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**Datasheet for the decision
of 23 January 2023**

Case Number: T 0116/20 - 3.2.02

Application Number: 07753408.9

Publication Number: 2081634

IPC: A61M37/00, A61M39/02

Language of the proceedings: EN

Title of invention:

VENOUS ACCESS PORT ASSEMBLY WITH RADIOPAQUE INDICIA

Patent Proprietors:

Medical Components, Inc.
Innovative Medical Devices, LLC

Opponent:

BAUER WAGNER PRIESMEYER

Relevant legal provisions:

EPC Art. 54, 56, 84, 123(2)
RPBA 2020 Art. 13(1)

Keyword:

Novelty - (yes)

Inventive step - (yes)

Amendments - added subject-matter (no)

Late-filed objection - should have been submitted in first-
instance proceedings (yes) - admitted (no)



Beschwerdekammern

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Case Number: T 0116/20 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 23 January 2023

Appellant:

(Opponent)

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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
12 November 2019 concerning maintenance of the
European Patent No. 2081634 in amended form.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: S. Dennler
 Y. Podbielski

Summary of Facts and Submissions

- I. The opponent filed this appeal against the Opposition Division's interlocutory decision to maintain the contested patent on the basis of the auxiliary request 5 filed on 25 September 2019 during the oral proceedings before the Opposition Division.
- II. In its decision, the Opposition Division concluded that claims 1 and 10 of that request did not comprise added subject-matter, and that the subject-matter of claim 1 was novel in view of D1 and involved an inventive step starting from that document, even under consideration of D4, where D1 and D4 are the documents
- D1** US 60/658,518
D4 US 6,287,293 B1
- III. Oral proceedings before the Board were held on 23 January 2023.
- IV. The **appellant** (opponent) requested that the decision under appeal be set aside and that the patent be revoked in its entirety.
- V. The **respondents** (patent proprietors) requested that the appeal be dismissed and that the patent be maintained in the form found allowable by the Opposition Division (main request). As an auxiliary measure, they requested that the patent be maintained on the basis of one of auxiliary requests 1 to 15 filed with the submission dated 2 December 2022.

VI. Claims 1 and 10 of the **main request** ("claim 1" and "claim 10"), with claim 10 depending on claim 9, itself depending on claim 1, read as follows:

"1. A venous access port assembly (10) for implantation into a patient comprising a housing (12) having a discharge port (16), a needle-penetrable septum (14) and a cap (48) securable to the housing and retaining the septum securely in the assembly, the housing (12) having a housing base (28) defining a bottom wall (44) of at least one reservoir (22), with the housing base (28) having an outwardly facing bottom surface (54) and the housing base (28) including radiopaque markings (60) applied to a surface (54) of the housing base (28), characterized in that the venous access port assembly (10) is rated for power injection, the markings at least include indicia (70) that comprise the letters "CT" and convey, when an X-ray of the patient is taken after implantation of the venous access port assembly (10), that the venous access port assembly (10) can be used for power injection."

"10. The assembly (10) of claim 9, wherein the radiopaque markings (60) are printed onto the outer surface (54)."

VII. The description of the main request differs from the description of the contested patent in that, *inter alia*, paragraph [0014] has been deleted.

VIII. The **appellant's arguments** relevant for this decision can be summarised as follows.

Claims 1 and 10 - added subject-matter

Both claims 1 and 10 included added subject-matter.

Claim 1 left open how the letters "CT" were made. It thus covered not only embodiments where the letters were made of radiopaque material ("material letters"), but also embodiments where the letters were formed by voids in a radiopaque material, the voids being themselves in the shape of the letters "CT" ("immaterial letters"). However, only material letters "CT" had been disclosed in the application as filed, especially in paragraph [0019].

Claim 10 defined that the radiopaque markings were "printed" on the outer surface. The term "printed" merely required that marking fluid be deposited on the surface without modification of this surface. However, this was not supported by the application as filed, which only disclosed that marking fluid was "imprinted" (paragraph [0020] of the original description), i.e. requiring the marking fluid to be deposited in a recess formed at the surface.

Claim 1 - novelty in view of D1

The subject-matter of claim 1 was not novel over D1, especially in view of Exhibit A.

This annex was related to the access port disclosed in the rest of D1 (paragraph [0035]) and disclosed that a metal disc having an alphanumeric message etched on it could be incorporated in the port (item 5 of Exhibit A) to provide, when the port was X-rayed, information on the port type, namely that it was a "power port", i.e. a port rated for power injection (title of Exhibit A). The letters and/or numbers constituting the message were radiopaque indicia.

In addition, paragraph [0034] explicitly disclosed the letters "CT", which stood for "computed tomography", i.e. X-ray imaging, in connection with power injectable ports. Thus, the person skilled in the art would inevitably have inferred that the alphanumeric message etched in the disc for identifying the power port under X-ray imaging comprised the letters "CT". Therefore, D1 disclosed radiopaque indicia comprising the letters "CT", as required by claim 1.

Claim 1 - inventive step starting from D1

If the feature that the radiopaque indicia comprise the letters "CT" were found to be novel over D1, it would not render the subject-matter of claim 1 inventive.

The technical effect relied on by the respondents was indeed not specific to the letters "CT", but was achieved for any alphanumeric message without mirror symmetry, which was almost always the case. In fact, any set of two radiopaque markings would enable the person skilled in the art to determine the orientation of the port, as disclosed, for example, in D4 with two locator circles. The specific choice of the letters "CT" was purely arbitrary and these letters were explicitly disclosed in paragraph [0034] of D1. Hence, the feature that the radiopaque indicia comprise the letters "CT" could not support an inventive step starting from D1.

Deletion of paragraph [0014] of the description

This objection was raised by the appellant for the first time in its submission dated 18 July 2022 (point B.4). The appellant explained that this objection had

been prompted by the filing, by the respondents with their reply, of an auxiliary request having the same adapted description as the main request.

The removal of entire paragraph [0014] was not in line with the recent practice at the EPO according to which unclaimed embodiments were to be expressly specified as unclaimed and not simply deleted from the description. Further, it was incorrect to remove the alternative, described in that paragraph, that the radiopaque markings could also be applied to the inwardly facing surface of the bottom wall of the port, as this alternative was not excluded in the claims.

IX. The **respondents' arguments** relevant for this decision can be summarised as follows.

Claims 1 and 10 - added subject-matter

Claims 1 and 10 did not contain any subject-matter extending beyond the content of the application as originally filed.

Claim 1 required the indicia, including the letters "CT", to be "radiopaque markings". This meant that the indicia, thus the letters, were made of radiopaque material, in accordance with the disclosure of paragraph [0019] of the original description.

The objection to claim 10 was also not convincing because the terms "imprinted" and "printed" were synonymous.

Claim 1 - novelty in view of D1

The subject-matter of claim 1 was novel over D1. Paragraph [0034] merely disclosed the letters "CT" as an acronym for "computer tomography". This was not a direct and unambiguous disclosure that the alphanumeric message mentioned in Exhibit A comprised these letters. Thus, D1 did not disclose at least radiopaque indicia comprising the letters "CT".

Claim 1 - inventive step starting from D1

The letters "CT" did not have any mirror symmetry. Thus, as could be inferred from the last sentence of paragraph [0004] of the contested patent, these letters enabled a practitioner X-raying an implanted port to unambiguously determine the orientation of the port, including whether the port was being viewed from above or below. This would not be possible with letters having mirror symmetry, such as the letters "D8".

Starting from D1, the person skilled in the art would not have arrived at the claimed letters "CT" in an obvious manner, even taking into account D4. D1 did not address the problem of determining the orientation of the port based on an X-ray. It disclosed the alphanumeric message only as having the purpose of identifying the port type (title of Exhibit A). Consequently, there was no teaching or suggestion in D1 that the message could also be used to provide information about the port orientation. D4 did address the problem of determining the orientation of the port, but recognised itself that the taught solution, which relied on two radiopaque locator circles provided in the port, could not reveal whether the port was upside down (column 4, lines 38-41).

The subject-matter of claim 1 was therefore inventive starting from D1.

Deletion of paragraph [0014] of the description

The objection to the description should not be admitted into the appeal proceedings. It was indeed filed, for the first time, two years after the filing of the respondents' reply, thus very late. Moreover, the filing of an auxiliary request had not changed the description of the previously filed main request and thus could not be a reason for such a late filing. Furthermore, the objection was not *prima facie* relevant.

Reasons for the Decision

1. Subject-matter of the contested patent

The contested patent concerns a venous access port assembly for implantation into a patient. As defined in claim 1 and illustrated in Figure 8, reproduced below, the access port includes radiopaque markings (60) applied to a surface of the housing base (28), which include indicia (70) that comprise the letters "CT".

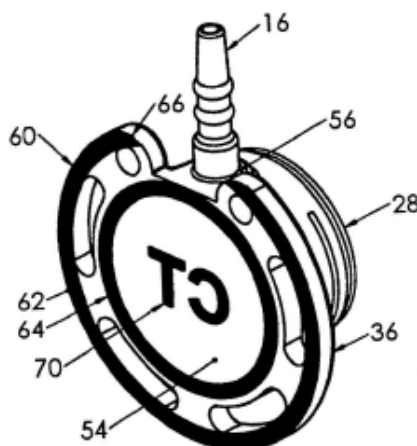


FIG. 8

Being radiopaque, these markings can be discerned on an X-ray and thereby provide information about the nature or characteristics of the access port assembly once it has been implanted in the patient.

In particular, the claimed access port assembly is rated for power injection (i.e. it is configured to withstand high injection pressures) and the letters "CT" can convey, when an X-ray is taken after implantation of the port assembly, that it can be used for power injection (paragraphs [0003] and [0004]).

As shown in the figure above, the letters "CT" can, for example, be applied in a mirror-image orientation on the outwardly facing bottom surface (54) of the port and thus appear on the X-ray as right-side up and easily readable when the port assembly is viewed from above (paragraph [0004]).

2. Added subject-matter

2.1 Claim 1

Claim 1 defines "radiopaque markings" which "at least include indicia (70) that comprise the letters "CT"". The claim does not explicitly specify how these letters are made but only defines a particular meaning that they are intended to convey when they are recognised on an X-ray of a patient in whom the port has been implanted.

According to the appellant, the omission in claim 1 that the letters "CT" are made of radiopaque material, i.e. that they are "material letters" in the appellant's terminology - thereby not excluding that

the letters may alternatively be "immaterial letters" - added subject-matter beyond the content of the application as filed.

The Board disagrees. Paragraph [0019] of the original description indeed discloses radiopaque indicia that comprise the letters "CT" using substantially the same wording as claim 1 (see first and second sentences), without expressly specifying that they are "material letters". It is true that the example illustrated in the figures 8 to 10 of the patent, to which paragraph [0019] refers, does comprise such "material letters" made of radiopaque material. However, from the text of that paragraph the person skilled in the art understands that what matters for the letters comprised in the radiopaque indicia is - regardless of how the letters are made in practice - that they can be discerned as letters "CT" on an X-ray of the patient ("the indicia would appear as "CT" when the X-ray is viewed"), so that a radiologist viewing the X-ray can derive the particular meaning associated to the indicia. "Immaterial letters" "CT", although having the opposite contrast to "material letters" "CT", would equally be discerned and recognised as letters "CT" on an X-ray and a radiologist would assign them the same meaning as the "material letters" "CT".

It follows that, regardless of whether "immaterial letters" fall within the definition of the letters "CT" given in claim 1, this claim does not present the person skilled in the art with information which was not originally disclosed. Claim 1 thus meets the requirement of Article 123(2) EPC.

2.2 *Claim 10*

Claim 10 defines that the radiopaque markings are "printed" onto the outer surface of the housing.

It is true, as argued by the appellant, that the term "printed" does not appear literally in the application as filed. The Board also agrees that the term "imprinted", which appears in paragraph [0020] of the original description, and the term "printed" are not synonymous. Like "embossed" (a term also used in the same paragraph), "imprinted" implies that the marking fluid is deposited in a recess formed in the imprinted surface. By contrast, the meaning of the term "printed" in claim 10 is more general and requires merely that the marking fluid be deposited on the surface, without necessarily implying any modification of that surface.

However, paragraph [0020] of the original description discloses not only that the marking fluid is "embossed or imprinted", but also generally that it may be "otherwise applied onto the surface of the housing base". The application mentions in this respect a particular "ink", a term commonly used in connection with "printing". In the Board's view, this other alternative supports the broad meaning of the claimed term "printed" put forward by the appellant. Claim 10 therefore also meets the requirement of Article 123(2) EPC.

3. Novelty in view of D1

3.1 It is common ground that D1 discloses an access port assembly having a metal disk with an alphanumeric message etched in it incorporated in the bottom of the port (item 5 of Exhibit A in combination with paragraphs [0035] and [0036]). This alphanumeric

message includes indicia comprising letters and/or numbers.

- 3.2 A point of dispute between the parties is whether D1 further discloses that the alphanumeric message specifically comprises the letters "CT" as required by claim 1 for the radiopaque markings.

In view of the title of Exhibit A ("Palpable power port: how to determine port type"), the Board agrees with the appellant that the message etched in the metal disk is intended to provide, when the port is X-rayed, information on the port type, for example that it is rated for power injection.

Nevertheless, contrary to the appellant's assertion, the person skilled in the art would not have inferred from the mere presence of the letters "CT" and the expression "Power injectable ports" in the same sentence in D1 (last sentence of paragraph [0034]) that the message disclosed in Exhibit A comprises those specific letters. Instead, as argued by the respondents, the letters "CT" in that sentence, which are placed in parentheses after the expression "computed tomography", are merely an acronym for that expression.

The Board thus shares the respondents' view that D1 does not directly and unambiguously disclose at least radiopaque indicia that comprise the letters "CT". The subject-matter of claim 1 is therefore novel over D1.

4. Inventive step starting from D1

- 4.1 As argued by the respondents, the letters "CT" have no mirror symmetry. As explained in paragraph [0004] of

the contested patent, these letters could, for example, be applied in a mirror-image orientation to the outwardly facing bottom surface of the port housing. In this case, they would appear right-side up on an X-ray when the port is viewed from above, and, conversely, mirror-inverted when the port is viewed from below. Due to the lack of mirror symmetry, the way the letters "CT" appear on an X-ray is uniquely correlated with the orientation of the port.

There is no such unique correlation for indicia comprising an arbitrary combination of letters and/or numbers. For example, as pointed out by the respondents, the letters "D8", being symmetrical about their horizontal middle axis (when read in their normal orientation), would be invariant - and would therefore appear in the same manner on an X-ray - if the port had been rotated 180° about that axis. The orientation of the port could therefore not be unambiguously determined solely from viewing the letters "D8" on an X-ray, at least with respect to that axis.

The Board therefore agrees with the respondents' formulation of the objective technical problem starting from D1, namely to enable a practitioner X-raying an implanted port to unambiguously determine the orientation of the port, including whether the port is being viewed from above or below.

- 4.2 Contrary to the appellant's argument, the person skilled in the art starting from D1 would not have arrived at the claimed solution in an obvious manner, even taking into account D4.
- 4.2.1 D1 does not address the technical problem of determining the port orientation. It only discloses the

alphanumeric message as having the purpose of identifying the port type (title of Exhibit A). Thus, in the absence of any teaching or suggestion in D1 that the message could be used to provide information about the port orientation, the person skilled in the art starting from D1 would have no motivation, even using their common general knowledge, to specifically select the alphanumeric message so that it has no mirror symmetry, let alone so that it specifically comprises the letters "CT".

In this respect, for reasons similar to those discussed above for novelty, the mere appearance of the letters "CT" in paragraph [0034] of D1 would not lead the person skilled in the art to use these letters as the alphanumeric message; nor would the fact that these letters are an acronym known in the art to stand for "computed tomography".

4.2.2 Contrary to the appellant's argument, it is irrelevant that the technical problem above may be solved by other alphanumeric messages which also do not have any mirror symmetry. Starting from D1, the person skilled in the art would select the alphanumeric message only with the purpose of conveying information about the port type and, thus, would not inevitably arrive at messages having no mirror symmetry, even less at the letters "CT". For example, nothing excludes that the port type could be identified by the letters "D8" which, as discussed above, have mirror symmetry.

4.2.3 Faced with the technical problem described above, the person skilled in the art starting from D1 would rather have sought to make the metal disk of Exhibit A asymmetrical while preserving the function of the alphanumeric message to identify the port type taught

in D1. For this purpose, it would have for instance been obvious to etch an additional indicium at an offset distance from the alphanumeric message. In this way, however, the person skilled in the art would not have arrived at the solution defined in claim 1.

4.2.4 It is undisputed that D4 addresses the problem of determining the orientation of the port under X-ray imaging by incorporating two radiopaque locator circles. The combination of D1 with D4 would therefore not have led to the claimed subject-matter either.

4.2.5 For the reasons above, the Board concludes that the subject-matter of claim 1 involves an inventive step starting from D1.

5. Deletion of paragraph [0014] of the description

5.1 The appellant objected to the description of the main request for the first time in its submission dated 18 July 2022, hence after it had filed its grounds of appeal. This objection is therefore an amendment to the appellant's appeal case which, pursuant to Article 13(1) RPBA 2020, may be admitted only at the discretion of the Board. According to this article, Article 12(4) to (6) RPBA 2020 applies *mutatis mutandis*.

5.2 The description of the main request is the adapted description that the respondents filed during the oral proceedings before the Opposition Division as part of their auxiliary request 5, eventually allowed by the Opposition Division. Thus, the appellant's objection to the description could - and should - have been filed in the first-instance oral proceedings in reaction to the filing of that request.

Even assuming that it might not have been evident to prepare and file it during the oral proceedings before the Opposition Division itself, this objection should then have been filed on appeal at the earliest stage possible. Instead, the appellant's objection was filed more than two years after the filing of the respondents' reply. The fact that, as explained by the appellant, the alleged deficiency of the description was only detected in respect of an auxiliary request having the same description and filed by the respondents with their reply cannot justify the admittance of the appellant's objection at such a late stage of the appeal proceedings.

Furthermore, the Board does not see *prima facie* any reason to suspect that, as asserted by the appellant, the deletion of paragraph [0014] of the description of the contested patent as granted rendered it inconsistent with the claims of the main request.

For these reasons, the Board, exercising its discretion, decided not to admit the appellant's objection to the description of the main request.

6. Conclusion

It follows from the above considerations that none of the appellant's objections admitted into the appeal proceedings prejudice the maintenance of the contested patent according to the respondents' main request, i.e. in the form found allowable by the Opposition Division.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated