stent is crimped onto said balloon to have an interior diameter D_1 and wherein portions of said balloon protrude to have an interior diameter greater than D_1."

"8. A method of manufacture of a stent delivery system comprising the steps of:
mounting at least one stent (20) on a balloon (36) of a balloon catheter (30);
covering the mounted stent with holding means (42, 44) adapted to prevent expansion of the mounted stent;
heating the mounted stent within the holding means to cause the balloon to conform to the shape of the stent, and
cooling the balloon catheter within the holding means so that the balloon adheres to the stent;
characterised in that
the mounting step comprises the step of crimping the stent (20) onto the balloon (36) such that it has an interior diameter D_1;
and wherein portions of the balloon expand to an interior diameter greater than D_1 during the heating step and remain at an interior diameter greater than D_1 after the cooling step."

VI. The following documents were in particular referred to in the appeal procedure:

A: WO 95/33422

D: US-A-4,800,882

H: Gianturco-Roubin Flex-Stent™ Coronary Stent, Instruction Manual, Cook Cardiology, 1997

I: Minutes of a hearing before the United States Department of Health and Human Services, Public Health Service, Food and Drug Administration, Circulatory System Devices Panel, 11 May 1992

J: Gianturco-Roubin, Coronary Stent, Technical Information, Suggested Instructions for Placement, Cook Cardiology, 1990, supplemented by photographs of a stent and a copy of a package label

J1: Declaration of Thomas A. Osborne of 17 June 2004

J2: Declaration of James R. Chiapetta of 1 September 2004

R: Declaration of Karl A. Jagger of 16 May 2007

S: Declaration of John Chen of 16 May 2007

VII. The appellant's arguments can be summarized as follows:

Submission of 14 June 2007

The novelty objection raised in its letter of 14 June 2007 was a necessary response to the respondent's new requests filed on 18 May 2007. This is not a new

objection, since from the outset of the opposition proceedings lack of novelty was a ground of opposition and reliance was placed on the Gianturco-Roubin stent. A novelty case based on that stent was made in the notice of opposition, page 17, paragraph IV.4, in view of document J using photographs of the stent. Declarations J1 and J2 were filed showing the availability of the stent. Thereafter there was no further necessity to rely on that stent so it was not discussed at the oral proceedings before the Opposition Division. On appeal the appellant had relied primarily on Document A but now, in response to one of the patentee's recent requests which referred to folded wings, the appellant now relied in addition to the previous photographs on the stent itself. It was correct that, as the patentee argued (see VIII below), similar requests had been filed in the opposition proceedings but they had been withdrawn in the oral proceedings. The submission of 14 June 2007 was highly relevant and should be admitted into the proceedings since otherwise an invalid patent might be maintained: the board has an obligation to admit relevant evidence however late if the validity of a patent is thereby questioned. There is no case law showing this cannot be allowed and the Rules of Procedure of the Boards of Appeal are only guidelines. The opponent must have an opportunity to reply to the patentee since otherwise the balance would be shifted in the patentee's favour. If this submission takes the respondent by surprise, the respondent took the appellant by surprise by changing its requests in the oral proceedings before the Opposition Division.

Main request

An interior diameter of the balloon is not defined in claim 1 of the main request so that it is not possible to compare this diameter with another diameter, in particular, with the interior diameter D_1 of the stent. The balloon is folded so that it is not clear where the interior diameter of the balloon is to be measured. This diameter can be measured at many positions all of which have a different diameter. Moreover, the expression "diameter" relates normally to a circular subject. However, the balloon is not circular in its frozen state. For all these reasons the subject-matter of claim 1 lacks clarity. The same applies to the subject-matter of claim 8.

The application as filed mentions neither an interior diameter of the balloon nor a relation of diameters. The drawings may not be used as a basis for the interior diameter of the balloon because these drawings are purely schematic and they do not show diameters. Moreover, Figures 4 to 6, which the respondent considers to show these diameters and their relation, correspond to the Boneau stent which is a very special prior art stent. No generalisation can be made on the basis of this stent. If dimensions are to be taken from Figures 4 to 6 then they belong to the Boneau stent. The features of claim 1 must be disclosed in the application as filed with respect to any stent rather than only for a particular one. Thus, the subject-matter of claim 1 extends beyond the content of the application as filed.

Document A discloses a stent including the feature of the characterising portion of claim 1. The process of encapsulation of the stent described on page 14, lines 14 to 36, in connection with Figure 7 is the same process for encapsulation described in the patent in suit and, therefore, must give rise to the same result. A person skilled in the art would recognize that any expansion of a balloon sufficient enough to urge a balloon towards the inner wall of a holding means, ultimately depressing the stent into the balloon, would also cause the relatively thin balloon to expand and fill at least some of the spaces between the stent and the sheath, resulting in a balloon having an interior diameter greater than the interior diameter of the stent. Also the description on page 5, line 28, to page 6, line 2, of document A, confirms that the diameter of the balloon must be greater than the diameter of the stent. Documents R and S further show that the balloon material used in document A necessarily results in protrusions as specified in claim 1. Thus, document A is novelty destroying for the subject-matter of claim 1 as well as of claim 8.

Document D shows the Gianturco-Roubin stent. Figure 3 of this document shows balloon portions at the ends of the stent which have a diameter greater than the diameter of the stent. Claim 1 does not specify where the interior diameter of the balloon is to be measured. Thus, the configuration shown in Figure 3 of document D is in accordance with the wording of claim 1. The photographs of document J, which were taken from a Gianturco-Roubin stent which was available before the priority date of the patent in suit, show the protrusions of the balloon beyond the stent wires.

Since the stent wires are at least twice as thick as the balloon material, it follows that the interior diameter of the balloon protrusions is greater than the interior diameter of the stent. Also document I, cf. page 45, refers to the Gianturco-Roubin and the fact that the balloon is a little bit larger in diameter than the diameter of the stent. The Gianturco-Roubin stent is also the subject of document H where on pages 3 to 5 the stent is shown and described and where on page 43 reference is made to the thickness of the wires. Consequently, documents D, I and J are novelty destroying for the subject-matter of claim 1. Even if these documents are not admitted for the discussion of novelty of claim 1 of the main request, they prove at least that the subject-matter of claim 1 does not involve an inventive step.

VIII. The respondent's arguments can be summarized as follows:

Submission of 14 June 2007

The appeal procedure is a new procedure so that all facts and evidence must be presented with the notice of appeal. The Notice of Opposition did contain an objection based on documents H, I and J but that was never pursued thereafter and there was never any previous reliance on the Gianturco-Roubin stent itself. No novelty objection on the basis of documents H, I and J was made in the Grounds of Appeal. Moreover, document H and the photographs of document J do not constitute prior art. It is unsure whether Document I, a transcript, is dated before or after the priority date. The new photographs of the Gianturco-Roubin stent are not produced as part of any evidence, just included in

the text of a letter containing written arguments. Even for a submission made in the month after the final deadline for submissions the appellant's submission is very late indeed. If it was indeed a response to a new request referring to folded wings, that should have been no surprise to the appellant as there were such requests in the opposition proceedings and indeed wings were mentioned in dependent claims of the patent as granted. The new submission of the appellant should therefore not be admitted. If the new objection is held to be admissible, that would be a ground for remittal of the case to the first instance.

Main request

Although not defined in terms of a specific value, it is clear what is meant in claim 1 by the interior diameter of the stent because the stent is circular. Claim 1 defines that portions of the balloon have an interior diameter greater than the interior diameter of the stent. It is irrelevant where the interior diameter of the balloon is measured. When the portion of the balloon where it is measured has an interior diameter greater than the interior diameter of the stent then it falls under the scope of claim 1 and claim 8. It follows that these claims are clear.

The passage on pages 4 to 6 of the application as filed discloses, as contrast to the prior art (interference fit), a stent encapsulation according to the invention wherein the balloon is expanded and protrudes into the spaces to fill the spaces between the stent and the sheath and, consequently, portions thereof have an interior diameter greater than the interior diameter of

the stent. The wording of claim 1, although different from the wording of pages 4 to 6, is perfectly consistent with this part of the description and with Figures 4 to 6 which are a demonstration of the encapsulation according to the invention. Furthermore, the description is not restricted to the Boneau stent. This stent is used as an example to which the invention may be applied. Thus, there is no extension beyond the content of the application as filed.

Document A is prior art in accordance with Article 54(3) EPC. As such it must be read strictly as novelty is concerned. According to the encapsulation of document A, the outer surface of the balloon material is softened and the stent is pressed into the softened material up to the half of its thickness (cf. page 10, second paragraph), which clearly means that the interior diameter of the balloon is not affected. As document A alone must be considered when assessing novelty of the subject-matter of claim 1, documents R and S are irrelevant. It follows that the characterising features of claim 1 and 8 are not disclosed in document A.

It is not at all clear where the photographs of document J originate from and of which date they are. Moreover, they do not show the interior diameter of the balloon and, therefore, cannot prove that this diameter is greater than the interior diameter of the stent. It also is uncertain which stent was subject of document I. Anyway, none of the documents I and J is more relevant than the "interference fit" prior art acknowledged in the patent in suit. The subject-matter of claims 1 and 8 thus involves an inventive step.

Reasons for the Decision

Main request

1. *Admissibility of late filed submissions*

The respondent objected to the admissibility of the submissions in the appellant's letter of 14 June 2007, and in particular pages 3 to 7 thereof in which it was argued that the subject-matter of claim 1 as maintained by the Opposition Division was not novel over the Gianturco-Roubin Flex-Stent. These submissions contained nearly four pages of argument referring to previously filed evidence (documents H, I, J, J1 and R) and to two-dimensioned photographs not previously filed. The new photographs, described by the appellant as "better" (than, presumably, those in document J), were not the subject of any statement or other evidence as to how or when they were prepared but were just included in the body of the letter which also indicated that a sample of this stent would be produced for inspection at the oral proceedings. These submissions were thus a mixture of new argument relating to existing evidence and new argument relating to new but imprecisely presented evidence. The conclusion of these new submissions was the allegation that claim 1 as maintained at first instance lacked novelty in view of the prior use or prior availability of the Gianturco-Roubin Flex-Stent.

The Board cannot agree with the appellant that it has an obligation to admit relevant evidence however late if the validity of a patent is thereby questioned. The

case law of the boards of appeal establishes quite clearly that the first instance and the boards of appeal have a discretion to admit late-filed submissions and that the exercise of this discretion depends on the facts of each case but pertinent matters may include the relevance of the new material, whether it could have been produced before and if so why it was not, whether other parties and/or the Board itself are taken by surprise, and how easily they can and whether they have adequate time to deal with it. Such considerations arise in relation to any late filed submissions, in other words any submissions filed after the end of the nine month opposition period (see generally "Case Law of the Boards of Appeal of the European Patent Office", 5th Edition 2006, pages 388 to 406).

In relation to appeal proceedings, there are additional constraints arising from the fact that this is a judicial procedure (*loc cit*, page 391) and from the need to comply with the Rules of Procedure of the Boards of Appeal ("RPBA"). In particular Article 10a(2) RPBA requires appellants and respondents to present their complete cases in, respectively, their statements of grounds of appeal and replies; and Article 10b RPBA makes any subsequent amendment by a party of its case a matter for the Board's discretion; provides that such discretion may be exercised in view of inter alia the complexity of the new subject-matter, the current state of the proceedings, and the need for procedural economy; and also provides that amendments sought to be made to a party's case after oral proceedings have been arranged shall not be allowed if they raise issues which the Board or the other party cannot reasonably be

expected to deal with without an adjournment of the oral proceedings. Contrary to the appellant's argument, the RPBA (see in particular Article 18) are not just guidelines but legislation enacted according to the EPC and must be observed by the Boards and by parties to appeal proceedings (see generally Article 23(4) and Rule 10(3) EPC and, as regards the particular Articles of the RPBA just cited, the decision of the Presidium of the Boards of Appeal of 28 October 2002 in the Annex to Administrative Council document CA/133/02 and the decision of the Administrative Council of 12 December 2002 at OJ EPO 2003, 60).

It was common ground between the parties that the appellant's submissions in question were filed very late in the proceedings. They were in fact filed by fax on the evening of 14 June 2007; the oral proceedings were on 18 June 2007 so, as two of the intervening days were non-working days, the respondent and the Board had only one working day to consider them. The respondent stressed that, even in relation to the deadline set by the Board in its communication of one month before the oral proceedings, the date of filing was very late. That communication set a limit of one month before the oral proceedings, referred to the Board's discretion to disregard late filed material and to point 2.5 of the "Guidance for parties to appeal proceedings and their representatives" (OJ EPO 2003, 419 to 430) which refers the reader directly to Article 10b RPBA (see the previous paragraph above).

As appears from VII and VIII above, there was much argument from the parties as to whether the content of the appellant's late submissions was in itself new or

not, whether or not they can be seen as a proper response to the respondent's requests filed on 18 May 2007, whether or not the new submissions took the respondent by surprise and, if so, whether that was justified by an earlier surprise. The Board sees no need to decide between each and every one of these competing arguments because the file itself shows the following. First, while the appellant did in its grounds of opposition make attacks on claim 1 of the patent in suit as granted on the basis of Document H with reference to Document I and on the basis of Document J (all those documents being said to relate to the Gianturco-Roubin stent), those attacks were not maintained in the first instance proceedings, the decision under appeal refers only to a novelty attack based on Document A, and in the appellant's grounds of appeal the only novelty attack was also so based. Second, none of the previous novelty attacks relating in any measure to the Gianturco-Roubin stent relied on prior use of the stent itself. Third, as the appellant candidly admitted at the oral proceedings, it had previously relied only on photographs of the Gianturco-Roubin stent and not on the stent itself which it now wished to produce. Fourth, the additional photographs included with the new submissions were also new evidence produced for the first time. In summary, there was a new novelty case, similar to but different from some such attacks made before but not maintained, based on newly alleged facts and, although supported in part by existing evidence, also supported by new evidence. While understandably seeking to link this new attack to the respondent's recently-filed new requests, the appellant clearly regarded it as potentially

destructive of the patent generally - its new submissions on this point concluded with the statement:

"Accordingly, the subject-matter of claim 1 as maintained by the Opposition Division not only lacks novelty vis-à-vis document A but also in view of the Gianturco-Roubin Flex-Stent."

That being the appellant's case, the question which inevitably arises is why the appellant did not make this case, and introduce its new evidence, at an earlier stage? The appellant referred at the oral proceedings to photographs in document J and the declarations filed in the opposition proceedings which showed that the Gianturco-Roubin stent was available before the priority date of the patent, an apparent reference to the declarations J1 and J2 of Mr Osborne and/or Dr Chiapetta both filed on 6 September 2004. The latter declaration shows that Dr Chiapetta, an employee of the appellant, had a sample of the Gianturco-Roubin stent in his possession in April 2003 when he gave it to another employee on 23 April 2003 to take the photographs appearing in document J, and that she gave it back to him thereafter. It appears accordingly that, at any time in the last four years, the appellant could have produced either the additional photographs and/or the actual stent in evidence. Instead however, as is almost common ground, arguments based on the Gianturco-Roubin stent were not pursued (as the respondent put it) or not necessary (as the appellant put it).

The Board cannot exercise its discretion in favour of a party which, while having in its possession the further evidence it now seeks to introduce and which it now

says provides a total anticipation, did not file that evidence and did not consider it necessary even to rely on the related evidence it had already filed. Moreover, the appellant's new submissions would, if admitted into the proceedings, amend the appellant's case by raising issues which the Board and the respondent could not reasonably be expected to deal with without an adjournment of the oral proceedings. Accordingly they should not be admitted into the proceedings pursuant to Article 10b(3) RPBA. This does not, as the appellant argued, shift the balance in favour of the respondent; rather, it avoids shifting the balance in favour of the appellant by allowing it to benefit from a procedural irregularity. The appellant's submissions of 14 June 2007 are therefore not admitted into the proceedings.

2. *Article 84 EPC*

Claim 1 specifies that the stent has an interior diameter D_1. Although this diameter is not directly shown in the drawings by a drawing line designated with "D_1", it is clear to a person skilled in the art that the interior diameter of the stent is the diameter of a circle which is tangent to the stent wires inside of the stent. Claim 1 further specifies that portions of the balloon protrude to have an interior diameter greater than D_1. Although the balloon in its frozen state does not have a circular shape, it is clear to a person skilled in the art that the interior diameter of the portions of the balloon is the distance from the inside of the peak of a protrusion of the balloon via the centre-axis of the stent to the inside of the peak of the opposite protrusion of the balloon. Thus, both diameters specified in claim 1 can unambiguously be

identified. The interior diameter of the balloon portions thus also can be identified if the balloon is folded as shown in Figures 4 to 6 of the patent in suit at four of the eight protrusions. Claim 1 does not specify that all portions are protruding so far that the resulting interior diameter of all portions is greater than D1. The definition of claim 1 is already met if at least two balloon portions protrude sufficiently into the space between two stent wires.

The Board is therefore satisfied that claim 1 as well as claim 8 meet the requirements of Article 84 EPC.

3. *Article 123(2) EPC*

Although the wording of the characterising portion of either claim 1 or of claim 8 is not as such that used in the application as filed, it is clear from page 4, line 15, to page 6, line 13, of this application (PCT publication), that the positional stability - which according to page 5, lines 11 to 17 of the application as filed is the problem to be solved by the invention - is achieved by expanding the balloon during the heating step to the extent that it forms protrusions in the spaces between the stent wires and by keeping the balloon in this expanded state. This process is illustrated in Figures 4 to 6 of the application as filed, Figure 6 showing the stent in its final state. Although these figures are schematic drawings, they unambiguously disclose together with the above cited passages of the description that the interior diameter of portions of the balloon is greater than the interior diameter of the stent. These figures, although stated on page 11, lines 3 to 5, of the application as filed

to show the Boneau stent, are not be interpreted as prior art. They are to be interpreted as demonstrating the application of the invention to a prior art stent such as the Boneau stent. Thus, Figures 4 to 6 are clearly to be identified as an example of the invention and thus they may form the basis for amendments. It is also clear from the description (cf. in particular page 13, lines 7 to 31 and page 16, lines 32 to 34) that the process shown in Figures 4 to 6 in combination with the Boneau stent is not restricted to this particular stent but that the invention is also applicable to other stents so that the amendment of claims 1 and 8 on the basis of the example represents an intermediate generalisation based on the disclosure of the application as filed.

The Board is therefore satisfied that the features of the characterising portions of claim 1 and 8 do not extend the subject-matter of the claims beyond the content of the application as filed so that the requirement of Article 123(2) EPC is met.

4. *Novelty*

Document A discloses that, in order to achieve positional stability of the stent, the exterior wall of the balloon is softened and the stent is pressed into the balloon material advantageously in a depth corresponding to from one twentieth to one half of the stent material thickness (cf. page 6, lines 9 to 17; page 10, lines 19 to 23, and 30 to 34; page 11, lines 1 to 9, and 24 to 32; page 13, line 30, to page 14, line 12) so that the balloon material is deformed and reduced in thickness by the stent wires (cf. Figures 5,

6A and 6B). There is no indication that the constellation should be a different one in the process described in the passage on page 14, lines 14 to 36, of document A. On the contrary, also that passage refers to softening of the catheter surface and pressing the stent into the surface. Thus, document A does not disclose or hint at expansion of the balloon so that it forms protrusions between the stent wires to such an extent that the interior diameter of the protrusions is greater than the interior diameter of the stent.

Documents R and S refer to certain stent balloon materials and their properties and conclude that the balloon of document A must necessarily protrude beyond the interior diameter of the stent. However, document A does not disclose the thickness of the balloon material. It only discloses that it is selected from a number of elastomeric polymers, preferably polyurethane, and that it may be reinforced by fibres of non-elastomeric thermoplastic material such as polyethylene or polyethylene terephtalate in order to prevent expansion of the balloon beyond a pre-specified limit (cf. page 16, lines 8 to 21). Thus, the implicit disclosure of document A, which the appellant concludes from documents R and S, is only speculation. Document A does not therefore disclose the features of the characterising portions of claims 1 and 8. For this reason, the subject-matter of claims 1 and 8 is to be considered novel with respect to document A.

5. *Inventive step*

5.1 Document A constitutes prior art according to Article 54(3) EPC and is therefore not to be considered with respect to inventive step (Article 56 EPC).

Document H was printed in 1997 and does thus not constitute prior art within the meaning of Article 54 EPC. It is therefore to be disregarded.

5.2 Document I mentions on page 45, lines 1 to 9, that the balloon of a Gianturco-Roubin stent "is a little bit larger in diameter than the diameter of the folded stent", and "the balloon material actually protrudes up between the wires a little way". This corresponds to the photographs of document J. Neither document I nor document J, however, show the relation between the interior diameter of the stent and the interior diameter of the balloon as they do not disclose anything about the thickness of the balloon material. Thus, documents I and J would not lead the skilled person to the features of the characterising portions of claims 1 and 8. As is shown in document J and stated in document I, the expansion of the outside of the balloon beyond the stent wires is very small. For this reason, a person skilled in the art would not be prompted, when regarding these documents, to construct a stent delivery system by a method which includes the step of the characterising portion of claim 8 and to provide in that way a stent delivery system which has the feature of the characterising portion of claim 1. As the subject-matter of claims 1 and 8 is not rendered obvious by documents I and J, it is irrelevant whether or not document I and the photographs of document J

constitute prior art within the meaning of Article 54(2) EPC.

Document D discloses a stent delivery system with the features of the preamble of claim 1. Document D neither mentions nor hints at protrusions of the balloon which have a greater interior diameter than the stent. It is clear from claims 1 and 8 and the description and the drawings of the patent in suit that the protruding portions of the balloon are meant to be within the stent area of the delivery system whilst portions outside the stent area are defined as retainers (cf. paragraph [0016] of the patent in suit). Document D shows in Figure 3 flaps 23a located outside the distal ends of the wire stent 10 which are folded over the catheter 22 (cf. page 3, lines 34 to 39). The flaps 23a of document D cannot therefore be considered protruding portions within the meaning of claims 1 and 8. Document D cannot therefore render the subject-matter of claims 1 and 8 obvious.

The Board is therefore satisfied that the subject-matter of claims 1 and 8 involves an inventive step and thus fulfils the requirements of Article 56 EPC.

Auxiliary requests

As the subject-matter of claims 1 and 8 of the main request is considered to fulfil the requirements of the EPC, it was not necessary to discuss the auxiliary requests.

For the same reason, there also was no need to continue the proceedings in writing or to remit the case to the first instance.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Meyfarth W. Zellhuber