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Datasheet for the decision of 14 October 2021

Case Number: T 0970/17 - 3.2.02

Application Number: 10183394.5

Publication Number: 2324879

IPC: A61M39/02, A61M39/04, A61M5/158, A61M5/162, A61M5/32, A61M39/08, A61M39/00

Language of the proceedings: EN

Title of invention:
Infusion apparatuses and related methods

Patent Proprietor:
C.R. Bard, Inc.

Opponent:
Smiths Medical ASD, Inc.

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 64, 69, 83, 84, 104(1), 108, 112(1)(a), 123(2), 123(3)
EPC R. 99(2)
RPBA Art. 12(4)
RPBA 2020 Art. 13(2)

Keyword:

Admissibility of appeal - (yes)
Admittance of claim requests - (yes / no)
Admittance of documents filed in appeal - (yes / no)
Amendments - extension beyond the content of the parent application as filed - (no) - extension beyond the content of the application as filed - (no) - extension of the scope of the patent ("aliud") - (no)
Novelty - (yes, after amendment)
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Late-filed objection - admitted - (no)
Referral to the Enlarged Board of Appeal - (no)
Apportionment of costs - (no)

Decisions cited:

G 0002/88, T 0352/04, T 0867/05, T 1898/07, T 0547/08, J 0014/19

Catchword:

Assessing compliance with Article 123(3) EPC does not include a test taking into account national infringement laws such as the rules on contributory infringement (point 6.2 of the Reasons).

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Case Number: T 0970/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 14 October 2021

Appellant: (Patent Proprietor)	C.R. Bard, Inc. 730 Central Avenue Murray Hill, NJ 07974 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Appellant: (Opponent)	Smiths Medical ASD, Inc. 160 Weymouth Street Rockland MA 02370-1136 (US)
Representative:	Thum, Bernhard Thum Mötsch Weickert Patentanwälte Siebertstr. 6 81675 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 14 February 2017 concerning the maintenance of European Patent No. 2324879 in amended form**

Composition of the Board:

Chairman	D. Ceccarelli
Members:	S. Dennler
	N. Obrovski

Summary of Facts and Submissions

I. The patent proprietor and the opponent both filed an appeal against the opposition division's decision to maintain the contested patent in amended form on the basis of what was then the proprietor's fourth auxiliary request.

II. Oral proceedings before the board took place on 14 October 2021.

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

The opponent further requested that two questions be referred to the Enlarged Board of Appeal.

The appellant/proprietor ("the 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 or one of the first to ninth auxiliary requests, all filed with its statement of grounds of appeal.

The proprietor further requested an apportionment of costs to its benefit.

III. Independent claim 1 of the **main request** reads as follows (amendments compared with claim 1 of the main request considered in the decision under appeal highlighted by the board):

> ***1.*** *Use of a septum in a vascular access port that comprises a housing,* ~~*the use comprising capturing*~~

~~of the septum by the housing, the septum being suitable for being repeatedly pierced or punctured with a hollow slender element such as a cannula or a needle,~~ wherein the housing captures the septum, the septum (80, 120, 610) including a radiopaque material configured to form a selected pattern (199) when an X-ray is taken through the septum.

IV. Independent claims 1 and 17 of the **first auxiliary request** read as follows (amendments compared with claims 1 and 15 as granted, respectively, highlighted by the board):

1. *A vascular access port for providing subcutaneous access to a patient, comprising*

*a septum (80, 120, 610) **~~characterized in that~~** ~~it~~ includ~~es~~ing a radiopaque material configured to form a selected pattern (199) when an X-ray is taken through the septum.*

17. *A method of identifying an access port (50) as being suitable for power injection, the method comprising:*

providing ~~an~~the access port (50) including a septum (80), the septum including a radiopaque material configured to form a selected pattern (199) when an X-ray is taken through the septum; and

using the pattern to identify the access port as being suitable for power injection.

V. Compared with claim 1 of the first auxiliary request, claim 1 of the **second auxiliary request** includes the additional word "implantable" before the word "vascular", so it begins as follows (amendment highlighted by the board):

1. *An implantable vascular access port for providing subcutaneous access to a patient, comprising (...)*

Independent claim 17 of the second auxiliary request is identical to claim 17 of the first auxiliary request.

VI. Claim 1 of the **third auxiliary request** reads as follows (amendments compared with claim 1 of the second auxiliary request highlighted by the board):

1. *An implantable vascular access port for providing subcutaneous access to a patient and structured for performing power injection, comprising*

a septum (80, 120, 610) including a radiopaque material configured to form a selected pattern (199) when an X-ray is taken through the septum for identifying the access port as being structured for power injection.

Independent claim 17 of the third auxiliary request is identical to claim 17 of the first auxiliary request.

VII. In the present decision the following documents are mentioned:

D1: US 5,662,600
D2: US 4,636,194
D4: US 6,287,293
D13: *Safety Considerations in the Power Injection of Contrast Media Via Central Venous Catheters during Computed Tomographic Examinations*, J. E. Carlson et al., Invest Radiol. 1992;27(5):337-40
D20: US 5,318,545

HE2: excerpt of the book *Medical Device Register*, 15th edition, 2000, Medical Economics, pages II-408 and I-278

HE3: excerpt of the *Code of Federal Regulations*, Title 21, 1 April 2016, section 880.5965 on "Subcutaneous, implanted, intravascular infusion port and catheter"

HE4: idem, section 882.5550 on "Central nervous system fluid shunt and components"

HE3a: excerpt of the *Code of Federal Regulations*, Title 21, 1 April 2004, including section 880.5965 on "Subcutaneous, implanted, intravascular infusion port and catheter"

HE4a: idem, including section 882.5550 on "Central nervous system fluid shunt and components"

HE5: excerpt of the book *Vascular Surgery*, R. B. Rutherford, 5th edition, 2000, W. B. Saunders Company, pages 295-299

HE6: *Reminders from FDA Regarding Ruptured Vascular Access Devices from Power Injection*, July 2004

HE7: *Implanted Ports, Computed Tomography, Power Injectors, and Catheter Rupture*, L. Hartkopf Smith, Clinical Journal of Oncology Nursing (2008), vol. 12(5), pages 809-812

European patent application No. 06751411.7 ("the parent application as filed"), published as WO 2006/116438 A2 according to the PCT, is also relevant to the present decision. The patent in suit was granted from its divisional application No. 10183394.5 ("the subject application as filed"). The description of the subject application as filed contains *verbatim* the description of the parent application as filed.

VIII. The **opponent's arguments**, as far as relevant for the present decision, can be summarised as follows.

(a) Admissibility of the proprietor's appeal and admittance of the proprietor's claim requests

Compared with the claims discussed during the first-instance proceedings, the claims of the new main request, first to sixth auxiliary requests and eighth to ninth auxiliary requests filed on appeal by the proprietor had been either broadened by deleting claimed features or limited by adding new features taken from the description. Moreover, in the main request and the first to sixth auxiliary requests, the scope of protection sought had been shifted from a septum as defined in claim 1 as granted (i.e. a specific product) to the use of a septum (i.e. a different claim category) or to an access port (i.e. to a different entity constituting an aliud).

Due to these substantial amendments, each of these requests represented a completely new case on appeal, one that was very different from that on which the decision under appeal was based. Under the case law, appellants were not allowed to build a new case or modify requests beyond the subject-matter of the first-instance proceedings. Where an appellant presented a line of reasoning in favour of new claims that differed substantially from the claims on which the impugned decision was based, it was not possible for the board and the other party to understand immediately why the decision was alleged to be incorrect without first having to make investigations on their own. This rendered the new claims inadmissible under further case law.

It followed that none of the claim requests filed by the proprietor with its statement of grounds of appeal

was admissible, so the proprietor's appeal itself was inadmissible.

(b) Admittance of documents HE2-HE7, D20, HE3a and HE4a

HE2-HE7 were filed for the first time on appeal. They were late-filed as they could have been filed during the first-instance proceedings. Moreover, HE3, HE4 and HE7 were post-published documents, and it was unclear whether HE6 had been unamended since its publication. The impact that these documents were intended to have on the case in hand was unclear too. For these reasons, they should not be admitted into the appeal proceedings.

Were HE2 or HE3 admitted, D20 should in turn be admitted too as an appropriate reaction by the opponent to counter the assumptions regarding the term "vascular" that the proprietor had made on the basis of those documents.

The proprietor did not assert any exceptional circumstances justifying the filing of HE3a and HE4a after the notification of the summons to oral proceedings. Hence, these documents should not be admitted either.

(c) First and second auxiliary requests - novelty of claim 1 over D1 and D2

Both D1 and D2 disclosed an implantable vascular access port comprising all the features of claim 1 of both the first and second auxiliary requests. In particular, the term "vascular" did not require the access port to allow for blood sampling. The subject-matter of claim 1

of these requests therefore lacked novelty over D1 and D2.

(d) Third auxiliary request

Claim 1 - added subject-matter

The features of claim 1 whereby the vascular access port was "structured for performing power injection" and the radiopaque material made it possible to "[identify] the vascular access port as being structured for performing power injection" were not disclosed in the parent and subject applications as filed. Rather, these documents disclosed the access port as being specifically structured for accommodating "a fluid flow rate of at least about 1 milliliter per second" (paragraphs [0077], [0078] and [0135]) and for accommodating "a particular flow rate, pressure, or both" (paragraph [0138]). Since this structure of the access port was not defined in claim 1, the claim contained added subject-matter.

Moreover, both the parent and subject applications as filed consistently presented mortise-and-tenon regions as essential for securely coupling the septum to the housing (paragraphs [0088]-[0089], Figures 2 and 6, claim 14 of the parent application as filed). They also consistently disclosed that the septum included a gel region (paragraph [0018], claim 61 of the parent application as filed). Since claim 1 of the third auxiliary request did not define any such features, it contained added subject-matter.

Claim 1 - extension of scope of protection conferred by the patent; request for referral to the Enlarged Board of Appeal

Claim 1 as granted defined a septum whereas claim 1 of the third auxiliary request defined an access port. This constituted a shift to a different, more complex physical entity and amounted to claiming an aliud which extended the scope of protection under Article 123(3) EPC. The opponent referred in particular to decisions T 352/04, T 867/05, T 1898/07 and T 547/08. The shift to a different physical entity had an impact on infringement proceedings. A third party manufacturing an access port housing could not have infringed the claims as granted, as these had been exclusively directed to a septum. Under claim 1 of the third auxiliary request, on the other hand, producing the access port housing without a septum could constitute a contributory infringing act under German patent law (see Article 64(3) EPC and Section 10 (1) PatG). The opponent also stated that claim 2 as granted, which had been directed to a "septum according to claim 1 in an access port", had contained additional limiting features which were not present in claim 1 of the third auxiliary request.

The opponent requested the referral of the following two questions to the Enlarged Board of Appeal:

"(i) When claims involving a change of the entity of a device claim (here: from a "septum (...)" claim to "an implantable vascular access port for providing subcutaneous access to a patient and structured for performing power injection, comprising a septum (....)") claim) are proposed in opposition appeal proceedings, what considerations should be taken into account when deciding on the admissibility of such amendments in regard to Article 123(3) EPC, in particular when considering the BoA decision T0867/05

indicating a change of the claimed entity in opposition proceedings as an inadmissible aliud?

(ii) Can a patent with granted claims directed to a "septum" (granted claim 1) and to a "septum according to claim 1 in an access port" comprising the additional features (granted claim 2):

> *a housing (60) defining an aperture for capturing the septum, the housing and septum defining a reservoir (66), the septum including a tenon region (270) and wherein the housing of the access port defines a complementary mortise region structured for accepting at least a portion of the tenon region of the septum.*

be amended during opposition appeal proceedings so that the claims are directed to "an implantable vascular access port" not having any of the features required by claim 2 in the granted version?"

Claim 1 - clarity

Claim 1 of the third auxiliary request was unclear. Although the clarity objection had been raised for the first time after the notification of the summons to oral proceedings, it was relevant and had to be considered.

Claim 1 - novelty over D1 and D2

The feature "structured for power injection" had no specific technical meaning and thus did not limit the scope of claim 1. "Power injection" was not defined in claim 1, which did not specify any particular range of pressure or flow rate, so the term had to be interpreted broadly.

HE5 (page 297, right-hand column, lines 30-31; page 299, Table 16-3) disclosed that there were situations suitable for either power or hand injection, which meant that the corresponding ranges of pressure and flow rate at least overlapped. Even the flow rate that the contested patent mentioned as being typical for power injection, namely about 1 ml/s (paragraph [0067]), could easily be achieved by hand injection. Hence, the devices in D1 and D2, which could be used with hand injection and were thus structured to withstand the associated pressures and flow rates, were also "structured for power injection". In particular, the injection pressure at least had to exceed the blood pressure to be able to infuse fluid into the heart cavity. Moreover, D1 and D2 were not limited to devices for draining cerebrospinal fluid from the brain, and D1 disclosed that the structure of these could be adapted to a "variety of pressure/flow characteristics" (D1, column 2, lines 59-65) by varying the thickness of the membrane valve.

D1 and D2 further disclosed using a radiopaque dot code (D1, column 5, lines 23-40) included in the septum to identify the ranges of pressure/flow characteristics of the device, thus disclosing the additional feature whereby the radiopaque material was configured to form a selected pattern "for identifying the access port as being structured for power injection".

Hence, the subject-matter of claim 1 was not novel over each of D1 and D2.

Claim 1 - novelty over D4

The vascular access port disclosed in D4 was also "structured for power injection" since this expression

was not limiting. It furthermore comprised a septum including a radiopaque ring 22 (Figure 1). This radiopaque ring was used to determine whether the port was oriented properly, which was equivalent to determining whether the port was suitable for injection, i.e. for power injection. The subject-matter of claim 1 was thus not novel over D4 either.

Claim 17 - novelty over D1, D2 and D4

The subject-matter of claim 17 was not novel over D1, D2 and D4 essentially for the same reasons as for claim 1.

Claims 1 and 17 - inventive step starting from D1 or D2 in combination with D13 or HE5

If the devices in D1 and D2 were not considered to be "suitable for power injection", this feature could not make the claimed device and method inventive.

The person skilled in the art knew, for example from D13 or HE5, that hand injection and power injection were two alternative ways of injecting fluid into an access port. In particular, D13 taught that, compared with manual injection, uniform delivery of contrast media via power injection increased the quality of the CT imaging while decreasing the operator's radiation exposure (page 337, right-hand column, second paragraph).

Starting from either D1 or D2, the person skilled in the art seeking to achieve these benefits would thus have obviously replaced the syringe used in manual injection with a power injector. Since a power injector could also be used at a low injection pressure/flow

rate, this would not have represented any technical difficulty. The devices in D1 and D2 could also be easily adapted to withstand higher pressures; for example, D1 and D2 disclosed that the membrane thickness could be increased. The person skilled in the art would thus have arrived at the subject-matter of claims 1 and 17 without exercising any inventive skill.

Sufficiency of disclosure

The claims referred to a septum including a radiopaque material configured to form a pattern. However, the contested patent did not contain any teaching about the type of radiopaque material to be used or how this material is joined to the septum. The claimed invention was therefore not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

(e) Request for apportionment of costs

The interruption of the oral proceedings at the opponent's request to prepare questions to be referred to the Enlarged Board of Appeal had been limited to 50 minutes. This could not be regarded as an abuse of rights as alleged by the proprietor and could not justify diverging from the rule that each party should bear the costs it had incurred. Moreover, the proprietor had not objected to the request for interruption and had not contested the admittance of the request for referral to the Enlarged Board of Appeal. It was only at the end of the oral proceedings that the proprietor requested an apportionment of costs. This request therefore had to be refused.

IX. The **proprietor's arguments**, as far as relevant for the present decision, can be summarised as follows.

(a) Admissibility of the proprietor's appeal and admittance of the proprietor's claim requests

In claim 1 of the main request, the feature "the septum being suitable for being repeatedly pierced or punctured with a hollow slender element such as a cannula or a needle" had been deleted to address the lack of clarity mentioned in the decision under appeal. Apart from the omission of the word "vascular" in claim 17, the claims of the first auxiliary request were identical to those of the first auxiliary request considered in the decision. Said claim 17 was, however, identical to claim 1 of the fourth auxiliary request allowed by the opposition division. The limitations added in the claims of the further requests were aimed at overcoming the novelty and inventive-step objections raised in the decision. They did not introduce any new matter compared with the previous discussions in the first-instance proceedings. All the claim requests filed on appeal were therefore admissible, so the appeal itself was admissible.

The claims discussed in the first-instance proceedings already included claims directed to the use of a septum and to a vascular access port. The opponent's objections in that respect concerned compliance with Article 123(3) EPC, i.e. the allowability of the appeal and not its admissibility.

(b) Admittance of documents HE2-HE7, D20, HE3a and HE4a

Although HE3 and HE4 had been published after the priority date of the patent, their content reflected

medical terms which had been established before that date.

D20 did not *prima facie* support the argument the opponent had tried to make on the basis of that document. The expression "access port" was used in D20 only as an abbreviation of "vascular access port". This did not demonstrate that both expressions designated the same type of device or that the term "vascular" did not differentiate a "vascular access port" from an "access port". D20 should therefore not be admitted into the proceedings.

HE3a and HE4a had the same content as HE3 and HE4 and had been published before the priority date of the patent in suit. Filing these documents thus solved the issues that the board had pointed out in its preliminary opinion sent with the summons to attend oral proceedings. These documents had only been found when rechecking the case after said preliminary opinion was received. Consequently, they should be admitted into the proceedings.

(c) First and second auxiliary requests - novelty of claim 1 over D1 and D2

As evidenced by HE2 (pages II-408 and I-278), the person skilled in the art recognised a "vascular access port" as being a specific medical device and not any access device providing access to the vasculature. In particular, a vascular access port had to provide access to the vasculature in two directions, i.e. it should enable not only injection but also blood sampling. By contrast, the devices disclosed in D1 and D2 were shunt systems for draining cerebrospinal fluid from the brain. They had an additional inlet and did

not allow for blood sampling. Hence, neither D1 nor D2 disclosed a "vascular access port", so the subject-matter of claim 1 of both the first and second auxiliary requests was novel over these documents.

(d) Third auxiliary request

Claim 1 - added subject-matter

The subject-matter of claim 1 was supported by both the parent application and the subject application as filed, so the requirements of Articles 76(1) and 123(2) EPC were met. In particular, the features whereby the vascular access port was "structured for performing power injection" and the radiopaque material made it possible to "[identify] the vascular access port as being structured for performing power injection" were disclosed in paragraphs [0008], [0077], [0078], [0135] and [0138] of the description of the parent application as filed.

Claim 1 - extension of scope of protection conferred by the patent; opponent's request for referral to the Enlarged Board of Appeal

Claim 1 of the third auxiliary request contained all the features of claim 1 as granted and was more limited than claim 1 as granted. National rules on infringement proceedings were not to be taken into account under Article 123(3) EPC. A referral to the Enlarged Board of Appeal was not justified.

Claim 1 - clarity

The opponent raised the clarity objection for the first time in its submission dated 14 September 2021, i.e.

after the notification of the summons to oral proceedings. Since the third auxiliary request had been filed with the proprietor's statement of grounds of appeal, this objection could and should have been filed earlier. There were no exceptional circumstances - nor did the opponent provide cogent reasons justifying any such exceptional circumstances - for raising the objection so late. Hence, this objection should not be admitted into the proceedings.

Claim 1 - novelty over D1 and D2

"Power injection" had a clear technical meaning in the art, as evidenced for example by HE5 and D13. This expression therefore limited the scope of claim 1.

The pressures arising in an access port when power injection was used were typically over about 40 psi, and could even rise well over 100 psi. By contrast, the devices in D1 and D2 were designed to drain a body fluid from one part of the body to another, especially cerebrospinal fluid from the brain into the heart atrium, where blood pressure was low. The pressures involved in these devices were in any case below 1 psi, i.e. about two orders of magnitude lower than pressures associated with power injection. The devices in D1 and D2 were designed accordingly and would not withstand much higher pressures. Moreover, given the total quantity of cerebrospinal fluid in the brain (about 125 ml), it was clear that the flow rates for which the devices in D1 and D2 were designed remained well below the flow rate of 1 ml/s mentioned in D13 for power injection. Consequently, the devices in D1 and D2 were not "structured for power injection".

In addition, the radiopaque patterns disclosed in D1 and D2 were related to pressure/flow characteristics of the internal valve which controlled the transfer of body fluid from the inlet to the outlet. These patterns were unrelated to the injection of fluid into the reservoir chamber 36 through the septum. The feature of claim 1 requiring that the pattern was "for identifying the access port as being structured for power injection" was therefore not disclosed in D1 and D2 either.

For these reasons, the subject-matter of claim 1 was novel over D1 and D2.

Claim 1 - novelty over D4

D4 was silent on the access port being structured for power injection. Furthermore, D4 failed to disclose a septum which "included" a radiopaque material. The radiopaque ring 22 was used to determine the orientation of the implanted port but had nothing to do with pressure. The subject-matter of claim 1 was therefore also novel over D4.

Claim 17 - novelty over D1, D2 and D4

Because none of D1, D2 or D4 disclosed an access port "suitable for power injection", they could not disclose a method as defined in claim 17 either. The subject-matter of claim 17 was therefore novel over these documents.

Claims 1 and 17 - inventive step starting from D1 or D2 in combination with D13 or HE5

D1 and D2 did not suggest using the disclosed devices to inject a contrast medium for the purpose of an imaging procedure. In addition, given the nature of the devices in D1 and D2, the person skilled in the art starting from these documents would never have contemplated using power injection with these devices. A power injector could not inject a contrast medium at the injection pressures for which the devices in D1 and D2 were designed. Pressures typical for power injection would clearly damage these devices. The subject-matter of claims 1 and 17 therefore involved an inventive step over both D1 and D2.

Sufficiency of disclosure

The proprietor did not comment on this issue during the appeal proceedings.

(e) Request for apportionment of costs

The opponent's late and unsuccessful request for referral to the Enlarged Board of Appeal amounted to an abuse of rights. This justified an apportionment of costs to the benefit of the proprietor, for reasons of equity.

Reasons for the Decision

1. The subject-matter of the contested patent

1.1 The patent relates to implantable vascular access ports, which provide a convenient way of repeatedly delivering a medical agent into a patient's vasculature (paragraph [0005]). As shown for example in Figure 6 reproduced below, these access ports typically include

a housing (56) defining a fluid reservoir (66) sealed by a needle-penetrable septum (80). The reservoir communicates with a predetermined location in the patient's vasculature through a catheter (73) attached to the access port. Once the access port and the catheter have been implanted, a fluid (F) may be infused into the vasculature by a needle (90) passed through the patient's skin and penetrating the septum. Hence, problematic repeated needle punctures into the vasculature can be avoided (paragraph [0005]).

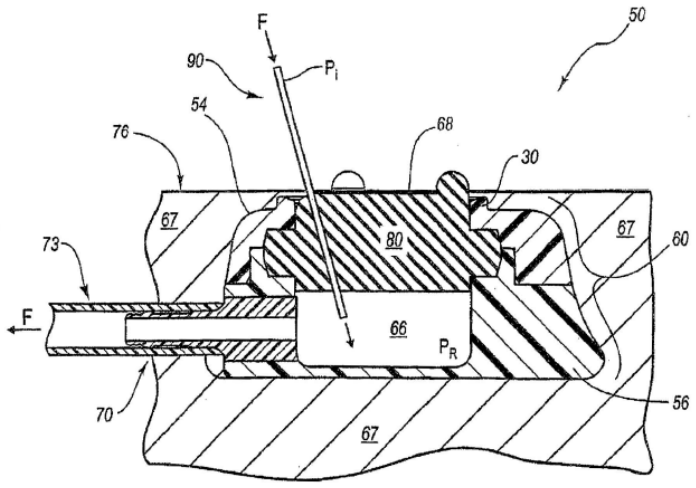


FIG. 6

1.2 A wide variety of medical imaging technologies require the use of a contrast medium that is infused into the patient's vasculature at a sufficiently high flow rate to reach and maintain a suitable concentration throughout a selected scan time and within a selected region of the anatomy (paragraphs [0001] and [0003]). If a vascular access port as described above is used to infuse the contrast medium, then because of the viscosity of the contrast medium and the small diameter of the infusion catheter in particular, maintaining the high flow rate requires the contrast medium to be injected at a high pressure to overcome the significant pressure drop taking place through the infusion system from the injector to the distal end of the catheter

(paragraph [0077] and Figure 7 reproduced below). This can be achieved using conventional systems for what is known as "power injection", configured for developing very high injection pressures (paragraphs [0002] and [0004]).

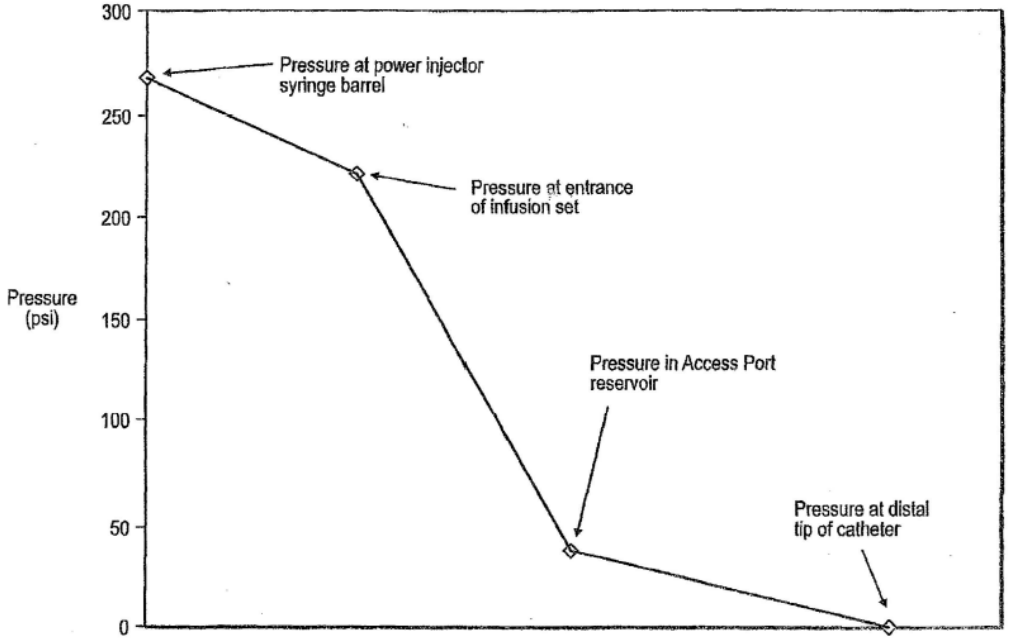


FIG. 7

1.3 When power injection is used to inject a fluid into an access port, a similarly high internal port pressure develops within the reservoir of the port (Figure 7 above). While access ports may be specifically structured to withstand such high internal port pressures (for example by constraining the septum within the housing by a mortise-and-tenon mechanism as disclosed in paragraphs [0078]-[0079] and shown in Figure 8), improperly pressurising an access port may cause it to rupture and thus may have dramatic consequences for the patient (paragraph [0004]).

The contested patent aims at providing a way of easily identifying whether an access port can be safely used with power injection (paragraphs [0100] and [0123]). To this end, the patent suggests providing the septum of

the port with a radiopaque material configured to form a selected pattern (199) when an X-ray is taken through the septum, as shown for example in Figures 34-35 reproduced below:

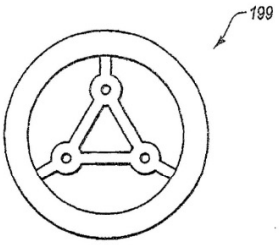


FIG. 34

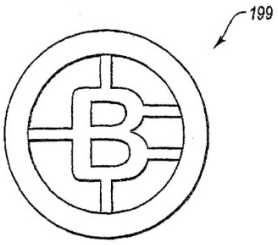


FIG. 35

Once the access port has been implanted, this pattern can be used to identify the access port as being suitable for power injection (paragraph [0100]).

2. Admissibility of the proprietor's appeal and admittance of the proprietor's claim requests

2.1 First auxiliary request

2.1.1 Claims 1-16 of the current first auxiliary request are identical to claims 1-16 of the first auxiliary request considered in the decision under appeal. The opposition division found these claims unallowable, formulating several objections in the decision (points 15, 17 and 19).

As submitted by the opponent, it is true that claim 17 differs from claim 17 of the first auxiliary request considered in the decision under appeal in that the word "vascular" has been omitted. However, due to this amendment, claim 17 is identical to claim 1 of the fourth auxiliary request, which was found allowable by the opposition division and on the basis of which the contested patent was maintained (point 23 of the decision).

2.1.2 The proprietor's statement of grounds of appeal, in particular points 4.1 and 4.2 in combination with points 3.1, 3.3 and 3.4, addresses the objections raised in the decision under appeal against claims 1-16. It provides reasons why, in the proprietor's opinion, the impugned decision should be set aside in respect of those claims but upheld as far as claim 17 is concerned.

Therefore, the proprietor's statement of grounds of appeal meets the admissibility requirements of Article 108 EPC, third sentence, in combination with Rule 99(2) EPC at least in respect of the first auxiliary request. As a consequence, the proprietor's appeal as a whole is admissible and the first auxiliary request is to be admitted into the appeal proceedings.

2.1.3 Claims directed to the use of a septum or to a vascular access port were already presented in the first-instance proceedings and considered by the opposition division (see for example the main request or the first auxiliary request considered in the decision under appeal). Therefore, filing claims to this effect on appeal does not amount to creating a fresh case, contrary to the opponent's argument.

The opponent's objection that the scope of these claims had shifted from the scope of the claims as granted concerns their compliance with Article 123(3) EPC, i.e. at most the allowability of the corresponding claim requests. This, however, has no bearing on the above conclusion regarding the admissibility of the proprietor's appeal and the admittance of the first auxiliary request. The same applies to the other requests containing any such claims.

2.2 Main request

Compared with claim 1 of the main request considered in the decision under appeal, the feature "the septum being suitable for being repeatedly pierced or punctured with a hollow slender element such as a cannula or a needle" has been omitted in claim 1 of the current main request.

This amendment, which leads to a broadening of the claimed subject-matter, does not address the reasons why the opposition division did not allow the main request, namely that claim 1 contained added subject-matter, as discussed in point 14.3 of the decision. Furthermore, the proprietor has not provided any reasons why this amendment was not submitted in the first-instance proceedings.

For these reasons, the board decided not to admit the main request into the appeal proceedings (Article 12(4) RPBA 2007, which applies in this case by virtue of the transitional provisions of Article 25(2) RPBA 2020).

2.3 Second and third auxiliary requests

The current second and third auxiliary requests are based on the first auxiliary request considered in the decision under appeal. In each of them, the subject-matter of claim 1 has been increasingly narrowed by the addition of further limiting features. These amendments represent an appropriate reaction by the proprietor to the opposition division's finding that the subject-matter of claim 1 of the first auxiliary request lacked novelty over D1 and D2 (point 19 of the decision).

The added features are not technically complex and merely relate to the definition of the access port as an implantable vascular access port and to its suitability for performing power injection, two issues which were already discussed in the first-instance proceedings as reflected by the decision under appeal.

Moreover, the proprietor filed these requests with its statement of grounds of appeal, i.e. at the earliest possible stage of the appeal proceedings.

For these reasons, the board decided to admit the second and third auxiliary requests into the appeal proceedings (Article 12(4) RPBA 2007).

3. Admittance of documents HE2-HE7 and D20

The proprietor filed HE2-HE7 for the first time with its statement of grounds of appeal. In response, the opponent filed D20 with its reply. The admittance of these documents is thus subject to Article 12(4) RPBA 2007.

3.1 The proprietor filed HE2-HE7 to support its view that the decision under appeal was wrong to disregard the expressions "vascular" and "suitable for power injection" as being limiting features that distinguished the claimed subject-matter from D1 and D2 (points 19.1-19.3 and 21.1-21.3 of the decision).

3.1.1 However, HE3, HE4 and HE7 were published after the priority date claimed by the contested patent. Therefore, these post-published documents have no bearing on the claim interpretation in the case in hand. The board also shares the opponent's concerns about HE6, which bears the statement "Originally

published July 2004" but was not retrieved from a web archiving service until 2017. It is thus unclear whether this document has been amended since then.

The proprietor did not provide counter-arguments in support of the admittance of these documents. The board therefore decided not to admit HE3, HE4, HE6 and HE7 into the proceedings.

3.1.2 On the other hand, HE2 and HE5 were published in 2000 and are thus prior art under Article 54(2) EPC. Both can be regarded as reflecting the common general knowledge of the person skilled in the art. The board therefore decided to admit these documents.

3.2 The opponent filed D20 in response to the filing of HE2 to counter the proprietor's arguments about the term "vascular" based on this document. D20 is prior art under Article 54(2) EPC. In view of the decision to admit HE2, the board found it appropriate to admit D20 as well.

4. Admittance of documents HE3a and HE4a

The proprietor filed these documents after the notification of the summons to oral proceedings.

According to Article 13(2) RPBA 2020, any amendment to a party's appeal case made after notification of a summons to oral proceedings is, in principle, not to be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

The issuing of the board's preliminary opinion on objections already on file, which, as explained by the

proprietor, triggered a further search that revealed HE3a and HE4a, does not constitute exceptional circumstances justified by cogent reasons for filing these documents at such a late stage. Consequently, the board decided not to admit these documents.

5. First and second auxiliary requests - novelty over D1 and D2

5.1 It is common ground that D1 discloses an implantable device (column 1, first paragraph; see Figure 2 reproduced below) comprising a septum (needle-penetrable dome 34; column 5, lines 3-6) including a radiopaque material configured to form a selected pattern when an X-ray is taken through the septum (dot code 70; column 5, lines 37-40).

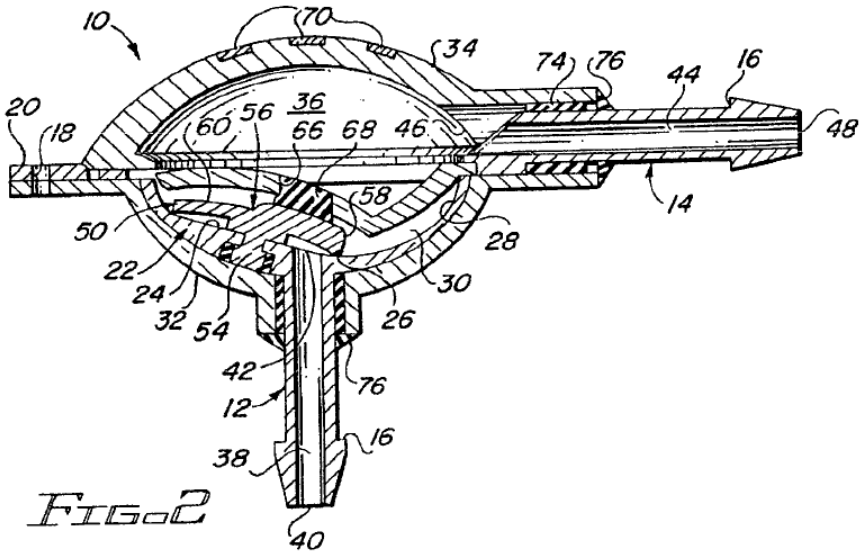


FIG-2

The device defines a subcutaneous, implantable reservoir (reservoir chamber 36) into which a fluid can be injected via a needle that is passed through the skin and penetrates the dome 34 (column 5, lines 3-6). The reservoir chamber 36 is connected via a catheter to a heart atrium (column 3, lines 36-44). Therefore, once implanted, the device in D1 enables a fluid injected into the reservoir to be ultimately infused into the

heart cavity, and thus to reach the patient's vasculature.

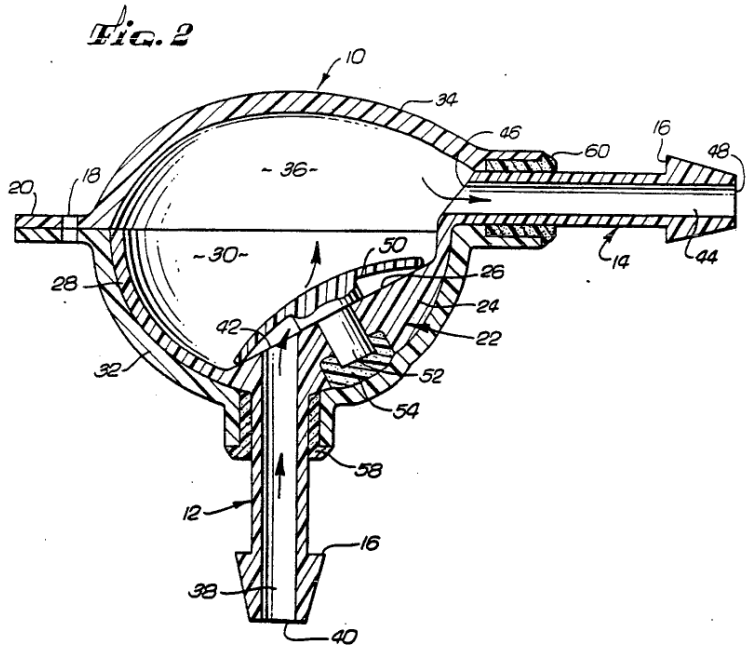
5.2 In dispute between the parties is whether this device represents a "vascular access port" as defined by claim 1.

On a plain reading of this expression, a vascular access port is a port configured to provide a route by which the patient's vasculature is "accessed", i.e. reached. Contrary to the proprietor's view, this does not necessarily require that blood can be aspirated from the vasculature through the access provided. The description of the contested patent itself discloses that a vascular access port is "for introducing a fluid into the vasculature" and provides "a convenient method to repeatedly deliver medicants to remote areas of the body" (paragraph [0005]), whereas sampling blood from the patient is presented merely as a secondary optional feature (paragraph [0005]: "*Additionally*, the port *may* be used to aspirate blood from the patient"; emphasis added by the board). HE2, to which the proprietor referred, does not support a different view.

Therefore, contrary to the proprietor's argument, the person skilled in the art would regard the device in D1, which provides access to the patient's vasculature as explained in point 5.1 above, as a "vascular access port", especially "for providing subcutaneous access to a patient". The fact that the device in D1 may additionally have further functions (such as the drainage of cerebrospinal fluid entering the reservoir through an additional inlet) does not contradict this conclusion.

It follows that the subject-matter of claim 1 of the first and second auxiliary requests is not novel over D1 (Article 54(1) and (2) EPC).

5.3 D2 discloses a similar device to D1 (see Figure 2 reproduced below, in which most of the features shown have the same reference sign as in D1), comprising the same features as claim 1, in particular a septum 34 including a radiopaque material (radiopaque dot code 56 not shown in Figure 2; see column 5, lines 38-44).



Hence, for the same reasons as discussed above for D1, the subject-matter of claim 1 of the first and second auxiliary requests also lacks novelty over D2 (Article 54(1) and (2) EPC).

6. Third auxiliary request

6.1 Claim 1 - added subject-matter

Contrary to the opponent's argument, the parent application as filed discloses a vascular access port that is generally "structured for performing power

injection", without any reference to a particular flow rate or injection pressure. This is already suggested in the last paragraph of the background section of the description, which states the technical problem addressed in the application (paragraph [0008]: "vascular access ports (...) structured for performing power injection may be advantageous"). In fact, the person skilled in the art understands from the application as a whole that the various flow rate or pressure values and ranges disclosed merely correspond to particular injection parameters which all fall under "power injection" (see for example paragraph [0135]: "identify the access port as suitable for power injection or may identify a maximum flow rate or pressure that may be safely accommodated by the access port"; see also point 1. above). The fact that claim 1 does not refer specifically to either flow rate or pressure is therefore not in breach of Article 76(1) EPC.

Moreover, the fact that the radiopaque material forms a pattern "for identifying the vascular access port as being structured for performing power injection" is disclosed in paragraph [0138] in combination with paragraph [0135].

Furthermore, the mortise-and-tenon mechanism to which the opponent referred is described in the parent application as filed merely as one of several example mechanisms for retaining the septum in the housing of the access port (paragraph [0088], first three sentences). This mechanism is not inextricably linked to the other features defined in claim 1. The same conclusion applies to a septum including a gel region (paragraph [0018]). Hence, omitting these features in

claim 1 does not result in subject-matter extending beyond the content of the parent application as filed.

It follows that the requirements of Article 76(1) EPC are met, contrary to the opponent's view. Since the description of the subject application as filed contains *verbatim* the description of the parent application as filed, the requirements of Article 123(2) EPC are also met.

6.2 Claim 1 - extension of scope of protection; request for referral to the Enlarged Board of Appeal

6.2.1 Extension of scope of protection

Under Article 69 EPC and the Protocol on its interpretation, the extent of the protection conferred by a European patent is determined by the claims, which must be interpreted with the help of the description and the drawings. In the case in hand, it is disputed whether claim 1 of the third auxiliary request confers a broader scope of protection than claim 1 as granted. Neither party has relied on the description or the drawings.

The scope of protection conferred by a patent claim depends in particular on its category and the technical features it includes (G 2/88, Reasons 3.3). Claim 1 of the third auxiliary request includes all the features of claim 1 as granted, as well as several additional technical features. Both claims are product claims. It follows that claim 1 of the third auxiliary request has a narrower scope of protection than claim 1 as granted (see G 2/88, Reasons 4.1).

In this context, it does not matter that claim 1 as granted was directed to a *septum* whereas claim 1 of the third auxiliary request is directed to a *vascular access port comprising the septum* according to claim 1 as granted.

The opponent argued that it would not be allowable under Article 123(3) EPC to claim a physical entity which is different from the physical entity claimed in the patent as granted. In the context of the case in hand, the opponent's arguments also amount to saying that, in a product claim, the entity claimed is defined by the first technical feature of the claim.

Under Article 123(3) EPC, however, what matters is not what the first technical feature in a claim is, but rather which technical features the claims include in their totality. In other words, the scope of protection is not necessarily different depending on whether a septum in combination with a vascular access port is claimed or a vascular access port comprising a septum. In any case, the scope of protection of claim 1 as granted, which is directed to a septum, is broader than that of claim 1 of the third auxiliary request, which is directed to a vascular access port comprising the septum according to claim 1 as granted.

The opponent's arguments relating to possible differences under German patent law with regard to contributory infringement do not change the above assessment. There is a difference between the "extent of the protection conferred" by a patent under Article 69 EPC and the "rights conferred" by a patent under Article 64 EPC. The latter depend on the rights conferred by a national patent in the relevant contracting state and do not need to be considered for

the purposes of Article 123(3) EPC. Accordingly, the national laws of contracting states in relation to infringement are not to be taken into account under Article 123(3) EPC either (G 2/88, Reasons 3.3).

The board is also not convinced by the opponent's argument that dependent claim 2 as granted, which was already directed to a septum in an access port, comprised additional technical features in comparison with claim 1 of the third auxiliary request. Under Article 123(3) EPC, the patent proprietor does not have to amend claim 1 as granted so as to include all the technical features of dependent claim 2 as granted. What matters under Article 123(3) EPC is merely whether an amendment results in an extension of the scope of protection, taking into account the totality of the claims. As stated above, claim 1 of the third auxiliary request has a narrower scope of protection than claim 1 as granted.

6.2.2 Request for referral to the Enlarged Board of Appeal

In view of the above, the questions proposed by the opponent for referral to the Enlarged Board of Appeal can be answered without doubt by reference to the law as interpreted by the Enlarged Board of Appeal.

Moreover, the facts considered in decisions T 352/04 and T 867/05, referred to by the opponent, are different from those in the case at issue. In this regard, the board agrees with the reasoning given in decision T 547/08, Reasons 3.2.

The opponent further alleges that decision T 1898/07, Reasons 19, supports the view that assessing compliance with Article 123(3) EPC includes a test that takes

account of national infringement laws and therefore, in the case in hand, also the rules on contributory infringement under German patent law. Regardless of whether this interpretation of T 1898/07 is correct, the board disagrees with this conclusion, in view of the Enlarged Board's different statement on this matter in G 2/88, Reasons 3.3.

For these reasons, the board refuses the opponent's request for referral to the Enlarged Board of Appeal.

6.3 Claim 1 - clarity

The proprietor filed the third auxiliary request with its statement of grounds of appeal. The opponent did not challenge the clarity of the claims of this request in its reply to the statement of grounds of appeal, nor did the board raise this issue in its preliminary opinion. It was not until after the notification of the summons to oral proceedings that the opponent raised a clarity objection against claim 1.

In the absence of exceptional circumstances which could justify raising the clarity objection at such a late stage of the appeal proceedings, the board decided not to take this objection into account pursuant to Article 13(2) RPBA 2020.

6.4 Claim 1 - novelty over D1 and D2

6.4.1 Contrary to the opponent's view, the expression "power injection" has a clear technical meaning in the art. This is not only derivable from the description of the contested patent (paragraphs [0002]-[0004]; see also point 1. above), but also clearly evidenced by HE5 (page 297, left-hand column, paragraph above Table

16-2; page 299, Table 16-3) and D13 (page 337, right-hand column, second and third paragraphs), both of which distinguish between power injection and manual injection, as argued by the opponent itself.

In particular, the fact that a vascular access port is structured for performing power injection does not mean that the access port should be merely suitable for a motorised injection process, at an arbitrary low flow rate and injection pressure, as alleged by the opponent. The feature of a vascular access port "structured for performing power injection" limits the subject-matter of claim 1 as it implies that the port is capable of withstanding high injection pressures which, when fluid is injected into the access port, lead to significant, potentially damaging internal port pressures developing within the reservoir of the port (D13, page 337, right-hand column, third paragraph and point 1. above).

The question to be answered is thus whether the access ports in D1 and D2 are suitable for withstanding such high internal port pressures.

6.4.2 The person skilled in the art learns from D13 that for typical power injection set-ups with a flow rate of 1 or 2 ml/s, the pressure measured at the port-catheter connection - which is even smaller than the internal port pressure itself, as illustrated in Figure 7 of the contested patent - ranges from about 8 psi to above 40 psi (page 339, Table 1). Given its dependence on flow rate and viscosity (for a laminar flow, this dependence is linear according to the Poiseuille's law; see D13, page 337, right-hand column, section "Methods"), the board notes that this pressure will increase to far over 100 psi for higher flow rates or thicker contrast

media, as also argued by the proprietor. This is additionally derivable from the description of the contested patent itself, which describes internal port pressures ranging from 37 to 185 psi (paragraph [0075]), with flow rates potentially as high as 5 ml/s (paragraph [0076]).

6.4.3 D1 and D2 are silent about injecting contrast media through the septum. The devices disclosed in these documents are designed to control the flow of a body fluid from one part of the body to another (typically cerebrospinal fluid from the brain to the heart) by means of a membrane valve (claim 1 of D1). Hence, these devices are designed to withstand low pressures of the order of magnitude of the body fluid pressures in question. Even when a fluid such as a drug is injected through the septum, the corresponding internal pressure developing within the port must remain within the same order of magnitude, particularly so as not to damage the membrane of the valve (especially when this membrane is thin enough to permit a "relatively low pressure differential" between the inlet and outlet; D1, column 5, lines 28-31). The opponent's argument that the injection pressure must be sufficiently high to infuse fluid into the heart cavity is not convincing. In order to reach the heart atrium, where the infused fluid is delivered together with the drained body fluid (D1, column 3, lines 40-43), the infused liquid only needs to develop a pressure in the same range as that of the cerebrospinal fluid to be drained.

Further support for the conclusion that the devices in D1 and D2 are designed for low-pressure applications is that the resilient dome 34 must be sufficiently resilient to be deformable by the mere pressure of a

finger, as put forward by the proprietor (e.g. D1, column 5, lines 6-8).

Therefore, even if, as argued by the opponent, D1 and D2 are not limited to devices for draining cerebrospinal fluid from the brain, the board shares the proprietor's view that the typical internal port pressures for which the devices in D1 and D2 are designed can be reasonably considered to be at most a few psi. Consequently, they are in any case significantly lower - by at least one order of magnitude - than the internal port pressures to be withstood by vascular access ports structured for performing power injection.

The picture is similar in terms of flow rate. As argued by the proprietor, the devices in D1 and D2 are dimensioned for the slow drainage of a body fluid (typically cerebrospinal fluid from the brain), with flow rates remaining well below those used with power injection.

For these reasons, the board concludes that D1 and D2 do not disclose vascular access ports "structured for performing power injection".

6.4.4 It follows from this conclusion that the radiopaque dot codes 70, 56 disclosed in D1 and D2 cannot be "for identifying the access port as being structured for power injection".

Therefore, the feature of claim 1 requiring that the radiopaque pattern is "for identifying the access port as being structured for power injection" is not disclosed in D1 and D2 either.

6.4.5 It follows that the subject-matter of claim 1 is novel over each of D1 and D2 (Article 54(1) and (2) EPC).

6.5 Claim 1 - novelty over D4

As argued by the proprietor, D4 does not contain any direct and unambiguous disclosure, whether explicitly or implicitly, of a vascular access port being "structured for performing power injection", in view of the interpretation of this expression established in point 6.4.1 above. Hence, the opponent's novelty objection fails for this reason alone.

What is more, the radiopaque locator ring 22 disclosed in D4 (corresponding to the radiopaque material as claimed) is not "included" in the septum 16 as asserted by the opponent, but rather consistently disclosed in D4 as a separate component distinct from the septum, intended to be placed above it (column 3, lines 51-53; column 4, lines 5-7; column 4, lines 22-24; claim 12) or formed with radiopaque paint or material painted on or deposited into holes provided on the port (column 4, lines 14-18).

It follows that the subject-matter of claim 1 is also novel over D4 (Article 54(1) and (2) EPC).

6.6 Claim 17 - novelty over D1, D2 and D4

As discussed with respect to claim 1 above, D1, D2 and D4 are not concerned with power injection and do not disclose, even implicitly, an access port "structured for performing power injection", i.e. "suitable for power injection".

Therefore, these documents cannot *a fortiori* disclose a "method of identifying an access port as being suitable for power injection" as defined in claim 17.

It follows that, at least for this reason, the subject-matter of claim 17 is novel over each of D1, D2 and D4 (Article 54(1) and (2) EPC).

6.7 Claims 1 and 17 - inventive step starting from D1 or D2 in combination with D13 or HE5

The opponent submitted that the subject-matter of claims 1 and 17 did not involve an inventive step in view of D1 or D2 in combination with D13 or HE5. These objections do not convince the board.

6.7.1 The opponent's line of reasoning is based *inter alia* on the assertion that the person skilled in the art starting from D1 or D2 would have sought to achieve uniform delivery of contrast medium to increase the quality of the CT imaging while decreasing the operator's radiation exposure. In the board's view, the very definition of this technical problem, which contains a pointer to the claimed solution, is based on hindsight since neither D1 nor D2 suggests using the disclosed access port to inject contrast medium in order to carry out CT imaging on a patient. The opponent's attack thus fails to convince at least for this reason.

6.7.2 What is more, in the board's view, the person skilled in the art would not have realistically contemplated using power injection with the devices in D1 and D2.

Contrary to the opponent's submission, power injection implies high pressures within the access port, which

could damage it (points 6.4.1 and 6.4.2 above). The person skilled in the art would have learnt from D13 as a whole that even an access port marketed with a recommended safety pressure limit of 40 psi should not be simply used with power injection without first carrying out thorough safety investigations, including detailed experimental studies, to assess whether it is actually suitable for power injection without risk for the patient (page 337, right-hand column, third paragraph). D13 would therefore have discouraged the person skilled in the art from using power injection with the devices in D1 and D2, which are designed for internal port pressures of no more than a few psi (point 6.4.3 above), i.e. well below 40 psi.

HE5, which does not address injection into an access port, does not support a different conclusion.

Without knowledge of the invention claimed, the person skilled in the art would therefore have had no motivation to make the devices in D1 and D2 "structured for performing power injection".

6.7.3 For these reasons, the board concludes that the subject-matter of claims 1 and 17 involves an inventive step over D1 and D2 (Article 56 EPC).

6.8 Sufficiency of disclosure

In accordance with established case law, the person skilled in the art may use their common general knowledge to supplement the information contained in the patent (*Case Law of the Boards of Appeal of the EPO*, 9th edition, 2019, II.C.4.1).

In the board's view, the person skilled in the art would have no difficulty in selecting appropriate materials for the septum and for the radiopaque material or in joining the material to the septum to form a radiopaque pattern as claimed.

Therefore, the board concurs with the opposition division's conclusion (point 18 of the decision under appeal) that the invention claimed is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC), contrary to the opponent's argument.

6.9 The opponent had no further objections against the claims of the third auxiliary request or against the description adapted by incorporating the amended paragraph [0009] filed by the respondent during the oral proceedings before the board on 14 October 2021. The board had no objections either.

7. Proprietor's request for apportionment of costs

According to Article 104(1) EPC, each party to opposition proceedings should bear the costs it has incurred unless a different apportionment of costs is ordered for reasons of equity.

The interruption of the oral proceedings requested by the opponent to prepare questions to be referred to the Enlarged Board of Appeal was limited to 50 minutes. Even if these questions could have been prepared in advance of the oral proceedings, the opponent's behaviour in the case in hand does not constitute an abuse of rights.

For an abuse of rights to be acknowledged, the opponent would have had to have exercised its right to make a request for referral to the Enlarged Board of Appeal not in pursuit of a legitimate aim, such as to receive an answer to the proposed questions, but rather primarily to cause damage to the patent proprietor. The burden of proof in that regard is on the person claiming the abuse of rights (see J 14/19, Reasons 13.1).

In the case in hand, the patent proprietor did not provide any proof as to the opponent's possible intention to cause harm, nor is the board aware of any such indication. The mere fact that the request was not allowed by the board, or was possibly unlikely to be allowed, does not constitute any such indication.

The board further notes that the proprietor did not raise any objection against the opponent's request for interruption of the oral proceedings, nor did the proprietor object to the admittance of the actual request for referral to the Enlarged Board of Appeal.

The board therefore sees no reasons of equity which could justify diverging from the principle of Article 104(1) EPC whereby each party should bear the costs it has incurred.

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 with the order to maintain the patent as amended in the following version:
- claims 1-17 according to the third auxiliary request filed with the proprietor's statement of grounds of appeal
- description paragraphs [0001]-[0008] and [0010]-[0141] of the patent specification and paragraph [0009] as filed during the oral proceedings before the board on 14 October 2021
- Figures 1-59 of the patent specification

3. The opponent's request for referral to the Enlarged Board of Appeal is refused.

4. The proprietor's request for apportionment of costs is refused.

The Registrar: The Chairman:

D. Hampe D. Ceccarelli

Decision electronically authenticated