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Datasheet for the decision of 20 March 2013

Case Number: T 1407/08 - 3.2.02

Application Number: 00890039.1

Publication Number: 1029518

IPC: A61F 2/06

Language of the proceedings:

Title of invention:

Aortic graft for treating abdominal aortic aneurysms and use of the graft

Patent Proprietor:

Barone, Hector Daniel

Opponent:

Cook Incorporated

Headword:

Relevant legal provisions:

EPC Art. 53c), 54, 83, 123(2), 111(1) RPBA Art. 12(2), 13(1)

Keyword:

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"Insufficiency of disclosure (no)"
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Decisions cited:

T 0220/83, T 0493/95, T 0934/02, T 0219/83, T 1695/07, T 1798/08, T 0748/98, T 0248/85

Catchword:

[&]quot;Exception to patentability (no)"

[&]quot;Added subject-matter (no, after amendment)"

[&]quot;Novelty (yes, after amendment)"

[&]quot;Admission of new line of argument (no)"

[&]quot;Remittal (yes)"



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Boards of Appeal

Chambres de recours

Case Number: T 1407/08 - 3.2.02

DECISION

of the Technical Board of Appeal 3.2.02 of 20 March 2013

Appellant: Barone, Hector Daniel

(Patent Proprietor) Maza 1948

Capital Federal, BS.AS. (AR)

Representative: Tomlinson, Edward James

Frohwitter

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted 30 April 2008 revoking European patent No. 1029518 pursuant

to Article 101(3)(b) EPC.

Composition of the Board:

C. Körber

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Summary of Facts and Submissions

I. The appeal was filed by the patent proprietor against the decision of the Opposition Division posted on 30 April 2008 to revoke the patent because of lack of novelty over E1 and E5.

The notice of appeal was filed on 7 July 2008 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 10 September 2008.

II. Oral proceedings were held on 20 March 2013.

The appellant requested that the decision under appeal be set aside and that a patent be maintained on the basis of the main request or, in the alternative, of auxiliary request 4, both filed with letter dated 10 September 2008, or auxiliary request 5, filed with letter dated 8 March 2013.

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

Auxiliary requests 1 to 3, filed with letter dated 10 September 2008, were withdrawn during the oral proceedings.

III. Claim 1 according to the main request reads as follows:

"An aortic graft for treatment of abdominal aortic aneurysms, the graft comprising a tubular hollow material for intraluminal insertion in the aorta, the aorta having an upper proximal aortic neck and a lower

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distal aortic portion forming an iliac bifurcation dividing into two iliac arteries, the graft characterized by:

a compliant graft main portion (13, 33, 59) made of compliant flexible fabric material and having a generally cylindrical shape with an upper end (18, 39, 60) for secure attachment to the aortic proximal neck (5), and a lower free end (20, 41, 42, 61, 75, 76) constructed so as to wholly reside at a position inside the aneurysm above the iliac bifurcation (3, 4), the upper end of the main portion being stented with a balloon expandable stent fixed only at the upper end thereof for anchoring to the aorta neck, and the lower free end of the main portion having a thread (65, 74) for restricting a diameter of a lower edge of the compliant graft main portion to a predetermined maximum value, and

at least one compliant graft iliac portion (14, 34, 35) entirely made of compliant flexible fabric material and having a generally elongated cylindrical shape with a lower end (24, 47, 53) for secure attachment to one of the iliac arteries, and an upper end (23, 46, 52) for secure attachment in fluid communication to the lower end (20, 41, 42, 61, 75, 76) of the graft main portion, the graft iliac portion also being stented according to a pattern selected from the group consisting of:
i) the iliac portion being stented at both ends thereof;

ii) the iliac portion being stented at both ends with
additional stents in between;
and

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iii) the iliac portion being stented with one long entire stent only,

wherein in an expanded state, said upper end of the graft iliac portion has a diameter larger than said predetermined maximum value of the diameter of the lower edge of the graft main portion."

Claim 1 according to the fourth auxiliary request reads as follows:

"An aortic graft for treatment of abdominal aortic aneurysms, the graft comprising a tubular hollow material for intraluminal insertion in the aorta, the aorta having an upper proximal aortic neck and a lower distal aortic portion forming an iliac bifurcation dividing into two iliac arteries, the graft characterized by:

a compliant graft main portion (13, 33, 59) made entirely of a knitted compliant flexible fabric material and having a generally cylindrical shape with an upper end (18, 39, 60) for secure attachment to the aortic proximal neck (5), and a lower free end (20, 41, 42, 61, 75, 76) constructed so as to wholly reside at a position inside the aneurysm above the iliac bifurcation (3, 4), the upper end of the main portion being stented with a balloon expandable stent fixed only at the upper end thereof for anchoring to the aorta neck, and the lower free end of the main portion having a thread (65, 74) for restricting a diameter of a lower edge of the compliant graft main portion to a predetermined maximum value, and

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at least one compliant graft iliac portion (14, 34, 35) entirely made of compliant flexible fabric material and having a generally elongated cylindrical shape with a lower end (24, 47, 53) for secure attachment to one of the iliac arteries, and an upper end (23, 46, 52) for secure attachment in fluid communication to the lower end (20, 41, 42, 61, 75, 76) of the graft main portion, the graft iliac portion also having one balloon expandable stent attached at the upper (23) end and one balloon expandable stent attached at the lower (24) end thereof,

wherein in an expanded state, said upper end of the graft iliac portion has a diameter larger than said predetermined maximum value of the diameter of the lower edge of the graft main portion."

Claim 1 according to the fifth auxiliary request reads as follows:

"An aortic graft for treatment of abdominal aortic aneurysms, the graft comprising a tubular hollow material for intraluminal insertion in the aorta, the aorta having an upper proximal aortic neck and a lower distal aortic portion forming an iliac bifurcation dividing into two iliac arteries, the graft characterized by:

a compliant graft main portion (13, 33, 59) made entirely of a knitted compliant flexible fabric material and having a generally cylindrical shape with an upper end (18, 39, 60) for secure attachment to the aortic proximal neck (5), and a lower free end (20, 41, 42, 61, 75, 76) constructed so as to wholly reside at a position inside the aneurysm above the iliac

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bifurcation (3, 4), the upper end of the main portion being stented with a balloon expandable stent fixed only at the upper end thereof for anchoring to the aorta neck, and the lower free end of the main portion having a thread (65, 74) for restricting, when ends of the thread are knotted together, a diameter of a lower edge of the compliant graft main portion to a predetermined maximum value, the thread passing through a row of loops of the knitted compliant flexible fabric material, and

at least one compliant graft iliac portion (14, 34, 35) entirely made of compliant flexible fabric material and having a generally elongated cylindrical shape with a lower end (24, 47, 53) for secure attachment to one of the iliac arteries, and an upper end (23, 46, 52) for secure attachment in fluid communication to the lower end (20, 41, 42, 61, 75, 76) of the graft main portion, the graft iliac portion also having one balloon expandable stent attached at the upper (23) end and one balloon expandable stent attached at the lower (24) end thereof,

wherein in an expanded state, the expandable stent at said upper end of the graft iliac portion has a diameter larger than said predetermined maximum value of the diameter of the lower edge of the graft main portion."

IV. The following documents are cited in the decision:

E1: US-A-5 639 278.

E3: EP-A-0 861 638.

E5: WO-A-98 32 399.

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V. The arguments of the appellant can be summarised as follows:

Admissibility of the appeal

The word "entirely" used in relation with the main graft portion was also not present in the second auxiliary request in the opposition proceedings.

Moreover, in the statement setting out the grounds of appeal an explanation was given that the cancellation was justified in view of the presence of the thread. It was further to be noted that during the opposition proceedings this word was only introduced to exclude prior-art subject-matter.

Therefore the appeal could not be declared inadmissible only because of the absence of this word from claim 1 according to the main request.

Main request

Added subject-matter

Support for the main request could be found in figures 16 and 17, as well as in the corresponding parts of the description. The thread was described as being present to reduce the maximum diameter of the lower end of the main graft portion in order to be able to retain the upper stent of the iliac portion. The nature of the material used for the main graft portion did not play any role for that function. In paragraph 0082 of the application as published it was mentioned that the main graft portion could be manufactured from any compliant material, such as a knitted fabric material, thus

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indicating that the material did not necessarily have to be knitted. So the requirements of Article 123(2) EPC were met.

Fourth auxiliary request

Insufficiency of disclosure

The requirements of Article 83 EPC were met, because the application as a whole disclosed how to obtain the restricted diameter of the thread that was part of claim 1.

Exception to patentability

Article 53(c) EPC expressly allowed the patenting of products for use in any method for treatment of the human body by surgery or therapy. According to established case law (T 1695/07) product claims did not fall under the exception clause. Therefore the graft of claim 1 did not fall under the exceptions to patentability listed in this article.

Added subject-matter

The person skilled in the art would understand that the only reason for the use of the thread at the lower end of the main graft portion was because the main graft portion was knitted. But this did not mean that the iliac portion had to be knitted as well. This was confirmed in paragraph 0027 of the application as published, where it was mentioned that at least the upper portion of the graft was made of knitted material. This clearly left it open whether the iliac

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portion should be of the same material or not. Furthermore there was no technical reason why the two portions should be made of the same material.

The description insisted on the function the thread had to fulfil, namely to restrict the diameter, and this was what was expressed in the claim.

In paragraphs 0047 and 0061 of the application as published it was indicated that there was a stent only at the upper end of the main graft portion. Nothing else was meant by the wording used in the claim.

The last sentence of paragraph 83 provided a basis for the thread, without it being threaded through the edge loops of the knitted textile.

The relationship between the diameters of the lower end of the main graft portion and the upper end of the iliac portion was also mentioned for instance in claim 2 of the application as published, without reference to a stent.

Novelty

Admission of late line of argument based on E3

This line of argument was not present in the appeal proceedings up to the oral proceedings and should not be admitted into the proceedings at least because it placed the appellant in an unfair position, not having had the opportunity to prepare itself. Moreover, E3 was prima facie not relevant against novelty because it did not disclose any knitted graft, it did not disclose a

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stent at the upper end of the main graft portion only and it did not disclose a thread for reducing the diameter at the lower edge of the main graft portion.

Novelty over E5

All the embodiments shown in E5 had at least one stent at one of the lower ends of the main graft, unlike the claimed main graft portion which had a stent at its upper end only.

A knitted fabric, as possibly used for a graft according to E5, could expand because of the loops made by the threads composing the fabric. That was the reason why according to the present invention a separate thread was used to limit the expansion to a predetermined diameter.

Moreover, there was no mention in E5 that balloon expandable stents could be used.

At least for these reasons the graft according to claim 1 was novel over E5.

Remittal

The respondent should not be authorised to present arguments in relation to the ground of lack of inventive step, because it had not submitted any during the appeal proceedings. The Board should decide definitively on the allowability of claim 1.

Should the Board not be in a position to decide definitively on the allowability, then the appellant

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would agree to remittal to the department of first instance to examine inventive step.

VI. The arguments of the respondent can be summarised as follows:

Admissibility of the appeal

The patentee was reopening the debate on features which had already been decided upon in the first-instance proceedings. Appeal proceedings were intended to revise the impugned decision, not to reintroduce problems already solved in the first-instance proceedings. For instance, the patentee had deleted the word "entirely", and not enough explanations were given in the statement setting out the grounds of appeal as to why this deletion should be allowable.

Therefore the appeal was inadmissible.

Main request

Added subject-matter

In the paragraphs of the description dealing with the embodiment according to figures 16 and 17, the thread was disclosed only in relation to a graft main portion made of a knitted fabric, so that there was no disclosure of the use of a thread in combination with a main graft portion made of any material.

For this reason, claim 1 according to the main request did not fulfil the requirements of Article 123(2) EPC.

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Fourth auxiliary request

Insufficiency of disclosure

The application taught to use a particular thread in order to obtain the maximum predetermined diameter. The claim was silent however about the nature of the thread. Moreover, the last feature of the claim described only how the graft was to be assembled, without indicating any structural features. It was not disclosed how the person skilled in the art should know when this last requirement was fulfilled. At least for these reasons the person skilled in the art was not able to carry out the claimed invention. So the requirements of Article 83 EPC were not met.

Exception to patentability

Claim 1 contained product features and method features. In particular the last feature of the claim required a particular way of expanding the stent within the body of the patient. If the stent was not expanded as mentioned, the product would not fall under claim 1, and the person actually creating or manufacturing the final product could only be the surgeon who in fact would assemble the graft portions within the body to create the claimed product. For this reason claim 1 had to be seen as a product-by-process claim whereby the manufacturing process of the product was a method of treatment of the human body by surgery excluded from patentability. Therefore claim 1 should be excluded from patentability pursuant to Article 53(c) EPC.

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Added subject-matter

Compared to the specific embodiment of figures 16 and 17, which were said to form the basis for the present claim, claim 1 was too general in that:

- i) different materials could be used for the graft main portion and the graft iliac portion,
- ii) the stent fixed at the upper end of the main graft portion could extend over the whole length of the main graft portion,
- iii) the thread was not threaded through the edge loops of the knitted portion,
- iv) the thread material was not limited,
- v) the maximum diameter of the lower part was not obtained by making a knot in the thread,
- vi) the large diameter mentioned in the last clause of the claim should be the diameter of the stent as disclosed in paragraph 0084 of the application as published and not that of the upper end of the leg portion.

Therefore claim 1 did not fulfil the requirements of Article 123(2) EPC.

Novelty

Admission of late line of argument based on E3

E3 was already present in the opposition proceedings and was not a complicated document, so that the appellant and the Board would have no difficulties understanding it. E3 was relevant for examination of novelty since it prima facie disclosed all the features

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of claim 1. In particular, the material used for the graft was said to be conventional, which according to the patent in suit could be knitted material, a thread was present at the lower edge of the main graft portion when the graft was cut as mentioned in column 7, lines 39 to 44, and the wording of claim 1 also covered stents in the main graft portion which extended the whole length of it, as disclosed in E3.

Therefore the new line of argument against novelty based on E3 should be admitted into the appeal proceedings.

Novelty over E1 was not objected to.

Novelty over E5

The feature of the thread, added over the version of claim 1, the subject-matter of which was considered to lack novelty by the Opposition Division, was also disclosed in E5. As a matter of fact the graft could be knitted or woven, as mentioned in the first paragraph of page 4, and the lower edge was provided with a constriction 62 as could be seen on the figures or as mentioned on page 9, first paragraph. However, a knitted graft was made out of threads, so that the constriction 62 mentioned in E5 necessarily included a thread of the knitted fabric. The wording of claim 1 did not require a separate thread. E5 encompassed the use of balloon expendable stents.

Hence, the subject-matter of claim 1 was not novel.

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Remittal

If the Board was of the opinion that the subject-matter of claim 1 was novel, then the respondent would agree to remittal to the department of the first instance for further prosecution.

Reasons for the Decision

1. Admissibility of the appeal

The impugned revocation decision was taken on the basis of a lack of novelty objection over the state of the art according to E1 and E5. Over the main request decided upon in the opposition proceedings, present main request, which was filed with the statement setting out the grounds of appeal, additionally includes the following feature for the main graft portion:

"the upper end of the main portion being stented with a balloon expandable stent fixed only at the upper end thereof for anchoring to the aorta neck, and the lower free end of the main portion having a thread (65, 74) for restricting a diameter of a lower edge of the compliant graft main portion to a predetermined maximum value"

and at the end of the claim, the feature describing the relationship between the main graft portion and the graft iliac portion at their overlap:

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"wherein in an expanded state, said upper end of the graft iliac portion has a diameter larger than said predetermined maximum value of the diameter of the lower edge of the graft main portion."

It appears to the Board that the scope of the present main request is restricted by the introduction of these features compared to the scope of the main request dealt with in the impugned decision. Moreover, on page 3 of the statement setting out the grounds of appeal the appellant explained where in the originally filed application documents support can be found for the amendments, and on page 4 of the same statement why the subject-matter of claim 1 of the main request in appeal is novel over E1 and E5.

According to the respondent the appellant is reopening the debate on already decided matter, in particular by deleting a feature ("entirely") from the main request defended before the Opposition Division without adequately sustantiating that deletion in the statement setting out the grounds of appeal.

The Board does not share this opinion. While it is true that in the present main request the word "entirely" in the wording "a compliant graft main portion (13, 33, 59) entirely made of compliant flexible fabric material..." has been deleted, for this amendment too the appellant gave an explanation in the last but one paragraph of page 3 of the statement setting out the grounds of appeal.

It is established case law that for an appeal to be admissible the appellant must give in a logical order

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the legal and factual reasons why it considers that the impugned decision is to be set aside (T 220/83, OJ EPO 1986, 249, T 493/95). This is sufficient. It is not necessary that the reasoning presented is convincing and/or leads to the expected result.

It is also established case law that, as an exception to the requirement to substantiate the appeal, the filing of a claim which renders the impugned decision obsolete is enough for the appeal to be admissible (T 934/02).

In the present case both conditions are fulfilled, since the "thread" feature present in the present main request was not in any of the main, first and second auxiliary requests dealt with in the impugned decision, and, as mentioned above, the appellant gave reasons, in its statement setting out the grounds of appeal, why the subject-matter of present main request was novel.

Therefore, the other requirements for admissibility being also fulfilled, the appeal is admissible.

Main request

2. Added subject-matter

As mentioned above, the "thread" feature has been added to claim 1 of the patent as granted.

According to the appellant the support for this feature is to be found in originally filed figures 16 and 17 and in the corresponding parts of the originally filed

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description, namely paragraphs 0081 to 0084 of the published application.

However, it is explicitly mentioned in paragraph 0083 that figure 17 shows a knitted construction. In the same paragraph it is explained that the lower leg portion must be properly retained in the main graft portion and that in order to guarantee such a firm connection between the upper main graft portion and the lower leg portion, which would not be given by the elastic knitted construction, a thread is arranged at or close to the edge which is to be made inelastic.

The appellant considered that the thread was disclosed as being there in order to reduce the diameter of the lower end of the graft main portion. The material of the graft main portion was therefore not decisive for that function.

As mentioned above, the presence of a thread was only disclosed in combination with a knitted fabric for the graft main portion. Nowhere in the published application is there a disclosure of the use of a thread with a graft main portion made of any other material.

At least for this reason, claim 1 of the main request does not fulfil the requirements of Article 123(2) EPC.

Fourth auxiliary request

3. Insufficiency of disclosure

According to the respondent, claim 1 indicates neither the nature of the thread nor the way the predetermined

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diameter was obtained and therefore does not fulfil the requirements of Article 83 EPC.

The Board does not share this opinion. Article 83 EPC requires that the application (or patent) discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Therefore it is not necessary that the claim comprises all the information necessary for the carrying out of the claimed invention. In the present case, paragraphs 0076 to 0079 state that the thread can be inelastic or controllably elastic and that the predetermined diameter can be obtained by a knot made in the thread by the physician, his assistant or the manufacturer. Therefore there is no doubt that the person skilled in the art is able to carry out the feature objected to.

4. Exception to patentability

The respondent considered that claim 1 was a so-called product-by-process claim and that it fell under the exception of Article 53(c) EPC because the process used to manufacture the product claimed was executed on the patient, i.e. was of a surgical nature.

It is clear that in the present case the aortic graft will effectively only be in its final assembled state in the human body. This is however of no relevance for the allowability of the product claim under Article 53(c) EPC.

The Board points out that according to established case law, a so-called product-by-process claim must be

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considered to be nothing else but a product claim in which a particular way of defining the product is chosen, namely by describing steps of its manufacturing process. The use of such a way of defining the product is not to be understood as implying that something different from a product is meant to be defined or protected. In other words, it is only a way of defining a product, but the manufacturing steps are not protected and do not fall under the scope or ambit of the claim (T 219/83, OJ 1986, 211, point 10. of the reasons; T 0748/98, point 2. of the reasons; T 0248/85, OJ EPO 1986, 261, point 6.4 of the reasons).

In the present case this means that even if the final aortic graft is normally obtained after assembly in the body of the patient during surgery, the surgical steps of introducing the different parts or portions of the graft into the body and assembling them while in the body do not fall under the scope of the claim and therefore cannot lead to an objection under Article 53(c) EPC. The claim does not define any method falling under the exception of Article 53(c) EPC, it defines a product which, according to established case law (T 1695/07, T 1798/08), does not fall under the exception clause.

For the sake of completeness the Board notes that it may also be possible to assemble the different parts of the claimed graft in an artificial aorta, should it become necessary to test whether a product falls under the scope of the claim or not.

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5. Added subject-matter

The respondent considered that claim 1 according to the fourth auxiliary request did not fulfil the requirements of Article 123(2) EPC because its wording was too general in that:

- i) different materials could be used for the graft main portion and the graft leg portion,
- ii) the stent fixed at the upper end of the main graft portion can extend over the whole length of the main graft portion,
- iii) the thread was not threaded through the edge loops of the knitted portion,
- iv) the thread material was not limited,
- v) the maximum diameter of the lower part was not obtained by making a knot in the thread,
- vi) the large diameter mentioned in the last clause of the claim should be that of the stent and not that of the upper end of the leg portion.

The Board does not share this opinion.

Feature i): while in relation to the embodiment shown in figures 16 and 17 it is mentioned that the main graft portion is made of knitted fabric, no such information is given in relation to the graft leg portion. In connection with the other embodiments it is indicated e.g. at the end of paragraph 0071 of the published application that the graft portions may be manufactured from any suitable textile or fabric material, at least partially elastic or inelastic, either a woven or a knitted material. Also in original claim 1, it is mentioned that both graft portions are

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made of a compliant flexible fabric material but not that they are made of the <u>same</u> compliant flexible material. It follows that there is no teaching in the originally filed application that both graft portions must be made of one and the same material.

Feature ii): in the opinion of the Board this feature has to be read in the light of the other features of the claim and in the light of the patent as a whole, in particular the problem intended to be solved by the graft of claim 1. It is clear from the wording of the feature preceding the one at issue in the claim that the main graft portion has an upper end for secure attachment to the aortic proximal neck and a lower free end. This is already a hint that there is some kind of attachment means at the upper end of the main graft but nothing at its lower free end. When looking at the problem to be solved, namely to avoid the lower part of the graft remaining twisted or folded, or in other words ensuring this lower part is able to unfold and untwist, it becomes clear that the lower portion of the main graft portion cannot be stented. Moreover, there appears to be no point in incorporating a thread into the lower part of the main graft portion, as required further on in the claim, if there is already a stent present there which can fulfil the retaining function the thread is meant to fulfil. The Board therefore considers that the statement in feature ii) that the upper end of the main portion is stented with a balloon expandable stent fixed only at the upper end thereof, when read in the context of the claim and the patent as a whole, excludes the presence of a stent elsewhere than at the upper end of the main graft portion. And this undisputedly was originally disclosed.

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Feature iii): in the opinion of the Board there is no need to indicate that the thread is threaded through the edge loops of the knitted textil as the last sentence of paragraph 0083 of the published application states that in order to assure the desired retention a thread, either inelastic or controllably elastic, is arranged at the edge, close to the edge or portion of the graft desired to be converted into inelastic, without any restriction as to how the thread is placed.

Feature iv): the indication that the thread is for restricting a diameter (...) to a maximum value necessarily implies that the thread must have the mechanical properties which allow the thread to be able to limit the diameter. In other words, it is implicit that it must be inelastic or have a controlled elasticity, as originally disclosed. Its material does not need to be further defined.

Feature v): The present wording is that there is a thread for restricting a diameter of a lower edge of the compliant graft main portion to a predetermined maximum value. The Board considers that the indication that the thread is for restricting the diameter ... to a predetermined maximum value is supported inter alia by the last sentence of paragraph 0083 of the published application stating that to assure the desired retention a thread, either inelastic or controllably elastic, is arranged at the edge, close to the edge or portion of the graft desired to be converted into inelastic. The person skilled in the art would recognise that the important function of the thread is to limit the diameter and that the manner of doing it

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described in relation with the embodiment of figures 16 and 17, i.e. by making a knot for that purpose, is not essential.

Feature vi): it is self-evident that if the upper end of the graft iliac portion has a diameter larger than the predetermined maximum value of the diameter of the lower edge of the graft main portion, and if this larger diameter is obtained after expansion of the stent attached at the upper end of the iliac portion, this can only mean that the stent in its expanded state has a diameter larger than the predetermined maximum value as well. Accordingly, the definition in claim 1 corresponds to the disclosure in paragraph 0084 of the published application.

Hence, claim 1 of the fourth auxiliary request fulfils the requirements of Article 123(2) EPC.

- 6. Novelty
- 6.1 Admission of the late novelty objection based on E3

According to Article 12(2) RPBA, the reply of the respondent to the statement setting out the grounds of appeal should contain its complete case. In the present case, E3 was cited against the novelty of the subject-matter of claim 1 neither in the decision under appeal nor in the reply of the respondent to the statement setting out the grounds of appeal, but for the first time at the oral proceedings held in the appeal proceedings.

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For this reason, this line of argumentation must be considered a late amendment of the respondent's case, and its admission into the appeal proceedings is at the Board's discretion pursuant to Article 13(1) RPBA. According to the same article such discretion is to be exercised in view inter alia of the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy. In the present case, the document not being complex and having already been introduced with the notice of opposition, the Board decided to check its prima facie relevance for an objection of lack of novelty to the subject-matter of claim 1 in order to decide whether or not to admit this amendment of the respondent's case into the appeal proceedings.

Claim 1 requires the graft main portion to be made of knitted compliant fabric material. For this feature the respondent could not cite a passage in E3 explicitly mentioning it. It referred solely to a passage mentioning that conventional methods and conventional materials were used to manufacture the stent-graft, which however does not disclose any specific knitted fabric material. The respondent could not point to any passage in E3 defining the word "conventional" for the purposes of this document, either.

Claim 1 requires that only the upper end of the main graft portion is stented. This feature appears not to be disclosed in E3, since all the embodiments appear to show stents extending over the whole length of the main graft portion.

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Claim 1 requires the presence of a thread at the lower free end of the main graft portion. This feature appears not to be present in the graft according to E3 either, since it is explicitly mentioned that the reinforcement is attached to the midsection (column 7, lines 9 to 15).

Already the prima facie lack of disclosure of at least these features in E3 justifies the Board declining to admit the new lack of novelty objection into the appeal proceedings.

- 6.2 The respondent explicitly stated that it no longer had any lack of novelty objection based on document E1. The Board shares this view.
- 6.3 Novelty over E5

Claim 1 requires the presence of a thread at the lower end of the graft main portion for restricting the diameter of the lower edge to a predetermined maximum value. This feature is not disclosed in E5. While the figures and the description, for example page 9, lines 1 to 3, show or mention a restriction 62 having a diameter smaller than the inner diameter of the stent 50 at the lower end of the graft main portion, nowhere in the description is it explained how this restriction is obtained.

The respondent submitted that since the main graft portion may be made of a knitted or woven fabric (page 3, line 25 to page 4, line 4) there will necessarily be a thread (of the fabric) at the restriction, so that the feature of the claim that the

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lower edge has a thread for restricting the diameter of the lower edge is disclosed.

The Board does not agree with this way of reading the claim. Unless otherwise provided, the usual way of reading a claim in which several items are mentioned or listed is that these items are separate. This is all the more true when, as in the present case, this is in line with the teaching of the patent as a whole. In paragraph 0078 of the patent it is explained that the elastic (knitted) construction would not guarantee the desired retention of the stent in the lower portion of the main graft portion and that therefore an inelastic or controllably elastic thread is arranged at the lower edge of that main graft portion. Thus, interpreting this feature as covering the situation in which the thread is a normal thread of the fabric used for the graft main portion cannot be regarded as in line with the teaching of the patent as a whole.

Claim 1 requires the presence of balloon expandable stents at the upper end of the main portion, at the lower end and at the upper end of the graft iliac portion. However, in E5 it is mentioned (page 7, lines 11 to 16) that the stents used in the invention described there are self-expanding. The respondent could not cite any passage of E5 explicitly mentioning the use of balloon expandable stents, and referred only to the general wording used in claim 1 or in the introductory part of the description. Such general wording is however not a disclosure of specific balloon expandable stents.

As explained with respect to feature ii) in point 5 above, claim 1 requires the presence of a balloon expandable stent only at the upper end of the main graft portion, which excludes the presence of such stents below the upper end. This feature is not disclosed in E5, as all the embodiments described in that document at least have a stent in one of the two leg elements of the main graft portion. The embodiment shown in figure 8, specifically pointed to by the respondent, also has such a stent 51 in the right-hand leg element.

6.4 Therefore, subject-matter of claim 1 according to the fourth auxiliary request is novel (Article 54 EPC).

7. Remittal

The appellant considered that the Board should not allow the introduction into the proceedings of any new lines of arguments against inventive step, not even based on E1 and E5 present in the appeal proceedings, because the respondent had not presented any line of arguments against inventive step in its reply or replies to the statement setting out the grounds of appeal. In the absence of any such lines of argument the Board should make a final decision on the allowability of the claim. The appellant would only agree to remittal if the Board could not make a final decision in the appeal proceedings.

The decision under appeal was based on lack of novelty over E1 and E5, so that for the Board to examine and decide on the appeal, i.e. confirm or set aside the decision under appeal, an argumentation by the

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appellant as to the presence of novelty and, if the respondent considered it useful, an argumentation as to the absence of novelty, were the only elements necessary for the Board's decision. In other words, in the appeal proceedings any argumentation in favour or against the presence of an inventive step was not a prerequisite for deciding on the appeal, because the examination of inventive step was not part of the impugned decision. Therefore, it cannot be argued that the respondent should have filed an argumentation against inventive step from the outset, i.e. with its reply to the statement setting out the grounds of appeal, when this did not play any role for deciding on the appeal.

As explained above, the subject-matter of claim 1 according to the fourth auxiliary request was found novel, so that the Board has to set aside the decision under appeal. In such a situation, pursuant to Article 111(1) EPC, it is within the discretionary power of the Board either to remit the case to the department of first instance or to exercise any power within the competence of that department.

Should the Board decide to exercise the power to examine inventive step, then the respondent (as well as the patent proprietor) would have a right to be heard, i.e. the right to present its case regarding inventive step. Since the ground of opposition of lack of inventive step, as explained above, was not the subject of the impugned decision, and hence not to be decided upon in confirming or setting aside that decision, an argumentation on that ground presented by the respondent could not be held to be inadmissible because

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of lateness. If the Board decided to exercise any power within the competence of the first instance not touched upon in the impugned decision, the parties would have a right to present a complete case.

For these reasons the Board cannot follow the opinion of the appellant that the respondent should not be given an opportunity to argue against inventive step and that the Board should immediately and definitively decide on the allowability of the claim.

In the present file, in the opposition proceedings the respondent used a combination of documents E3 and E5 against inventive step of the subject-matter of claim 23 of the granted patent, including the thread now claimed at the lower edge of the main graft portion. In the appeal proceedings this combination was however commented upon neither by the parties nor by the Board. Hence, given that at least E3, which has not been discussed in the appeal proceedings with regard to inventive step, might play a role for the assessment of inventive step, that the Board and the parties could not reasonably have been expected to deal with inventive step at the same oral proceedings, and in order not to deprive the parties of the opportunity of presenting their case before two instances, the Board decided not to exercise the powers of the department of first instance on that matter but to remit the case to that department for further prosecution.

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Order

For these reasons it is decided that:

1. The decision under appeal is set aside

2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:

D. Hampe

E. Dufrasne