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**Datasheet for the decision  
of 29 September 2020**

**Case Number:** T 1363/16 - 3.2.02

**Application Number:** 04753283.3

**Publication Number:** 1631188

**IPC:** A61B5/04

**Language of the proceedings:** EN

**Title of invention:**  
ELECTROPHYSIOLOGY CATHETER

**Applicant:**  
STEREOTAXIS, INC.

**Headword:**

**Relevant legal provisions:**  
EPC Art. 54, 84, 123(2)

**Keyword:**  
Novelty - auxiliary request 4 (yes)  
Claims - clarity - main request and auxiliary requests 1 to 3  
(no) - auxiliary request 4 (yes)  
Amendments - added subject-matter - main request and auxiliary  
requests 1 to 3 (yes) - auxiliary request 4 (no)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
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Case Number: T 1363/16 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 29 September 2020**

**Appellant:** STEREO TAXIS, INC.  
(Applicant) 4041 Forest Park Avenue  
St. Louis, MO 63108 (US)

**Representative:** Hedges, Martin Nicholas  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 21 January 2016  
refusing European patent application No.  
04753283.3 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** M. Alvazzi Delfrate  
**Members:** S. Böttcher  
N. Obrovski

## **Summary of Facts and Submissions**

I. The applicant filed an appeal against the decision of the Examining Division to refuse European patent application No. 04753283.3. The Examining Division held that claim 1 of the main request and of auxiliary request 1 did not meet the requirements of Articles 123(2), 83 and 84 EPC, and that the subject-matter of claim 1 of the main request and of auxiliary requests 1 and 2 lacked novelty over

D2: US 2002/0116043.

II. In the statement of grounds of appeal the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or one of auxiliary requests 1 to 3 filed therewith.

III. With a communication under Rule 100(2) EPC dated 20 May 2020, the appellant was informed that, in the Board's view, claim 1 of the main request and of the auxiliary requests 1 to 3 included added subject-matter (Article 123(2) EPC) and lacked clarity (Article 84 EPC).

IV. By letter of 17 July 2020, the appellant filed an amended set of claims under auxiliary request 4.

V. Oral proceedings took place on 29 September 2020 by video conference.

VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or one of auxiliary requests 1 to

3, all filed with the statement of grounds of appeal, or on the basis of auxiliary request 4, filed during the oral proceedings and replacing the previous auxiliary request 4.

VII. Claim 1 of the main request reads as follows:

"A magnetically guidable medical device (20) comprising an elongate body (26) having a proximal end (22) and a distal end (24); a magnetically responsive tip element (46) affixed adjacent the distal end (24) of the body; and at least two magnetically responsive auxiliary elements (48, 50) affixed to the body and spaced proximally from the tip element (46), characterised by each of the magnetically responsive elements (46, 48, 50) separated from adjacent elements (46, 48, 50) by flexible portions (54, 56, 58) of the body the portions not all being of equal lengths; the flexible portions (26a) having a selected material and selected cross-sectional geometry configured to allow the given flexible portion to exhibit a selected deflection along a selected length adjacent to where mechanically coupled with a given one of the magnetically responsive elements, and the given magnetically responsive element having a magnetic dipole moment selected in relation to the selected deflecting to provide, in the presence of a magnetic field, a selected shape of the medical device adjacent to where the given flexible portion and the given magnetically responsive element are mechanically coupled."

VIII. Claim 1 of auxiliary requests 1 to 3 is identical to claim 1 of the main request.

IX. Claim 1 of auxiliary request 4 reads as follows:

"A magnetically guidable electrophysiology catheter (20) comprising an elongate body (26) in the form of a tube having a proximal end (22) and a distal end (24); a magnetically responsive tip element (46) affixed adjacent the distal end (24) of the tube; and at least two magnetically responsive auxiliary elements (48, 50) affixed to the tube and spaced proximally from the tip element (46), said magnetically responsive auxiliary elements (48, 50) being affixed in the form of a sleeve around the tube, characterised by each of the magnetically responsive elements (46, 48, 50) separated from adjacent elements (46, 48, 50) by flexible portions (54, 56, 58) of the body the portions not all being of equal lengths."

- X. The arguments of the appellant as far as relevant for the decision can be summarised as follows:

Main request and auxiliary requests 1 to 3

Claim 1 of the main request and of auxiliary requests 1 to 3 was based on paragraphs [0014], [0017] and [0023] to [0026], and on any of claims 4, 8 or 13 as originally filed. Hence, this claim met the requirements of Article 123(2) EPC.

Auxiliary request 4

Claim 1 of auxiliary request 4 included the feature that the auxiliary elements were fixed in the form of a sleeve, but not the tip element, since the tip was not disclosed as being in the form of a sleeve around the tube (Figure 1). Although it was mentioned in paragraph [0017] that the magnetic members could be affixed to the side wall in the form of a sleeve around the tube, this did not mean that all three magnetic members had

to be in the form of a sleeve. Since the functional requirements of the tip element were different to those of the auxiliary elements, it could be derived that only the auxiliary elements were in the form of a sleeve around the tube.

Hence, claim 1 of auxiliary request 4 met the requirements of Article 123(2) EPC.

The appellant did not submit arguments as to the objections of lack of clarity raised by the Board in the communication dated 20 May 2020.

## **Reasons for the Decision**

### 1. Subject-matter of the application

The application relates to a magnetically guidable electrophysiology catheter. The catheter comprises a tube having a proximal end and a distal end. Several magnetically responsive elements (46, 48, 50) (e.g. permanent magnets, permeable magnets, electromagnetic coils (paragraph [0004])) are spaced along the distal end of the catheter (Figure 1). Flexible portions of the catheter are disposed between the magnetically responsive elements. The interplay between the strength and orientation of each magnet member and the flexibility and length of each flexible segment allows segments of the catheter to be oriented in a selected direction with an applied magnetic field. Thus, the catheter may navigate and advance through delicate structures in the body, e.g. through a puncture in the

septal wall of the heart.

2. Main request - added subject-matter

2.1 The Board agrees with the Examining Division that the feature "a selected deflection along a selected length adjacent to where mechanically coupled with a given one of the magnetically responsive elements" cannot be derived directly and unambiguously from the description as originally filed (point 1.1.2 (ii) of the decision). In particular, paragraph [0025] of the description mentions that the magnetic member coupled at the distal end of a given flexible portion causes the deflection of the distal end of this flexible portion. In contrast, the claim covers the deflection of any selected length of the flexible portion adjacent a magnetic member, e.g. the complete length or the proximal end of the flexible portion adjacent the proximal magnetic member.

2.2 According to the appellant, the features "affixed adjacent the distal end of the body" (concerning the tip element) and "affixed to the body" (concerning the auxiliary elements) are based on paragraphs [0017] and [0023] of the description.

2.3 However, the description refers to an electrophysiology catheter in the form of a tube whereas the claims of the main request relate to any medical device. Hence, since the features of paragraphs [0017] and [0023] are only disclosed in connection with an electrophysiology catheter, the omission of the feature "electrophysiology catheter" in claim 1 constitutes an unallowable intermediate generalisation.



2.4 Moreover, the feature "affixed to the body" includes a further unallowable intermediate generalisation, since it is mentioned in paragraph [0017] that the magnetic members can be affixed to the side wall of the catheter in the form of a sleeve around the tube.

2.5 It follows that claim 1 of the main request includes added subject-matter and, therefore, does not meet the requirements of Article 123(2) EPC.

### 3. Main request - clarity

Claim 1 lacks clarity since it is not defined which "selected deflection" a given flexible portion should exhibit and which "selected shape of the medical device" should be provided by the dipole moment of a given magnetically responsive element. Furthermore, the deflection and the shape of the device in the presence of a magnetic field depends on the magnitude and orientation of this magnetic field. However, none of these parameters is defined in the claim. Hence, the person skilled in the art does not know how to select the material and the cross sectional geometry of the flexible portions and the dipole moment of the magnetic elements in order to obtain a device that falls within the boundaries of the scope of the claim.

Hence, the requirements of Article 84 EPC are not met.

### 4. Auxiliary requests 1 to 3

Since claim 1 of auxiliary requests 1 to 3 is identical to claim 1 of the main request, the objections mentioned above also apply to these auxiliary requests. Thus, none of these requests are allowable.

5. Auxiliary request 4 - support in the original application documents

5.1 Claim 1 of auxiliary request 4 is in essence based on the first part of claim 5, i.e. the part of claim 5 which was in common in all independent claims as originally filed, in combination with claim 8 as originally filed. The features "electrophysiology catheter" and "in the form of a tube" can be derived from paragraph [0014] of the description and Figure 1. The features "affixed adjacent the distal end" (concerning the tip element) and "affixed to the tube (...) in the form of a sleeve around the tube" (concerning the auxiliary elements) are based on paragraphs [0017] and [0023] of the description and Figure 1.

5.2 Consequently, the amendments made to claim 1 of auxiliary request 4 fulfil the requirements of Article 123(2) EPC.

5.3 Auxiliary request 4 - sufficiency of disclosure

The Examining Division considered that claims 3, 5 to 7 and 10 to 13 (i.e. claims 3, 6, 8, 10 and 12 to 15 of the main request) did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Since these claims have been deleted in auxiliary request 4, these objections are no longer pertinent.

6. Auxiliary request 4 - clarity

The objection raised against claim 1 of the main request has been overcome by deleting the contested

features. Claim 1 of auxiliary request 4 therefore meets the requirements of Article 84 EPC.

7. Auxiliary request 4 - novelty in view of D2

The subject-matter of claim 1 is novel over D2 since the magnetically responsive elements of the catheter of D2 are not affixed adjacent the distal end of the tube or affixed in the form of a sleeve around the tube, respectively. Furthermore, D2 does not disclose that the elements are separated from adjacent elements by flexible portions of the tube, the portions not all being of equal lengths.

8. Remittal to the department of first instance

As mentioned above, claim 1 of auxiliary request 4 meets the requirements of Articles 123(2), 83 and 84 EPC, and its subject-matter is novel over D2. However, the claims of auxiliary request 4 have not been examined with regard to novelty over the remaining prior art and with regard to inventive step by the Examining Division.

Under Article 111(1) EPC, the Board may in the present case either proceed further with the examination of the application or remit the case to the Examining Division for further prosecution. Since the appeal was pending on 1 January 2020, the revised version of the RPBA applies (OJ EPO 2019, A63). In particular, Article 11 RPBA 2020 is applicable.

Article 11 RPBA 2020 provides that the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so. However, this

provision has to be read in conjunction with Article 12(2) RPBA 2020, which provides that it is the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (see also T 0731/17 of 15 January 2020, point 7.3 of the Reasons, T 1966/16 of 20 January 2020, point 2.2 of the Reasons and T 0547/14 of 29 January 2020, points 7.1 and 7.2 of the Reasons, T 294/16 of 10 September 2020, point 2 of the Reasons).

This principle would not be respected if the Board were to conduct a complete examination of the application. In the present case, the Board would have to carry out a full examination of the application for compliance with the requirements of Articles 54 and 56 EPC, i.e. on matters on which the department of first instance has not taken any decision yet.

Consequently, the Board considers it appropriate to exercise its discretion under Article 111(1) EPC to remit the case to the department of first instance for further prosecution.

## **Order**

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division for further prosecution.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated