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Datasheet for the decision of 10 September 2013

Case Number: T 2375/09 - 3.2.02

Application Number: 03255564.1

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IPC: A61B 19/00, A61B 5/04, A61N 1/36

Language of the proceedings: EN

Title of invention:
Positioning system for neurological procedures in the brain

Applicant:
Biosense Webster, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 56, 123(2)

Keyword:
"Inventive step - (yes)"

Decisions cited:
T 0811/96, T 1374/07

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 2375/09 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 10 September 2013

Appellant: (Applicant)
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Representative:
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Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 23 July 2009 refusing European patent application No. 03255564.1 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: E. Dufrasne
Members: D. Ceccarelli
M. Stern

Summary of Facts and Submissions

I. The appellant lodged an appeal against the decision of the Examining Division, dispatched on 23 July 2009, to refuse European patent application No. 03 255 564.1.

II. The Examining Division's decision was based on a main request and an auxiliary request and considered the following documents:

D1: US-B-6,285,898;
D2: WO-A-98/33451;
D3: US-A-6,165,164;
D4: US-A-6,061,587;
D5: WO-A-96/05768.

The subject-matter of claim 1 of the main request was considered not inventive over the combination of document D2 with any of documents D1, D3, D4 and D5.

The subject-matter of claim 1 of the auxiliary request was considered not inventive over the combination of document D2 with documents D1 and D3.

As a result, neither of the requests met the requirements of Articles 52 and 56 EPC.

III. The notice of appeal was received on 22 September 2009 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 2 December 2009. With it, a main request and auxiliary request 1 were presented.

IV. The Board summoned the appellant to oral proceedings and provided its provisional opinion.

V. With letter dated 26 July 2013, the appellant filed claims according to auxiliary requests 2 and 3 for consideration during the oral proceedings.

VI. Oral proceedings were held on 10 September 2013.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of auxiliary request 2 filed with letter dated 26 July 2013 or, in the alternative, of auxiliary request 3 filed on the same date. It withdrew the main request and auxiliary request 1 and filed an adapted description for auxiliary request 2.

VII. Claim 1 of auxiliary request 2 reads as follows:

"Apparatus (18) for use in a brain (20) of a subject, comprising:

an instrument (50) adapted to be inserted into the brain (20);

one or more electrodes (28) on the instrument (50) at the distal end of the instrument (50) for sensing electrical activity of the brain (20) and transmitting an electrical activity signal responsive thereto;

one or more location sensors (40) located at the distal end of the instrument (50) for transmitting a location signal indicative of a location of the instrument (50); and

a control unit (90) for analyzing the electrical activity signal and the location signal and determining, responsive to the analysis, a position of

the instrument (50) with respect to an image of the brain, and electrophysiological information regarding tissue (30) at the position;

wherein the instrument (50) includes a delivery element (24) for delivering a pharmaceutical at a target location (30) responsive to the electrical signal and the location signal."

VIII. The appellant's arguments are summarised as follows:

According to claim 1 of auxiliary request 2, each of the electrodes, the location sensors and the delivery element had to be present in the instrument at the same time.

Document D2 did not envisage an instrument which contained at the same time one or more electrodes, one or more location sensors and a delivery element as claimed, but rather disclosed a list of sensing probes and a list of tool probes from which selections had to be made. Page 18 of document D2, for example, disclosed that a sensor probe was retracted and that a tool probe took its place in the instrument. The passage straddling pages 9 to 10 explained that a probe-cannula assembly could be replaced with a probe-tool assembly.

The combination of one or more electrodes, one or more location sensors and a delivery element as claimed was not merely an arbitrary selection but had the technical effect of allowing real-time feedback of the location of the instrument and tissue type in the brain during delivery of a pharmaceutical agent.

Document D2 disclosed location sensors situated on a stereotactic frame outside the brain when the instrument was in use. In contrast, claim 1 required that the location sensors were at the distal end of the instrument. This meant that the location sensors were inside the patient's brain when the instrument was in use.

As was clear in particular from the passage on page 4, lines 24-27, document D2 was concerned with miniaturisation of the instrument, in order to reduce the risks of neurological injury or possibly death when placing it (page 5, lines 16-20). For this reason, the skilled person would be taught away from providing the instrument with the combination of the electrodes, the location sensors and the delivery element as claimed.

The skilled person would not look at any of documents D1, D3 and D5, since they were concerned with cardiac procedures which could not be applied to the brain.

Even if the skilled person had considered documents D1, D3 and D5, he would not have been led to the invention as claimed, since D1 and D5 did not disclose the delivery of a pharmaceutical and D3 disclosed an instrument with a distal end having an outer diameter which was too large to be combined with the device of document D2 and its purposes (column 4, lines 52-53, column 5, lines 7-11 and column 6, lines 36-39 of document D3 compared with page 6, lines 11-21 and page 19, lines 3-6 of document D2).

Document D4 disclosed a brain drug delivery device with distal RF microcoils for improving a magnetic resonance

imaging process. Said coils were not location sensors. Moreover, document D4 was not concerned with improving the way of reaching a target area as the claimed invention, but rather with improving the visualisation of the drug delivery device. For these reasons, the skilled person would not consider combining the disclosures of documents D2 and D4.

Hence, the subject-matter of claim 1 of auxiliary request 2 was inventive.

Reasons for the Decision

1. The appeal is admissible.

2. The subject-matter of claim 1 of auxiliary request 2 is based on claims 1 and 14 as well as page 9, lines 7-11 and page 13, lines 23-25 of the application as originally filed.

The subject-matter of dependent claims 2-27 is based on corresponding dependent claims of the application as originally filed.

The Board is satisfied that auxiliary request 2 fulfils the requirements of Article 123(2) EPC.

3.1 It is undisputed that document D2 represents the closest prior art for the invention as defined in claim 1 of auxiliary request 2. Like the latter, document D2 concerns an apparatus comprising an instrument adapted to be inserted into a brain of a

subject, and the accurate positioning of said instrument (page 4, lines 14-16).

3.2 In particular, document D2 discloses an apparatus for use in a brain of a subject (page 4, lines 14-16), comprising an instrument adapted to be inserted into the brain (cannula 22 in figures 1-3 together with page 9, lines 27-30), a location sensor for transmitting a location signal indicative of a location of the instrument (encoders 87 and 90 in figure 2 together with page 13, lines 1-7) and a control unit for analyzing the location signal and determining, responsive to the analysis, a position of the instrument with respect to an image of the brain (computer system 20 in figure 1 together with page 4, lines 18-22, page 4, line 29 to page 5, line 1 and page 10, lines 12-16).

In the passage from page 14, line 26 to page 15, line 18, document D2 discloses a list of sensors and tools comprised of a sub-list of sensors (page 14, line 26 to page 15, line 15) including an electrode for sensing electrical activity of the brain (page 15, line 15) and transmitting an electrical activity signal responsive thereto (page 5, lines 24-28), and a sub-list of tools (page 15, lines 16-18) including an irrigator as delivery element for delivering a pharmaceutical at a target location (page 15, lines 17-18). Each of said sub-lists is of a certain length.

On page 14, lines 22-25, document D2 discloses that "one or more" of said "sensors and / or [...] tools" may be included in a probe (24 in figures 1-3). However, in order to obtain the specific combination of

the electrodes and the delivery element as claimed in claim 1 of auxiliary request 2, two individual elements would have to be selected from said list.

When illustrating its embodiments, document D2 also explicitly refers to a "probe-cannula" and a "probe-tool" (page 9, line 25 to page 10, line 2). However, even under the assumption that the "probe-cannula" and the "probe-tool" could be both part of the instrument, in order to obtain the specific combination of the electrodes and the delivery element as claimed in claim 1 of auxiliary request 2, two individual elements would have to be selected from the two sub-lists of sensors and tools.

According to the established case law of the boards of appeal on selection inventions, while selecting one element from a known single list does not confer novelty on the element involved, the respective selection of two individual elements from two disclosed lists of a certain length is to be considered as new. Furthermore, decisions T 811/96 (point 1.6, last paragraph) and T 1374/07 consider that a selection of two individual elements from one list is equivalent to a twofold selection from two identical lists.

The Board therefore concludes that the apparatus of document D2 also comprises only either one of:
- an electrode on the instrument for sensing electrical activity of the brain and transmitting an electrical activity signal responsive thereto, the control unit being also for analyzing the electrical activity signal and providing electrophysiological information regarding tissue at the position of the instrument,

or

- the instrument including a delivery element for delivering a pharmaceutical at a target location responsive to the location signal.

3.3 Hence, the subject-matter of claim 1 of auxiliary request 2 differs from the disclosure of document D2 in that it defines the combination of the two alternatives of the above paragraph and in that the location sensors are located at the distal end of the instrument.

3.4 The Board shares the appellant's view that the differentiating features have the technical effect of allowing real-time feedback of the location of the instrument and tissue type in the brain during delivery of a pharmaceutical agent.

3.5 Also in view of an objective of the invention as formulated in the application (page 4, lines 10-12), the objective technical problem to be solved by said differentiating features can be regarded as being to achieve a more effective and safe local pharmaceutical treatment of neurological disorders.

3.6 As the appellant correctly points out, an object of the invention of document D2 is to minimise invasiveness through miniaturisation (page 4, lines 24-27). Providing the location sensors at the distal end of the instrument and the differentiating combination of features as referred to in point 3.3 above would go against said object, since it would necessarily involve an increase in the size of the instrument. Therefore, the disclosure of document D2 teaches away from the invention as claimed in claim 1 of auxiliary request 2.

Although, contrary to the appellant's opinion, documents D1 (column 32, lines 22-26) and D5 (page 16, lines 26-32 and page 37, lines 23-25) deal with medical procedures in the brain, said documents do not disclose any local delivery of pharmaceuticals via a delivery element of the instrument. At least for this reason, they cannot address the objective technical problem and would not be considered by the skilled person.

In the impugned decision (point 1.7) the Examining Division expresses the view that the catheter of document D3 would be suitable for use in brain treatment. The Board however remarks that the disclosure of document D3 is not concerned with any such use, nor does it discuss any problems relating to the latter. It follows that also document D3 cannot address the objective technical problem and would be disregarded by the skilled person.

Document D4 is mainly concerned with tracking drug delivery in the brain using magnetic resonance imaging (MRI) (column 1, lines 6-15). Drug delivery is performed by means of an instrument (catheter 4, figures 1-5) inserted into the brain. The instrument comprises location sensors at its distal end (microcoils 9, 9a, 10 and 10a, figure 4 together with column 17, lines 61-63), a delivery element for delivering a pharmaceutical, and detection elements for sensing electronic activity (delivery tube 29 and detection element 32, figure 5 together with column 19, lines 3-13). However, document D4 does not disclose a control unit for analyzing both an electrical activity signal provided by the detection elements and a

location signal provided by the location sensors and determining, responsive to the analysis, a position of the instrument with respect to an image of the brain. On the contrary, document D4 teaches the use of MRI combined with conventional placement techniques (column 1, lines 10-15). Also in the light of the disclosure of document D2, page 2, line 30, to page 3, line 2, document D4 is therefore neither concerned with the accurate positioning of the instrument, nor does it address the objective technical problem. Hence, document D4 too would be disregarded by the skilled person.

3.7 It follows that the subject-matter of claim 1 of auxiliary request 2 involves an inventive step (Article 56 EPC).

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 with the order to grant a patent on the basis of:

   – claims 1 to 27 of auxiliary request 2 filed with letter dated 26 July 2013;

   – adapted description, pages 1 to 15, filed during oral proceedings; and

   – the figure as originally filed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne