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Datasheet for the decision of 2 October 2018

Case Number: T 0088/16 - 3.2.08

Application Number: 07025241.6

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IPC: A61F2/44, A61F2/46

Language of the proceedings: EN

Title of invention:
Stackable interlocking intervertebral support system

Patent Proprietor:
Nuvasive, Inc.

Opponent:
Spine Wave Inc.

Headword:

Relevant legal provisions:
EPC Art. 76(1), 84, 111(1), 123(2), 123(3)
RPBA Art. 13

Keyword:

Decisions cited:

Catchword:

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Case Number: T 0088/16 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 2 October 2018

Appellant: (Patent Proprietor)	Nuvasive, Inc. 7475 Lusk Boulevard San Diego, CA 92121 (US)
Representative:	Grund, Martin Grund Intellectual Property Group Patentanwalt und Solicitor PartG mbB Postfach 44 05 16 80754 München (DE)
Respondent: (Opponent)	Spine Wave Inc. Three Enterprise Drive, Suite 210 Shelton, CT 06484 (US)
Representative:	Zwicker, Jörk ZSP Patentanwälte PartG mbB Hansastraße 32 80686 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 4 November 2015 revoking European patent No. 1929978 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	C. Herberhold
Members:	M. Alvazzi Delfrate
	T. Karamanli

Summary of Facts and Submissions

I. By its decision posted on 4 November 2015 the opposition division revoked European patent No. 1 929 978.

The opposition division was of the view that the patent could not be maintained as granted because the term "biocompatible" in claim 1 extended beyond the content of the parent application EP 01958933.2 as originally filed. Auxiliary requests 1-7 then on file were found to contravene the requirements of Article 123(3) EPC, due to replacement of the term "biocompatible" in claim 1. Auxiliary request 8 was not admitted into the proceedings.

II. The appellant (patent proprietor) lodged an appeal against this decision in the prescribed form and within the prescribed time limits.

III. Oral proceedings before the Board of Appeal were held on 2 October 2018. For the course of the oral proceedings reference is made to the minutes. At the end of the oral proceedings the requests were as follows:

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the claims of the main request, filed as auxiliary request 1 during the oral proceedings of 2 October 2018 or alternatively on the basis of the claims of one of auxiliary requests 1 to 6, which were filed as auxiliary requests 5 to 7 with a letter dated 1 September 2015 and as auxiliary requests 9 to 11 with the statement of the grounds of appeal, respectively.

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

IV. Claim 1 of the **main request** reads as follows:

"An apparatus for the distraction of two vertebral surfaces in a given direction within a spine, characterised by:
a plurality of narrow elongated portions (10, 20A, 20B) composed of biocompatible material configured to be consecutively stacked upon one another to form a structure extending in a given direction within a spine,
said plurality of elongated portions comprising
- at least one center portion (10) having top and bottom recesses (11B, 11A);
- a top portion (20B) having a bottom recess (21B), the bottom recess in the top portion interlocking with the top recess in the uppermost center portion when the top portion is positioned on top of the uppermost center portion; and
- a bottom portion (20A) having a top recess (21A), the top recess in the bottom portion interlocking with the bottom recess in the lowermost center portion when the lowermost center portion is positioned on top of the bottom portion,
each elongated portion (1O, 20A, 20B) having
- a top surface (14, 22B)
- a bottom surface (12, 22A) disposed parallel to said top surface (14, 22B)
- a leading edge (13, 25)
- a trailing edge,
- first and second side surfaces extending between said top and bottom surfaces (14, 22B, 12, 22A), and

- a tapered surface extending from said leading edge (13, 25), said tapered surface dimensioned to engage a ramping structure disposed within one of the recesses on an adjacent portion,
- said tapered surface configured to facilitate distraction of said two vertebral surfaces in said given direction during consecutive insertion into said spine,
each of said elongated portions (1O, 20A, 20B) having
- a length dimension defined by the distance between said leading edge (13, 25) and the trailing edge,
- a width dimension defined by the distance between said first and second side surfaces, and
- a height dimension defined by the distance between said top and bottom surfaces (14, 22B, 12, 22A),
- wherein said length dimension is greater than said width dimension."

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

D6: I. Gotman "Characteristics of metals used in implants" J. Endourol., Vol. 11 (6), abstract, 1997;
D7: M. Plecko et al. "Osseointegration and biocompatibility of different metal implants - a comparative experimental investigation in sheep", BMC Muscoloskeletal Disorders, 13:32, 2012;
D11: WO -A- 02/05733 (= parent application as published of the application, on the basis of which the patent in suit was granted);
D15: US -A- 2014/0012311;
D16: "biocompatible - definition of biocompatible by Medical dictionary", http://medical-dictionary.thefreedictionary.com/biocompatible;
D18: WO -A- 99/60957.

VI. The arguments of the appellant may be summarised as follows:

Admission of the main request into the appeal proceedings

Claim 1 of the main request was based on claim 1 as granted with the addition of features already present in previous auxiliary request 5. Thus, all the features had already been considered in the written procedure and the new main request should be admitted into the appeal proceedings.

Article 76(1) EPC

The patent did not comprise subject-matter which extended beyond the content of the parent application as filed (D11), in accordance with Article 76(1) EPC.

It was acknowledged that D11 did not explicitly mention the term "biocompatible". However, the definition of "biocompatible" varied with time and the envisaged application, since no material was completely free from risks. For instance, stainless steel was considered biocompatible in some documents, such as D18 cited by the respondent, and non-biocompatible in others. D11 disclosed in paragraph [54] that the implant was made of any suitable bio-implantable material. It was thus clear that the material had to be biocompatible. This was also implied by the fact that the claimed device was conceived to be implanted in the body. In that sense, the claimed device was different from the temporarily inserted devices of D18, which were not implants but inserts, i.e. tools to be used during surgery. Thus, it was clear that the material of the implant of D11 was biocompatible.

D11 in paragraph [02] disclosed a stackable interlocking intervertebral support system. Indeed, in all the embodiments the elongated portions were stacked upon one another. Thus, elongated portions configured to be consecutively stacked upon one another as stipulated by claim 1 were disclosed in D11. Moreover, although paragraph [43] described that when the portions were stacked together the assembly formed an "X" shape, paragraphs [44] and [45] disclosed that other configurations were possible. There was thus no need to include the "X" shape in claim 1 in order to comply with the requirements of Article 76(1) EPC.

A geometry according to claim 1, wherein in each elongated portion the bottom surface was disposed parallel to the top surface, was not literally disclosed in D11. However, such a geometry was clearly shown in the drawings, e.g. Figure 20, which showed an assembly with four portions according to present claim 1. The arrangement, also shown in Figure 20, wherein the bottom surface of the uppermost center portion was brought into contact with the top surface of the bottom portion, was not inextricably linked to the now claimed geometry. This arrangement was related instead to the fact that the bottom and top surfaces of two different portions were parallel, and not to the feature whereby the bottom and top surfaces of the same portion were parallel. Thus, the amendment did not constitute an unallowable intermediate generalisation.

The feature whereby the tapered surfaces were configured to facilitate distraction of two vertebral surfaces in the given direction during consecutive insertion into the spine was disclosed in paragraph [49] and claim 24. It was clear thus that since

positioning each of the top, center and bottom portions in the patient's intervertebral space assisted in prying apart adjacent vertebrae, the tapered ends, i.e. the tapered surfaces, facilitated the distraction.

The wording in claim 1 specifying that each of the elongated portions had a length dimension defined by the distance between the leading edge and the trailing edge, a width dimension defined by the distance between the first and second side surfaces, and a height dimension defined by the distance between the top and bottom surfaces, wherein said length dimension was greater than said width dimension, was a mere repetition of the elongated shape already defined in the claim. No difference could be seen between the elongated shape mentioned in the claim and the "narrow elongated" shape disclosed in D11.

The feature that each elongated portion had a tapered surface extending from the leading edge was likewise disclosed in D11. Indeed, in several places D11 mentioned a tapered end, and a tapered end inevitably comprised a tapered surface. It was true that, according to paragraph [14], the engagement of the tapered end and the ramping structure was such that the separate portions of the assembly were "slip-fit" together. However the "slip-fit" was nothing other than the result of the engagement and the interlocking recesses, which were already defined in claim 1. Hence, in that respect too, no contravention of Article 76(1) EPC was present.

Articles 123(2) and (3) and 84 EPC

Claim 1 also satisfied the requirements of Articles 123(2) and (3) and 84 EPC.

Remittal to the opposition division

There was no objection to a remittal of the case to the opposition division for further prosecution.

VII. The arguments of the respondent may be summarised as follows:

Admission of the main request into the appeal proceedings

The main request was intended to address objections already submitted in the written procedure. Hence, it could and should have been submitted at an earlier stage of the proceedings. Thus, it should not be admitted into the appeal proceedings.

Article 76(1) EPC

Claim 1 of the main request extended beyond the content of the earlier application as filed (D11), contrary to the requirements of Article 76(1) EPC. The feature that the elongated portions were composed of "biocompatible" material was not directly and unambiguously derivable from D11. The term biocompatible was nowhere mentioned in D11. A bioimplantable material as disclosed in paragraph [54] of D11 was merely a material which could be implanted in a living being, whereas a biocompatible material, as defined in D16, was a material that did not pose risk of injury, toxicity or rejection by the immune system over both the short term and the long term; it could thus be permanently implanted. Also, D15 used both of the terms biocompatible and bioimplantable, making clear that the two terms had different meanings. Furthermore, D18 showed that

intervertebral distraction devices could also be used as temporary tools, and thus did not need to be biocompatible. Therefore, the use of a biocompatible material was neither explicitly nor implicitly disclosed in D11.

Additionally, no clear disclosure of elongated portions configured "to be consecutively stacked upon one another", as required by claim 1, could be found in D11. In the embodiments exhibiting elongated portions stacked upon one another as shown in D11 the assembly always formed an "X" shape, while claim 1 was completely silent in that respect.

The feature whereby for each elongated portion the bottom surface was disposed parallel to the top surface was likewise not disclosed in D11. The drawings could not be taken as a basis either, because this feature was not disclosed for an assembly with more than three portions. In any event, the feature represented an unallowable intermediate generalisation since it was only disclosed in combination with the fact that the bottom surface of the uppermost center portion was brought into contact with the top surface of the bottom portion as shown in Figure 20.

Tapered surfaces configured to facilitate distraction of two vertebral surfaces in the given direction during consecutive insertion into the spine were also not disclosed in D11. Paragraph [49] was silent on the role of the top and bottom portion in prying apart adjacent vertebrae. Claim 24 did not mention the tapered surfaces at all. In general, D11 did not mention tapered surfaces, only tapered ends. Further, a trailing edge and a leading edge were not mentioned in D11.

Present claim 1 also specified that each of the elongated portions had a length dimension defined by the distance between the leading edge and the trailing edge, a width dimension defined by the distance between the first and second side surfaces, and a height dimension defined by the distance between the top and bottom surfaces, wherein said length dimension was greater than said width dimension. While this could be regarded as an elongated shape, D11, paragraph [53], disclosed that the shape was not merely elongated but "narrow elongated".

Finally, according to paragraph [14] of D11, the engagement of the tapered end and the ramping structure was such that the separate portions of the assembly could be "slip-fit" together. The omission of this feature in claim 1 was a further unallowable intermediate generalisation.

For these reasons the requirements of Article 76(1) EPC were not satisfied.

Articles 123(2) and (3) and 84 EPC

There were no further objections in respect of Article 123(2) and (3) EPC. In respect of Article 84 EPC, reference was made to the written submissions in the letter dated 31 August 2018 (point 8).

Remittal to the opposition division

There was no objection to remittal of the case to the opposition division for further prosecution.

Reasons for the Decision

1. Admission of the appellant's main request into the appeal proceedings

The main request was filed at the oral proceedings before the Board. Hence, its admission into the proceedings is at the Board's discretion (Article 13 RPBA).

Claim 1 of the main request is based on claim 1 as granted with the addition of features already present in previous auxiliary request 5 (which was also auxiliary request 5 underlying the appealed decision). Thus, the Board and the respondent could reasonably be expected to deal with the issues raised by this request without adjournment of the oral proceedings.

It is true that, since it addresses objections already submitted in the written procedure, the main request could have been submitted at an earlier stage. However, it must also be taken into consideration that a number of different objections under Article 100(c) EPC, most of which were not decided upon by the opposition division, had been raised against the patent as granted. Taking all the different scenarios arising from the possible findings of the Board on all said objections into account would have entailed filing a disproportionately high number of requests. Therefore, the submission of the main request at the oral proceedings is considered to be an appropriate reaction to the Board's view on the appellant's former main request.

In these circumstances the Board exercised its discretion under Article 13 RPBA and decided to admit the appellant's main request into the appeal proceedings.

2. Article 76(1) EPC

The application on which the patent in suit is based was filed as a divisional application of the earlier application EP 01958933.2 (in the following reference is made to the published international application D11). According to Article 76(1) EPC, a European patent must not comprise subject-matter which extends beyond the content of the earlier application as filed.

2.1 Claim 1 of the main request is based on claim 1 of D11, with the addition of several features, in particular that the elongated portions are composed of biocompatible material. The opposition division found that the patent could not be maintained as granted because the term "biocompatible" extended beyond the content of the parent application as originally filed. It must thus be assessed whether the person skilled in the art, using their common general knowledge, would derive directly and unambiguously from the whole disclosure of D11 that the elongated portions are composed of biocompatible material.

It is undisputed that D11 does not mention *expressis verbis* the term "biocompatible". In order to assess whether or not this feature is implicitly disclosed, its meaning has to be established. According to D16 "biocompatible" is defined as something that does not pose risk of injury, toxicity or rejection by the immune system. The respondent argued, in accordance with the opinion of the opposition division, that for a

biocompatible implant material said risk did not arise over both the short term and the long term of implantation, and that there was no disclosure in D11 that the claimed device was to be implanted for the long term.

The Board does not share this view. The device disclosed in D11 is an intervertebral support system, wherein the different portions are surgically inserted into the patient and therein assembled to interlock with each other (see claims 1 and 17 and paragraphs [49] to [52]). Although it may be theoretically possible to surgically remove the support system at some point in time by further surgery, it is clear for the person skilled in the art, reading the description of the interlocking mechanism, that this is not intended. In other words, the person skilled in the art derives directly and unambiguously that the intervertebral support system disclosed in D11 is intended for long-term implantation. Therefore, there is no need to establish whether a biocompatible implant must be suitable for long-term implantation or whether it suffices for it to be suitable for short-term implantation. It is concluded that for the person skilled in the art, the "suitable bio-implantable material" mentioned in paragraph [54] of D11 is implicitly a biocompatible material.

Thus, no contravention of Article 76(1) EPC can be seen in this respect.

2.2 Claim 1 also recites that the elongated portions are configured "to be consecutively stacked upon one another".

This exact wording is not to be found in D11. However, D11 refers to a stackable intervertebral support system (paragraph [02]). In all the embodiments, the elongated portions are stacked upon one another. Thus, elongated portions configured to be consecutively stacked upon one another are disclosed in D11.

It is true that paragraph [43] describes that when the portions are stacked together, the resulting assembly forms an "X" shape (see also Figures 1-4 and 18-21). However, paragraphs [44] and [45] disclose that the interlocking recesses may also be positioned closer to one end of their respective portions than another, such that the assembly may approach a "V" shape (paragraph [44]), or that the angles between each of the 4 "arms" of the assembly need not be perpendicular to one another but may be 60° or 120° apart (paragraph [45] and Figure 9B). Thus, the feature that elongated portions are configured to be consecutively stacked upon one another is not structurally or functionally linked with the feature that they form an "X" shaped assembly. Accordingly, no added subject-matter arises from the omission of the latter feature. Thus, no contravention of Article 76(1) EPC can be seen in this respect.

2.3 Claim 1 also stipulates that for each elongated portion the bottom surface is disposed parallel to the top surface.

This feature is not literally disclosed in D11. However, the drawings, albeit of schematic nature, clearly show elongated portions with bottom and top surfaces parallel to each other.

The respondent argued that this feature was not disclosed for an assembly with more than three portions. The Board does not share this view because in Figure 20 the assembly comprises four portions.

The respondent also argued that the addition of the feature whereby for each elongated portion the bottom surface is disposed parallel to the top surface represented an unallowable intermediate generalisation, because said feature was only disclosed in combination with the fact that the bottom surface of the uppermost center portion (12) is brought into contact with the top surface of the bottom portion (20A), as shown in Figure 20. However, this argument is not convincing because the contact between the bottom surface of the uppermost center portion and the top surface of the bottom portion is linked to the fact that two surfaces of two different portions are parallel and not to the feature added to the claim, which recites that the bottom and top surfaces of the same portion are parallel.

Thus, no contravention of Article 76(1) EPC can be seen in this respect.

2.4 Claim 1 also specifies that the tapered surfaces are configured to facilitate distraction of two vertebral surfaces in the given direction during consecutive insertion into the spine.

Paragraph [49] discloses that the tapered end of the center portion tends to pry apart adjacent vertebrae, providing the surgeon with a "self-distracting" vertebral support system, but it is silent on the role of the top and bottom portion in prying apart adjacent vertebrae. This is disclosed in claim 24, which states

that positioning each of the top, center and bottom portions in the patient's intervertebral space assists in prying apart adjacent vertebrae. Hence, it is clear that the tapered surfaces of the bottom and top portions too play a role, during insertion, in the distraction of the vertebrae (see also paragraph [51]). It is true that a direct interaction of the tapered surfaces of top and bottom portions with the vertebrae to be distracted is not disclosed in said claim. Said direct interaction is however not stipulated by the feature added to claim 1 either, since it merely requires the tapered surfaces to be configured to facilitate distraction of two vertebral surfaces in the given direction during consecutive insertion into the spine.

Thus, no contravention of Article 76(1) EPC can be seen in this respect.

2.5 Claim 1 specifies that each of the elongated portions has a length dimension defined by the distance between the leading edge and the trailing edge, a width dimension defined by the distance between the first and second side surfaces, and a height dimension defined by the distance between the top and bottom surfaces, wherein said length dimension is greater than said width dimension. In other words, claim 1 defines an elongated shape.

D11, paragraph [53], discloses that the shape is "narrow elongated". Since no difference can be established between a narrow elongated shape as originally disclosed and the elongated shape presently defined in the claim no contravention of Article 76(1) EPC can be seen in this respect either.

2.6 Claim 1 also stipulates that each elongated portion has a tapered surface extending from the leading edge. D11 discloses that each portion has a tapered end which, as also stipulated by present claim 1, engages the ramp of an adjacent portion (see, for instance, claim 25).

Since a tapered end always comprises a tapered surface, no added subject-matter can be seen in the fact that present claim 1 refers to tapered surfaces extending from the leading edge instead of tapered ends.

Nor can there be any objection to the reference in claim 1 to a leading edge and a trailing edge, since the tapered end, which is advanced first (see, for instance, claim 25), can be seen as providing a leading edge, whereas the opposed edge can be seen as providing the trailing edge.

It is correct that according to paragraph [14] the engagement of the tapered end and the ramping structure is such that the separate portions of the assembly may be "slip-fit" together, with pressure between the adjacent vertebrae holding each of the pieces of the assembly together, while present claim 1 does not mention any "slip-fit". However, the "slip-fit" is the inherent result of the engagement and the interlocking recesses as defined in claim 1. Hence, no feature has been omitted and no contravention of Article 76(1) EPC can be seen in this respect.

3. Articles 123(2) and (3) and 84 EPC

3.1 Since the disclosures of the parent and divisional applications are essentially identical, the requirements of Article 123(2) EPC are also fulfilled.

3.2 Regarding the requirements of Article 123(3) EPC, no objections were raised by the respondent. The Board also has no objections, since claim 1 comprises all the features of granted claim 1.

3.3 In its letter dated 31 August 2018 (point 8), the respondent also argued that claim 1 lacked clarity because the expressions "the uppermost" and "the lowermost" center portion lacked an antecedent. However, the Board is not convinced by this argument: the term "the" in the expressions "the uppermost" and "the lowermost" is used because of the superlative and does not, therefore, require an antecedent. Hence, Article 84 EPC does not prejudice the maintenance of the patent in amended form according to the appellant's main request.

4. Remittal to the opposition division

In the decision under appeal, the opposition division did not consider the grounds for opposition under Article 100(a) and (b) EPC, which had also been raised in the notice of opposition. Therefore, it being the primary object of the appeal proceedings to review the decision under appeal in a judicial manner, the Board considers it appropriate to remit the case to the opposition division for further prosecution pursuant to Article 111(1), second sentence, EPC. The parties did not object to a remittal.

5. In view of the above, the Board sees no need to decide on the appellant's auxiliary requests.

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 for further prosecution.

The Registrar: The Chairman:

C. Moser C. Herberhold

Decision electronically authenticated