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Datasheet for the decision of 17 May 2024

Case Number: T 1904/21 - 3.2.01

Application Number: 08771600.7

Publication Number: 2164559

IPC: A61M39/02

Language of the proceedings: EN

Title of invention:
VENOUS ACCESS PORT WITH MOLDED AND/OR RADIOPAQUE INDICIA

Patent Proprietor:
Medical Components, Inc.

Opponent:
BAUER WAGNER PRIESMEYER

Headword:

Relevant legal provisions:
EPC Art. 100(a), 100(b), 54, 56

Keyword:
Grounds for opposition - insufficiency of disclosure (no) - lack of patentability (no) - added subject-matter (no)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 1904/21 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 17 May 2024

Appellant: (Opponent)	BAUER WAGNER PRIESMEYER Grüner Weg 1 52070 Aachen (DE)
Representative:	Pellengahr, Maximilian Rudolf Bauer Wagner Pellengahr Sroka Patent- & Rechtsanwalts PartG mbB Grüner Weg 1 52070 Aachen (DE)
Respondent: (Patent Proprietor)	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 (US)
Representative:	Mewburn Ellis LLP Aurora Building Counterslip Bristol BS1 6BX (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 August 2021 rejecting the opposition filed against European patent No. 2164559 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	G. Pricolo
Members:	M. Geisenhofer
	M. Millet

Summary of Facts and Submissions

I. The appeal was filed by the opponent (appellant) against the decision of the opposition division rejecting the opposition filed against the patent in suit.

II. The opposition division held that

- the subject-matter of the claims as granted was novel over documents

  D1 WO 2006/096686 A1
  D2 US 50/658 518
  D3 US 4 673 394
  D4 WO 2006/116438 A2
  D5 WO 2008/048361 A1

  and involved an inventive step when starting from any of document D1 - D4 as closest prior art;
- the granted patent disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art; and
- the subject-matter of the claims as granted did not extend beyond the content of the application as filed.

III. Oral proceedings were held before the Board.

(a) The appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked.

(b) The respondent (patent proprietor) requested that the appeal be dismissed and the patent be maintained as granted, in the alternative that the patent be maintained in amended form based on one

of the auxiliary requests 1 – 8 filed with the reply to the statement of grounds of appeal.

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

"*A venous access port assembly (72, 74) for implantation into a patient, comprising:*

a housing having a base (28) defining a bottom wall of at least one reservoir, the housing further having a discharge port (16) extending from the at least one reservoir, and the base having a flange (36) adjacent to the at least one reservoir, the flange extending outwardly from the base about a perimeter of the at least one reservoir, and including indicia molded therein indicating a characteristic of the assembly; and

a needle-penetrable septum communicating with the housing;

characterized in that the flange is comprised of a metal material and the indicia are formed by voids in the flange as if cut or punched out of the flange, whereby the indicia are visible by X-ray examination when the assembly is subcutaneously implanted in a patent."

V. The appellant's arguments can be summarised as follows:

(a) Claim 1 as granted exhibited a plurality of unallowable amendments. The same applied to claims 2 and 3.

(b) The invention according to claim 1 could not be put into practice by a skilled person.

(c) The subject-matter of claim 1 was not novel over D1 - D4, respectively, at least not inventive when starting from one of these documents.

(d) Document D5 and all lines of argument based on this document were withdrawn from the procedure (cf. letter dated 17 April 2024).

VI. The respondent's arguments can be summarised as follows:

(a) Claim 1 was based on a combination of originally filed claims and the feature "*indicia are formed by voids in the flange as if cut or punched out of the flange*" was disclosed in paragraph [0029] of the description as originally filed.

(b) The patent disclosed the invention in a manner sufficiently clear and complete for the skilled person to carry it out.

(c) None of the documents D1 - D4 disclosed indicia that were formed by voids in the flange as if cut or punched out of it.

(d) Such indicia were not rendered obvious either.

Reasons for the Decision

Amendments

1. The claims as granted do not define subject-matter which extends beyond the content of the application as filed (Article 100(c) EPC).

1.1 The opposition division held that independent claim 1 as granted is based on a combination of originally filed claims 1, 5, 6 and 9, and the information that the voids in the flange are as if cut or punched out taken from paragraph [0029] of the originally filed description (reasons section 16).

1.2 The appellant disagreed and argued that the claims as originally filed provided disclosure for only a very general definition of a port which lacked a flange (but only referred to a peripheral surface). Hence only the two embodiments disclosed in paragraph [0029] and shown in figures 11 - 13 could form a suitable basis for granted claim 1. The disclosure of these particular embodiments, however, was generalized in a plurality of points such the amendments were not allowable:

1.3 The appellant alleged that due to omitting the term "*integrally*", claim 1 as granted covered embodiments with indicia that were moulded in a separate part, which part could then be attached to the flange, whereas the originally filed application only disclosed indicia integrally moulded with the flange.

The Board disagrees. Claim 1 requires indicia that "*are formed by voids in the flange as if cut or punched out of the flange*" such that it is excluded that the indicia are moulded in a separate part attached to the flange. On the contrary, the indicia must necessarily be integral to the flange since otherwise it would not be possible to achieve an appearance complying with the condition "*as if cut or punched out of the flange*".

1.4 The appellant alleged that paragraph [0029] of the originally filed description only disclosed indicia being provided in a base flange. Claim 1, however, was not restricted to a base flange but covered any location for the flange at any height compared to the reservoir.

The Board disagrees. Claim 1 requires "*the base having a flange*", i. e. that the flange is part of the base of the access port. The flange hence cannot be arranged

independently from the base at any height compared to the reservoir but is necessarily arranged at the same height as the remaining part of the base, the flange hence being a "*base flange*".

1.5 The appellant objected that the expression "*indicia are formed by voids in the base flange material*" was amended to read in claim 1 "*indicia are formed by voids in the base flange*", i. e. the term "*material*" was omitted.

The Board does not see a difference in meaning. A void in the flange will in any case be a void in the material of the flange (a void being by definition a space surrounded by material).

1.6 In this context, the Board also disagrees with the appellant's argument that paragraph [0029] only concerns an intermediate state and that the voids in the flange are later filled. Such a filling is not described in the context of the embodiments of figures 11 - 13, these embodiments forming the basis for claim 1.

1.7 The appellant argued that paragraph [0029] only disclosed indicia being the letters "CT" whereas claim 1 also covered other letters, signs or pictograms, these alternative indicia hence lacking disclosure in the originally filed application. Furthermore, not any letters were suitable as indicia.

The Board considers the amendment to be an allowable generalization since the particular letter combination "CT" is not inseparably linked to the concept of providing information in the form of indicia in the flange. Voids in the flange can form almost any

combination of letters, contrary to the appellant's allegation that cutting or punching out is only possible for the specific letters "C" and "T". It is not apparent why other letters such as "I", "N" or "S" should not be mouldable in the flange such that they appear to be punched out. Even if there were unsuitable letters or signs (such as closed geometries, e. g. "O" or "D"), the skilled person would recognize that these geometries are less suitable and simply refrain from using these letters or sings.

1.8 The appellant further objected that the term "*peripheral surface*" used in originally filed claim 1 was replaced by "*flange*". In their view, the peripheral surface mentioned in originally filed claim 1 was different from the flange mentioned in paragraph [0029].

The Board disagrees. Originally filed claim 1 defines a peripheral surface including indicia. This peripheral surface could either be the bottom of the reservoir (embodiment shown in figures 8 - 10) or the flange (embodiments shown in figures 11 - 13). Claim 1 as granted specifies the peripheral surface to be the flange such that no new information is added but the claim is restricted to the embodiment of figures 11 - 13.

1.9 The appellant further argued that the flange was inextricably disclosed with suture openings in it in the application as originally filed whereby a void in general was not a suture opening. These suture openings were not mentioned in granted claim 1, and this amounted to an unallowable intermediate generalization.

The Board disagrees. Whether the flange comprises suture openings for fixing the port within a human body is irrelevant for the concept of providing indicia in the flange that can be visualized by X-ray. When the voids forming the indicia are also used for suturing, this additional function is not inextricably linked to the concept of providing indicia.

Furthermore, in the absence of a convincing reason why the voids forming the indicia cannot be used at the same time for suturing the port in place, the Board considers any void in the flange to be a suture opening.

1.10 The appellant further alleged that voids forming the indicia were inextricably linked to the information that these voids were positioned "*alongside suture openings*". Since claim 1 was not citing this particular arrangement, it included an unallowable generalization.

The Board disagrees. Indicia formed by a plurality of voids have a geometry defined by the shape of the edges of the voids forming an opening. This opening (as set out above) can in any case be used for suturing such that claim 1 at least implicitly still requires the voids to be positioned alongside suture openings.

1.11 The appellant alleged that the term "*as if cut or punched out*" was disclosed in paragraph [0029] only in the context of the indicia being voids, i. e. in the embodiment of figure 13. Claim 1 as granted, however, also covered voids forming indicia according to the embodiment of figure 12.

In the Board's view, the term "*as if cut or punched out*" refers to both embodiments. Both embodiments are

described in a block in one and the same paragraph [0029] whereby the skilled person implicitly reads the information on how the voids should look like to refer to both embodiments (cf. first line of the paragraph: "*two alternative embodiments 72, 74*").

1.12 The appellant's arguments with regard to the hypothetical embodiments shown in their statement of grounds of appeal on page 13 are not convincing either.

Contrary to the appellant's allegation, the letters "CT" of the left embodiment are not provided within the flange but within protuberances extending into the circular voids in the flange. They are hence not "*arranged in the flange*" as required by claim 1.

In the right hypothetical embodiment, the letters "CT" are not "*formed by voids in the flange*" but the letters are arranged in a circular void. This embodiment is hence not covered by claim 1 either.

It is thus irrelevant whether these hypothetical embodiments were disclosed in the application as originally filed or not.

1.13 The appellant finally alleged that only the embodiment of figure 13 would fall under claim 1 such that claim 2 (referring to the embodiment of figure 12) resulted in an unallowable amendment.

The Board disagrees. Claim 1 recites indicia that are formed by voids in the flange. It hence remains open whether the voids as such have a shape that corresponds to the letters (embodiment of figure 13), or whether the geometry of several voids provides a part of the flange in the form of a ridge between the voids, the

ridge having a geometry that resembles particular letters (embodiment of figure 12).

1.14 With regard to claim 3, the appellant argued that there was no disclosure that "*the assembly may comprise in any other part of the assembly than the flange radiotransparent material*".

However, original claim 10 referring to original claim 1 and reciting that the assembly is at least partially comprised of radiotransparent material leaves open what parts of the assembly are made of radiotransparent material. Moreover, as pointed out by the opposition division (point 16.3 of the decision) basis for claim 3 is not only to be found in original claim 10, but also in paragraph [0023] of the application as filed disclosing that parts other than the flange (e.g. the skirt) may be of radiotransparent material.

1.15 With letter dated 27 October 2023, the appellant further argued that the originally filed claims did not provide disclosure for a combination of claims 1, 5, 6 and 9 since claims 5, 6 and 9 each referred directly to claim 1.

1.15.1 The respondent requested to not admit this line of argument.

1.15.2 In the Board's view, the features of claims 1, 5, 6 and 9 can be combined since the embodiments of figures 12 and 13 both provide disclosure for a port with a flange with indicia formed by voids, i. e. a combination of the features of originally filed claims claims 1, 5, 6 and 9.

Since the raised objection cannot convince in substance, it can be left undecided whether this line of argument can be admitted into the procedure.

1.16 The Board hence sees no reason to deviate from the opposition division's decision with regard to added subject-matter.

Sufficiency

2. The patent in suit discloses the invention in a manner sufficiently clear and complete for a skilled person to carry it out (Article 100(b) EPC)

2.1 The opposition division held that the patent provides enough information such that the invention can be carried out by the skilled person (reasons point 17).

2.2 The Board shares the opposition division's finding that figures 11 - 13 disclose two ways of carrying out the invention whereby in both embodiments the indicia are formed by voids in the flange as if cut or punched out of the flange.

2.3 The appellant disagreed and alleged that it was not possible to mould a flange with voids, and at the same time to cut or punch out these voids.

The Board notes that according to the wording of claim 1, the voids in the flange need not be cut or punched out but only shall have the appearance of voids that were cut or punched out ("*as if cut or punched out*"). The skilled person is aware of standard techniques for moulding objects such as an access port. These techniques include use of moulding forms to produce a flange with apertures such that these apertures

resemble apertures that are cut or punched out of the flange.

2.4 The appellant further argued that the skilled person was not aware of a way how to implant the port assembly "*in a patent*" as required by claim 1.

A skilled person with the will to understand the invention, if not any reader of the patent in suit, understands that the possibility to implant the assembly "*in a patent*" as recited in claim 1 is a spelling error and should read "*in a patient*".

2.5 The appellant also alleged that claim 2 contradicted claim 1. Indicia being voids in the flange as required by claim 1 could not be at the same time within a suture opening.

The Board disagrees. Claim 1 does not define indicia being voids but requires the indicia to be formed by voids in the flange. Two adjacent voids can define a ridge therebetween, the ridge having a particular geometry forming a letter or a pictogram.

2.6 The appellant finally alleged that it was not possible to use a flange made of radiotransparent material that at the same time allowed to recognize the indicia in the flange by X-ray.

The Board disagrees. The appellant's argument is based on the assumption that the flange in its entirety is made of radiotransparent material. However, claim 3 requires that a part of the assembly (hence not necessarily the flange) is made of radiotransparent material. Even if the flange is made of radiotransparent material, only a part of the flange

can be made thereof such that the other parts of the flange provided with indicia still can be made of metal.

2.7 The Board hence sees no reason to deviate from the opposition division's decision with regard to sufficiency.

Novelty

3. The subject-matter of independent claim 1 of the patent in suit is novel over D1 - D4, respectively (Article 54 EPC).

3.1 The opposition division held that **document D1** lacks
- a flange comprised of a metal material; and
- indicia molded into the flange such that they are visible by X-ray examination.

The subject-matter of claim 1 was hence considered to be novel over D1.

3.1.1 The appellant disagreed and argued that D1 described in paragraph [0009] that the access port of D1 was provided with a feature that was perceivable in the implanted state of the access port via X-ray as set out in paragraph [0042] or [0072]. The identifiable feature comprised three suture apertures as set out in paragraphs [0062] and [0068]. This required implicitly that the flange with the suture openings was made of metal.

3.1.2 The Board notes that claim 1 of the patent in suit defines a flange including indicia that are formed by voids (in plural). It is hence excluded that a circular aperture (e. g. one of the suture openings of D1) as such can be considered as an indicium. The Board hence

does not follow the appellant's understanding that e.g. the three suture openings disclosed in figure 20 of D1 form three indicia.

In document D1, only the particular geometrical arrangement of the suture openings can be considered to provide an indicium, however not a plurality of indicia as required by claim 1.

3.1.3 Furthermore, document D1 does not clearly and unambiguously disclose that the feature identified by X-ray is the geometrical arrangement of the suture openings.

(a) The "feature" referred to in D1 may be perceived by palpation, by way of other physical interaction or by visual observation using inter alia X-ray as set out in paragraph [0042].

(b) Paragraph [0062] then explains that the suture apertures may form an identifiable feature, however without mentioning how the suture apertures are perceived. It is thus not excluded that these apertures are identified by other means than X-ray, e. g. by palpation.

(c) With regard to using X-ray for identifying the feature, D1 refers in paragraph [0072] only to a metal feature in the form of a plate or other metal geometry that can be identified on an X-ray examination, whereby the plate's size, shape, or both allow for identification of the access port. Voids forming the indicia were not mentioned in this passage.

(d) D1 hence lacks a clear and unambiguous disclosure of indicia formed by voids moulded in the flange such that they are visible by X-ray examination.

3.1.4 In this context, the flange of D1 must not necessarily be comprised of a metal material either.

(a) The metal feature mentioned in paragraph [0072] in the form of a particularly shaped metal plate can also be arranged on the bottom of the reservoir or at any other location being different from the flange.

(b) Paragraph [0045] of D1 refers to titanium as a suitable bio-compatible material for producing the body of the access port. However, this passage does not require the entire access port to be made of titanium such that it is not clearly and unambiguously disclosed in D1 that also the flanges with the suture openings are made of metal material.

3.1.5 The Board hence shares the opposition division's decision and considers D1 to lack the two distinguishing features cited in paragraph 3.1 above.

3.2 The opposition division further held that **document D2** discloses similar content as D1 such that D2 does not anticipate the subject-matter of claim 1 either.

3.3 The appellant referred in a first line of argument similarly as set out with regard to D1 to the suture openings providing a feature that can be noticed by X-ray.

3.3.1 Applying the same arguments as set out above with regard to D1, the Board disagrees. The use of X-ray mentioned in [0037] is not disclosed as technique to locate the suture openings.

3.3.2 Other indicia being arranged in the flange are not described.

3.4 In a second line of argument, the appellant referred to the handwritten inventor's report attached at the end of D2 indicating on page 13 under point 5 at the end "(X-RAY)".

3.4.1 The Board notes that D2 reads in point 5 as follows:

"*May incorporate a metal disk in the bottom of plastic port. The disc could have an alphanumeric message etched in the port disc that would be visible on radiograph (X-ray)*"

This passage hence refers to adding a (separate) metal disk with indicia to the bottom of the plastic port.

These indicia, however, are neither formed by voids in the flange, nor does the flange necessarily comprise metal material. Furthermore, these indicia are not moulded as if cut of punched out of the flange, but etched. Etching produces a metal plate having portions with different thicknesses but not voids extending through the plate.

3.4.2 The Board therefore shares the opposition division's decision that the subject-matter of claim 1 is also novel over D2.

3.5 The opposition division further held that **document D3** lacks indicia moulded into the flange, the indicia

being formed by voids as if cut or punched out of the flange whereby these indicia are visible by X-ray examination. The subject-matter of claim 1 was hence considered to be also novel over D3.

3.5.1 The appellant argued that D3 used similarly to D1 and D2 suture openings arranged in the flange. The particular position could be considered as indicia in the sense of the patent in suit.

3.5.2 The Board disagrees. In contrast to D1, D3 does not describe that the particular arrangement of the suture openings allows to derive a characteristic of the access port. The arrangement of the suture openings hence is not an indicium, notwithstanding a plurality of indicia, and in particular not indicia formed by voids.

3.6 The opposition division finally held that the subject-matter of claim 1 is also novel over **document D4** since D4 lacks similarly to D3 indicia moulded into the flange, the indicia being formed by voids as if cut or punched out of the flange whereby these indicia are visible by X-ray examination.

3.6.1 The appellant disagreed and argued that paragraph [0138] describes the access port to comprise a radiographic marker in the form of a pattern, symbol or other indicium indicating a particular flow rate, pressure, or both. Since the port was made of titanium according to paragraph [0083], these markers/indicia were visible in a X-ray picture.

3.6.2 The Board notes that D4 does not provide information on where the marker is arranged and whether a plurality of markers (hence indicia in plural) are used. In

particular, D4 does not describe the marker to be one of the suture openings or the arrangement of the plurality of suture openings.

3.6.3 Furthermore, D4 lacks a flange where these markers are arranged. Even if one would consider the sidewall of the access port to form a flange and even if one would assume that a plurality of markers are arranged on this sidewall, the resulting indicia still would not be formed by voids as if cut or punched out of the flange as required by claim 1.

3.6.4 The Board therefore shares the opposition division's decision on novelty and considers none of documents D1 - D4 to anticipate the subject-matter of claim 1 of the patent in suit.

Inventive step

4. The subject-matter of independent claim 1 of the patent in suit is not rendered obvious (Article 56 EPC).

4.1 The opposition division held that the subject-matter of claim 1 is not rendered obvious when starting from either of documents D1 - D4 as closest prior art.

4.2 The appellant disagreed and argued in a first line of argument when starting from D1 as closest prior art that it was obvious to use a flange made of metal.

4.2.1 In the Board's view, the relevant question is not whether the skilled person would produce the port known from D1 from a metal but whether the skilled person would replace the indicium provided by the plurality of circular voids arranged in the flange in a particular

geometrical arrangement by a plurality of indicia, the indicia being formed by voids in the flange.

4.2.2 In the absence of prior art document teaching the concept of providing a plurality of indicia visible by X-ray whereby these indicia are formed by voids in a flange, the Board considers the subject-matter of claim 1 as not obvious.

4.3 The appellant argued in a second line of argument starting from D1 that it was obvious to incorporate the metal plate mentioned in paragraph [0072] into the flange, thus arriving at a flange made at least partially of metal and comprising indicia formed by voids.

4.3.1 The Board does not agree. The flange of D1 in general does not allow to incorporate a metal plate such that the plate is clearly visible by X-ray since most parts thereof are inclined with regard to the port's bottom such that the plate is not clearly visible and identifiable on a X-ray picture typically taken perpendicular to the patient's skin and hence also perpendicular to the port's predominant extension. The only part of the flange lying parallel to the plane of the predominant extension of the port is where the suture openings (66) are arranged. However, it is impossible to arrange a metal plate at this part of the flange without influencing the suture openings' function.

The skilled person hence would not consider arranging the metal plate of paragraph [0072] on the flange but only on the bottom or top of the reservoir.

4.3.2 Even if the skilled person would consider incorporating the metal plate into the flange, the indicia still are not formed by voids in the flange as if cut or punched out. As set out in paragraph [0072], the metal feature consists in the size, shape, or both which is not a plurality of indicia, in particular not a plurality of indicia formed by voids in the metal plate.

4.3.3 The skilled person hence neither arrives at the subject-matter of claim 1 using the first line of argument, nor the second line of argument when starting from D1.

4.4 The same reasoning as with regard to the second line of argument applies when starting from document D2 as closest prior art.

The skilled person has no teaching at hand leading to a modification of the metal plate described in point 5 of the hand written notices of the inventor. In particular, there is no reason apparent why the skilled person would consider replacing the etched indicia by indicia formed by voids which are then incorporated into the flange.

4.5 The same applies when starting from D3 or D4 as closest prior art: Since no teaching is available in the prior art on file to use indicia formed by voids in a flange such that these indicia can be perceived using X-ray, the skilled person can in any case not arrive at the subject-matter of claim 1.

4.6 The Board hence also shares the opposition division's view with regard to inventive step such that there is no reason to deviate from the opposition division's decision.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

H. Jenney G. Pricolo

Decision electronically authenticated