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Datasheet for the decision of 16 December 2014

Case Number: T 2480/12 - 3.2.08

Application Number: 06745251.6

Publication Number: 1919402

IPC: A61F2/34

Language of the proceedings: EN

Title of invention:
ENDOPROSTHESIS FOR ORTHOPEDIC APPLICATIONS

Patent Proprietor:
Sintea Biotech S.p.A.

Opponent:
Adler Ortho S.r.l.
Ala Ortho S.r.l.

Headword:

Relevant legal provisions:
RPBA Art. 12(1), 12(2), 12(4), 13(3)
EPC Art. 54, 56

Keyword:
Novelty - auxiliary request (yes)
Inventive step - auxiliary request (yes)
Late-filed argument-
adjournment of oral proceedings would have been required (yes)

Decisions cited:

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Catchword:

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Case Number: T 2480/12 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 16 December 2014

Appellant: (Opponent)	Adler Ortho S.r.l. Ala Ortho S.r.l. Via Guelfa 9 / Via dell'Innovazione 9 40138 Bologna / 20032 Cormano (MI) (IT)
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Respondent: (Patent Proprietor)	Sintea Biotech S.p.A. Via Aquileia 33/H 20021 Baranzate (Milano) (IT)
Representative:	Postiglione, Ferruccio Gregorj S.r.l. Intellectual Property Via Muratori, 13 b 20135 Milano (IT)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 5 October 2012 rejecting the opposition filed against European patent No. 1919402 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	T. Kriner
Members:	C. Herberhold
	D. T. Keeling

Summary of Facts and Submissions

I. By its decision posted on 5 October 2012 the Opposition Division rejected the opposition against European patent No. 1 919 402.

II. The opposition division held that the claims as granted were novel over the disclosure of documents D1 and D6 and inventive over any combination of the disclosure of documents D1, D3, D6 and D9.

III. The appellant (opponent) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.

IV. Oral proceedings before the Board of Appeal were held on 16 December 2014.

At the end of the oral proceedings the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

The respondent (patent proprietor) requested that the appeal be dismissed (Main Request), or, in the alternative, that the decision under appeal be set aside and the patent maintained in amended form on the basis of the claims of the first auxiliary request as filed by letter of 14 November 2014, or, on the basis of the claims of the second auxiliary request as filed at the oral proceedings on 16 December 2014, or on the basis of the claims of auxiliary requests 3 to 10 as filed by letter of 14 November 2014.

The respondent further requested that document D9 should be considered not publicly available and thus not be admitted.

V. Claim 1 of the main request (corresponding to the patent as granted) reads as follows:

"Endoprosthesis (4) for orthopaedic applications comprising
- a prosthesis body (8) suitable for interfacing between a first and a second bone or portions of bone,
- the prosthesis body (8) being provided with a first wall (12) suitable for interfacing with said first bone and a second wall (14) suitable for interfacing with said second bone,
- means for fixing the prosthesis body (8) suitable for obtaining a fixing of the prosthesis (4) to at least one between the first and the second bone,
- the prosthesis body (8), at at least one of said walls (12, 14) comprising a fixing interface (30) suitable for favouring the osteo-integration with an associable bone,
- the fixing interface (30) is spaced from one of the walls (12, 14) of the prosthesis body (8) by a plurality of spacer elements (38) integrally connected to the prosthesis body (8) for forming a meatus (42) between the interface (30) and the wall (12, 14), said meatus (42) determining cavities and undercuts suitable for seating growing bony tissue,
the fixing interface (30) comprising a reticular structure having a plurality of meshes (48) integrally interconnected to each other, **characterized in that** the meshes (48) have circular or elliptical section relative to a section plane perpendicular to the associable wall (12, 14) of the prosthesis body (8)."

VI. Claim 1 of the first auxiliary request is based on claim 1 of the main request with the additional feature:

"wherein said endoprosthesis is realised by an electron beam melting technique or a laser sintering technique."

VII. Claim 1 of the new second auxiliary request is based on claim 1 of the first auxiliary request with the additional feature wherein:

"the meshes (48) comprise a central hole (52) so as to take on a ring configuration."

Independent method claim 29 of the second auxiliary request is based on the subject-matter of claims 34 and 36 as granted combined by a logical "or" with deletion of the phrase:

"~~or additional production methods~~"

The wording of independent claim 29 thus reads as follows:

"A method of manufacture of an endoprosthesis according to any one of claims 1 to 28, said method comprising FFF (Free Form Fabrication) techniques, wherein said FFF technique is an EBM (Electron Beam Melting) technique comprising the steps of:
- arranging powder material on a support, into a vacuum chamber,
- addressing, according to the desired geometry, an electronic beam on the powder, said beam having a specific energy sufficient for causing the instant and local melting of a portion of powder material impinged thereby, so as to obtain the desired geometry,

- removing the powder not impinged by the beam,

or

wherein said FFF technique is a selective laser-sintering technique comprising the steps of:
- arranging powder material on a support, into a vacuum chamber,
- addressing, according to the desired geometry, a laser beam on the powder, said laser beam having a specific energy sufficient for causing the instant and local melting of a portion of powder material impinged thereby, so as to obtain the desired geometry,
- removing the powder not impinged by the laser beam."

VIII. The following documents played a role for the present decision:

D6: US-A-5,108,435;
D9: "Direct Manufacturing with Electron Beam Melting (EBM)", Presentation by Arcam EBM System dated December 28, 2005;
D1O: Declaration by Mr P Ohldin of Arcam EBM System dated May 20,2008;
D11: Web page related to the EuroMold Trade fair;
D12: Declaration by Mr P Ohldin of Arcam EBM System dated April 29, 2009.

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

Main request - Novelty

Document D6 disclosed in Figure 8 and the description column 6, lines 8 to 15 the femoral component of a hip prosthesis provided with an integral cast lattice

element forming a tissue ingrowth surface having all the features of the fixing interface according to claim 1. In particular, the lattice element was described in column 3, lines 20 to 22 as being in the form of a wire mesh, the term wire clearly indicating a circular cross-section of the cross-members. This interpretation was in accordance with the indication of a particular diameter of the cross-members in column 4, lines 52 to 55, the term diameter implying by itself a circular cross-section and also being used only in this sense, for instance in the context of the diameter of the spherical protrusions. From this disclosure the person skilled in the art would thus clearly and unambiguously derive the cross-section of the cross-members to be circular.
Regarding the further claim features, it was known to the person skilled in the art that a hip prosthesis comprised further elements, such as the femoral neck and head as well as an acetabular component. Given the very broad wording "means for fixing the prosthesis body...to at least one between the first and the second bone", any interaction keeping the component in place, such as the anchoring of the femoral component tip to the bone, or any connection with the hip bone had to be considered "means for fixing" as claimed. In this respect it had also to be kept in mind that the prosthesis body was only defined as suitable for interfacing between first and second portions of bone, i.e. even with portions of one and the same bone, the feature of a first and second wall suitable for interfacing with these portions thus being fulfilled by basically any prosthesis wall.

Consequently, the subject-matter of claim 1 was not new over the disclosure in document D6.

First auxiliary request - Novelty

The added feature according to which the endoprosthesis was realised by an electron beam melting technique or a laser sintering technique was a product by process feature. In order for a so defined product to be novel, the product *per se* needed to be novel. However, there was no way to distinguish the prosthesis made by electron beam melting or laser sintering techniques from the cast prosthesis disclosed in D6. Consequently claim 1 of the first auxiliary request lacked novelty in view of D6.

First auxiliary request - Inventive step

Even if novelty of the subject-matter of claim 1 of the first auxiliary request were to be acknowledged, it did not involve an inventive step.

Starting from D6 as closest prior art, the problem to be solved was to provide an alternative manufacturing method to produce the already known femoral component. In this respect, document D9 disclosed on page 2, last slide, electron beam melting as a fast and economical fabrication method resulting in a "better than cast" product such that the person skilled in the art was clearly incited to apply electron beam melting for manufacturing the D6 prosthesis, the applicability of the method in the medical field being further suggested by several slides in D9, pages 5 and 6, showing medical implants so produced.

Regarding the respondent's newly introduced objection that D9 was not publicly available, Mr Ohldin's statement D10 gave evidence that the presentation D9 was sent by him to the visitors of the EuroMold trade

fair in January 2006. D9 had been intensely discussed before the opposition division, it had further been relied on in the statement of grounds of appeal, where the appellant had also offered to further elaborate on the point of public availability if need be. However, up to the oral proceedings before the Board, the respondent had never shown the slightest doubts that the document had indeed been available to the public. Consequently, if said objection was admitted and led to the conclusion that the teaching of document D9 was not publicly available, this would not only be procedurally extremely unfair to the appellant, but would also trigger a request to adjourn the oral proceedings in order to allow the provision of further evidence, with the costs of the then necessary additional oral proceedings to be assigned to the respondent.

Second auxiliary request - Inventive step

While it was true that document D6 did not disclose a ring configuration of the meshes, this particular form was an arbitrary selection without any technical effect, as the patent specification did not disclose any particular advantage of the ring configuration *per se*. Paragraph [0063] of the specification referred to the effect of a circular shape of the mesh. However, the circular shape had to be considered different from the ring configuration, because the circular shape of the mesh and the ring configuration of the meshes were claimed in different dependent claims. With respect to paragraphs [0050] and [0052] of the specification, these passages referred to a circular ring pattern - a wording again not identical to the one claimed. Moreover the favourable results in terms of bio-mimesis and osteo-integration mentioned in paragraph [0052] were based on the dimensional values indicated and thus

could not be assigned to the ring configuration as such.
Consequently, the ring configuration was a design feature without inventive merit. As the manufacturing of the prosthesis by electron beam melting had already been found obvious and as it solved an unrelated partial problem, the subject-matter of claim 1 of the second auxiliary request was not inventive.

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

Main request - Novelty

Even if D6 disclosed a lattice in the form of a wire mesh with the cross-members of said lattice having a particular diameter, this did not clearly and unambiguously disclose the cross-section of the cross-members relative to a section plane perpendicular to the associable wall to be circular. Wires of non-circular cross-section were known and a diameter could well be determined for such non-circular cross sections.
In fact, as could be seen from the mould as shown in D6, Figures 4 to 6, a circular cross-section of the cross-members would make it impossible to pull the casted metal lattice out of the mould after casting.

Furthermore, the claim required the presence of "means for fixing the prosthesis body.... to at least one between the first and second bone", i.e. of a device element different from the fixing interface. In this context the appellant had only made vague reference to further parts of a hip prosthesis allegedly known to the skilled person as fixedly connected to a first or

second bone, without providing the feature by feature analysis required for novelty evaluation.

Thus, the disclosure in D6 differed from the claimed subject-matter not only in the cross-section of the cross-members, but it also had not convincingly been shown to disclose a first wall suitable for interfacing with a first bone and a second wall suitable for interfacing with a second bone, nor had means for fixing the prosthesis body to at least one between the first and the second bone been demonstrated.

Consequently the subject-matter of claim 1 was novel over D6.

First auxiliary request - Novelty

Claim 1 of the first auxiliary request defined an endoprosthesis made by electron beam melting or by a laser sintering technique, whereas the D6 prosthesis was produced by casting. The difference between these manufacturing techniques was well known to the person skilled in the art and produced easily verifiable characteristics on the product: the 3-D free forming techniques resulted not only in a micrographically differentiable structure, but also were of higher precision, thus showing less marks of finishing.

First auxiliary request - Inventive step

Document D9 was a copy of a presentation allegedly sent by email to visitors of a trade fair. There was however no proof that any recipient had actually received the document. It could also not be excluded that - in the event that the document was indeed received by a recipient - the person was bound to secrecy. Moreover,

the only indication that the presentation had in fact been sent came from a simple written statement, which was not even an affidavit. In this context, not raising an objection against public availability of D9 earlier could not be seen as a tacit agreement. Given the strict standards of the EPO regarding public availability, it could therefore not be considered proven that the information in document D9 had become available to the public and the document should consequently be disregarded when assessing inventive step.

Even if the document was to be considered, it would not disclose that electron beam melting was indeed capable of producing the fine reticular structure required for the D6 lattice. The person skilled in the art could thus not have assumed that the D6 component could be manufactured by electron beam melting.

Second auxiliary request - Inventive step

D6 provided no disclosure of the particular ring configuration of the meshes now claimed. According to the patent specification, paragraph [0063], the circular shape of said meshes further favoured the bony growth, the problem to be solved thus being to provide an osteo-integrative surface with improved bone ingrowth and thus osteo-integration.

The ring configuration of the meshes was neither disclosed in any of the cited documents, nor was it known to the person skilled in the art as of particular benefit towards favouring bony growth.

The provision of the ring configuration favouring the bony growth was thus inventive.

Reasons for the Decision

1. The appeal is admissible.

2. Main request

2.1 Novelty:

D6 was published on 28 April 1992 and is thus prior art under Article 54(2) EPC.

Figure 8 of D6 shows a tissue ingrowth surface produced on the outside of the femoral component of a hip prosthesis (D6, column 6, lines 8 to 15). It is known to the person skilled in the art that a femoral component of a hip prosthesis comprises a stem, which anchors the component to the femoral bone, as well as a neck and a femoral head section, with the ball-formed prosthetic femoral head of said component being adapted to be held within the acetabular cup (which may be equally prosthetic) of the hip bone.

Therefore, the femoral component disclosed in D6 is an:

Endoprosthesis for orthopaedic applications comprising
- a prosthesis body (the femoral component mentioned above, implicitly comprising stem, neck section and ball-formed head) suitable for interfacing between a first (the femoral bone) and a second bone (the hip bone) or portions of bone,
- the prosthesis body being provided with a first wall (the wall of the femoral stem, comprising the tissue ingrowth surface as shown in Figure 8) suitable for

interfacing with said first bone and a second wall (the outer wall of the ball-shaped femoral head) suitable for interfacing with said second bone,
- means for fixing the prosthesis body suitable for obtaining a fixing of the prosthesis to at least one between the first and the second bone (the ball shape femoral head is adapted to be fixedly held within the acetabular cup thus qualifying as "means for fixing the prosthesis body" to the hip bone),
- the prosthesis body, at at least one of said walls comprising a fixing interface (the tissue ingrowth surface shown in Figure 8) suitable for favouring the osteo-integration ("tissue ingrowth surface", see column 6, line 9) with an associable bone (i.e. with the femoral bone).

As can be seen in Figures 1-3, 7 and 8,

the fixing interface is spaced from one of the walls of the prosthesis body (Figures 3 and 8) by a plurality of spacer elements (No. 16) integrally connected to the prosthesis body ("integral cast lattice element forming a tissue ingrowth surface", see column 6, lines 8-11) for forming a meatus between the interface and the wall (between spacer elements No. 16 and under lattice cross-members No. 12), said meatus determining cavities and undercuts suitable for seating growing bony tissue, the fixing interface comprising a reticular structure having a plurality of meshes integrally interconnected to each other (see the lattice structure shown in Figure 1).

While it is true that there is no drawing showing the section of the meshes relative to a section plane perpendicular to the associable wall of the prosthesis body, the person skilled in the art will understand

from the overall disclosure that the meshes, i.e. the cross-members No. 12, have a circular section for the following reasons:

Firstly, D6 discloses that the "lattice element may be in the form of a wire mesh integrally cast with the base member and spaced therefrom" (column 3, lines 20 to 22). According to the Oxford English Dictionary, the term "wire" refers to a "metal formed into a long, slender, flexible rod or strand, usually circular in section". The person skilled in the art will - from this teaching – thus visualise a lattice with the cross-members having a circular cross-section.

Secondly, this understanding is in accordance with all the further elements of the lattice being of a round i.e. either circular or a spherical cross section: protrusions 14 are disclosed as a spherical (column 4, line 53), the spacer elements No. 16 are cylindrical (claim 1). There is no reason to assume that the cross-section of the cross-members should be any different.

Thirdly, in column 4, lines 52 to 55, it is stated that the cross-members No. 12 are 0.020" in diameter and the spherical protrusions No. 14 are 0.040" in diameter. Although there are definitions available for a diameter of non-circular or non-spherical section objects, the parallel use, within the same sentence, of the word "diameter" for a spherical object (spherical protrusions No. 14) and for the cross-members No. 12 again confirms the circular cross-section of the cross-members.

Therefore the disclosure of D6 provides the person skilled in the art with the clear and consistent, i.e.

unambiguous understanding that the cross section of the cross-members No. 12 is circular.

Thus, the subject-matter of claim 1 as granted is not new.

The respondent has argued that the cross-members could not have a circular cross-section because then it would not be possible to remove the lattice from the mould after casting. This argument is however not convincing for the following reasons:

Upon manufacture of the osteo-integrative lattice, firstly a wax or plastic lattice element is produced by injection moulding in a split die to form a grid-like three-dimensional network (column 4, lines 47 to 52). With the split of the split moulds being at the plane through the centres of the spherical protrusions, and with the spacer elements being cylindrical (see D6, claim 1) a lattice as shown in Figures 1 and 2 having cross-members with a circular cross-section can clearly be produced and removed from its mould.

In a second step, the wax or plastic lattice element is integrally joined to the outer surface of the implant, having a body also made from a meltable material such as wax or polystyrene (column 4, lines 56-58).
Then, the piece pattern (No. 24) - i.e. the wax or plastic model of the femoral component combined with the wax or plastic model of the osteo-integrative surface forming an integral structure - is repetitively coated in order to form a ceramic shell (column 5, lines 16-46 and column 6, lines 8-15). Thereafter the wax or plastic model is removed from the shell by heating the meltable material. Finally, the resulting void is filled with molten metal, thus forming the

integral cast lattice element on the outside of the femoral component (column 5, line 47 - column 6, line 7).

As the ceramic shell material thus - after casting - fully encloses the metal lattice which is integrally casted together with the femoral component basis, i.e. as the ceramic material fills all the meshes and *meati* and thus by itself forms a lattice fully entangled with the casted metal lattice, the shell cannot be "pulled out" no matter whether the cross-members have a circular or a rectangular cross-section.

As explicitly mentioned in D6 column 6, lines 1, 2, the shell needs to be "removed" from the integral one-piece casting, a process which will destroy the ceramic mould. The method of producing the femoral component disclosed in D6 thus is not in contradiction with a circular cross-section of the cross-members.

3. First auxiliary request

3.1 Novelty

Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the endoprosthesis has been additionally defined as "realised by an electron beam melting technique or a laser sintering technique".

In these techniques an electron or laser beam is piloted over subsequent layers of fine material powder. Slice by slice, according to the shape to be produced, the powder is instantly melted and then immediately re-consolidated at the desired locations, thus forming the

object in a sort of three-dimensional plotting, with the remaining unconsolidated powder material being eliminated thereafter, thus leaving the respective spaces empty.
As a result, the microstructure of the finished product still shows at least traces of the individual powder particles, recognizable e.g. on a micrograph, which are more or less melted and sintered together. The product obtained by these techniques can thus be differentiated from the product produced by a casting technique as described in D6.

Consequently the subject-matter of claim 1 is novel over the disclosure in document D6.

3.2 First auxiliary request - Inventive step

3.2.1 Closest prior art, differing feature and problem to be solved

Both parties agree that D6 is the closest prior art. As discussed above, the subject-matter of claim 1 differs from said disclosure in that the endoprosthesis is "realised by an electron beam melting technique or a laser sintering technique", i.e. in that a different manufacturing process is used, solving the problem to provide an alternative or - according to the respondent – better production method.

3.2.2 Public availability of D9

During the oral proceedings before the Board, the respondent requested that document D9, a presentation entitled "Direct Manufacturing with Electron Beam Melting (EBM)" by Arcam AB allegedly sent by email in January 2006 to the visitors of Arcam's stand at the

trade fair EuroMold 2005, should not be considered publicly available and thus not be admitted, because there was no proof that a single member of the public had actually received said email without being bound by a confidentiality agreement.

However, document D9 (as well as documents D10 and D11 providing evidence of the public availability of D9) had been part of the opposition proceedings and had then also been introduced into the appeal proceedings with the statement of grounds of appeal (see the passages cited below). Therefore, in accordance with Articles 12(1), (2) and (4) RPBA, documents D9-D11 are to be taken into account by the Board.

Moreover, public availability of document D9 had never been put into doubt, either before the opposition division, or in the written procedure on appeal.

As can be seen from the minutes of the oral proceedings before the opposition division (points 5.3 and 5.4), in the opposition proceedings inventive step was discussed in relation to the technique disclosed in document D9. Equally, the content of D9 is discussed in point 3.1 of the decision without any indication that its public availability was an issue.

Moreover, in the statement setting out the grounds of appeal, point IV.2, the appellant had formulated an inventive step objection using D9, also making reference to the fact that the public availability of said document had not been put into doubt by the opposition division and including a statement that the appellant reserved the right "to elaborate on this point [i.e. the public availability of document D9]

should the public availability of D9 become an issue in the appeal proceedings".

Prior to the oral proceedings on appeal, the respondent had never voiced any concerns in this respect. The request not to consider D9 publicly available thus amounts to an amendment sought to be made after oral proceedings have been arranged. As the appellant had offered to further elaborate on this point, for reasons of procedural fairness, he should be able to do so if the respondent's request were granted. This would inevitably require adjournment of the oral proceedings, as it would include collecting evidence from the alleged recipients of D9. Therefore, in accordance with Article 13(3) RPBA, the requested amendment to the respondent's case cannot be admitted.

With the amendment to the respondent's case not being admitted, the Board accepts the declaration of Mr Ohldin (D10) stating when (in January 2006), what (the attached Arcam presentation D9) was sent to whom (visitors of the EuroMold trade) as sufficient evidence that document D9 were made available to at least one member of the public not bound to secrecy.

Document D9 is thus considered to have been publicly available before the filing date of the patent. Therefore, it is prior art under Article 54(2) EPC.

3.2.3 Document D9 discloses direct manufacturing with electron beam melting. The method is described as fast and economical, resulting in parts having excellent - i.e. "better than cast" - material properties (page 2 last slide). The presentation further shows several examples of the application of electron beam melting in the medical field (see pages 5 and 6), in particular

for the acetabular cup of a hip prosthesis. The person skilled in the art, looking for an alternative or better way of manufacturing the D6 femoral component of a hip prosthesis, would thus consider it obvious to apply electron beam melting as taught in D9 in order to manufacture the D6 prosthesis, thus solving the problem posed.

Consequently, claim 1 of the first auxiliary request is not inventive.

4. Second auxiliary request - Inventive step

Claim 1 of the second auxiliary request has been further amended to define that "the meshes (48) comprise a central hole (52) so as to take on a ring configuration".

D6 discloses various pattern shapes for the tissue ingrowth surface, such as square, rectangular or triangular (column 5, lines 34-37). It does however not disclose a ring configuration of the meshes.

In accordance with the Oxford English Dictionary, a ring has to be considered a circular element. Therefore, the ring configuration now claimed is equivalent to a circular shape of the mesh elements.

By deleting dependent claims 4-7 as granted and by adapting the corresponding parts of the description, the above mentioned equivalence has been clarified. The appellant's objection, that the circular shape and the ring configuration were different shapes, has thus become moot.

As stated in paragraph [0063] of the patent specification, "the particular circular shape of the mesh elements further favours the bony growth". The problem to be solved may thus be formulated as modifying the osteo-integrative surface of the D6 prosthesis in such a way as to further improve bony growth and osteo-integration.

None of the available documents proposes a ring configuration of the meshes. There is furthermore no incitation from the common general knowledge to modify the pattern disclosed in D6 into a ring configuration.

The subject-matter of claim 1 of the second auxiliary request is thus inventive.

Independent method claim 29 defines a method of manufacture of an endoprostheses according to anyone of claims 1 to 28. With the endoprosthesis according to claims 1 to 28 being novel and inventive, so is the method for its manufacture.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of the following documents:

- Claims 1 to 31 of the second auxiliary request, as filed at the oral proceedings on 16 December 2014;
- Description, pages 1 to 15, as filed at the oral proceedings on 16 December 2014;

- Figures 1 to 3, as granted.

The Registrar: The Chairman:

V. Commare T. Kriner

Decision electronically authenticated