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Datasheet for the decision of 5 October 2021

Case Number: T 0194/18 - 3.2.08

Application Number: 05792374.0

Publication Number: 1791495

IPC: A61F2/95, A61F2/966, A61F2/01, A61F2/24, A61F2/958

Language of the proceedings: EN

Title of invention:
DELIVERY SYSTEM WHICH FACILITATES HYDRATION OF AN INTRALUMINAL MEDICAL DEVICE

Patent Proprietor:
Cook Medical Technologies LLC

Opponent:
BIOTRONIK AG

Headword:

Relevant legal provisions:
EPC Art. 100(a), 52(1), 54, 56, 100(c)

Keyword:
Novelty (yes) - Inventive step (yes)
Added subject-matter - main request (yes) - auxiliary request 1 (no)

Decisions cited:

Catchword:

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Case Number: T 0194/18 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 5 October 2021

Appellant: (Opponent)	BIOTRONIK AG Ackerstrasse 6 8180 Bülach (CH)
Representative:	Keil & Schaafhausen Patentanwälte PartGmbB Friedrichstraße 2-6 60323 Frankfurt am Main (DE)
Respondent: (Patent Proprietor)	Cook Medical Technologies LLC 750 North Daniels Way Bloomington, IN 47404 (US)
Representative:	Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 22 November 2017 rejecting the opposition filed against European patent No. 1791495 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairwoman	P. Acton
Members:	M. Olapinski
	C. Schmidt

Summary of Facts and Submissions

I. An appeal was filed by the opponent against the opposition division's decision of 22 November 2017 to reject the opposition against the patent in suit.

II. Oral proceedings by videoconference took place before the Board on 5 October 2021.

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

IV. The respondent (patent proprietor) requested that the appeal be dismissed - i.e. that the patent be maintained as granted - (main request) or that the patent be maintained on the basis of one of the auxiliary requests 1 to 7 filed with the letter dated 7 August 2018 or on the basis of auxiliary request 8, filed on 4 October 2021.

It further requested that document D10 not be admitted into the proceedings. If the Board admitted document D10, it requested that the case be remitted to the opposition division.

V. **Claim 1 as granted (main request)** reads:

"An intraluminal medical device delivery system, comprising:
(1) an elongate tubular member (812) having a distal end adapted for insertion into a body vessel;
(2) a dilator (820) disposed in said tubular member, said dilator having

a) a lumen formed (826) in an axial direction therein and

b) a distal end adapted for insertion into the body vessel,

(3) said tubular member and said dilator having a device chamber (830) formed therebetween; and

(4) an intraluminal medical device (828) disposed in the device chamber;

characterised by

(5) a plurality of hydration channels (854) extending radially outward from the lumen to the device chamber to provide fluid communication between the device chamber and the lumen, to facilitate hydration of said intraluminal medical device."

Claim 7 as granted reads:

"The delivery system according to any preceding claim, wherein the intraluminal medical device comprises a dehydrated material."

Claim 8 as granted reads:

"The delivery system according to any preceding claim, wherein the intraluminal medical device includes a bioactive that can be released from the intraluminal medical device upon hydration with a suitable fluid through the hydration channel."

VI. **Auxiliary request 1** differs from the main request in that dependent claims 7 and 8 are deleted.

VII. The following documents are relevant for the present decision:

D3: US 5 928 247

D6: US 2003/0125790 A1
D7: US 5 776 140
D8: WO 00/69368 A2
D9: WO 03/002020 A2
D10: WO 2005/055881 A2

VIII. The appellant's arguments regarding the main request can be summarised as follows.

Novelty - D6

Claim 1 of the patent as granted lacked novelty in view of D6 disclosing, in addition to Features 1-4, "side holes at any location for flushing and/or for injection of fluids". The quoted feature included side holes (hydration channels) at the specific location of the "device chamber" in D6 as required by Feature 5.

Novelty - D8

Claim 1 of the patent as granted lacked novelty in view of D8 disclosing, in addition to Features 1-4, a flushing system with openings "in the area where the proximal portion of the stent holder meets the distal portion of the inner tubular member" (page 21, lines 15-21). The openings could either be on the side of the stent holder (within the "device chamber" as required by Feature 5) or on the side of the inner tubular member (e.g. Figure 7 of D8). Page 11, lines 7-13, disclosed the same two alternatives. Hence, D8 disclosed Feature 5.

Furthermore, the "device chamber" was not restricted to the area of the "stent holder". Claim 1 defined the "device chamber" as the space between the elongate tubular member and the dilator without specifying its

axial extension. In D8, this space and thus the chamber extended proximally beyond the stent holder up to the location of the openings because otherwise the flushing fluid could not pass through to the stent. Therefore, Figure 7 in D8 also disclosed Feature 5.

Novelty - D9

D9 undisputedly disclosed a delivery system with Features 1-4. A device chamber ("reception space" for a stent) was formed between a "tubular inner core" 5 and a "sheath" 4 (Figures 1 and 2).

Figures 1 and 2 also showed a flushing opening (14) between the marker bands 13. It represented hydration channels extending radially outward to the "device chamber". The fact that the remaining figures of D9 showed the opening 14 at a different location did not disqualify the disclosure of Figures 1 and 2. Accordingly, Figures 1 and 2 of D9 also disclosed Feature 5.

Furthermore, Feature 5 was also derivable from Figures 2a and 3b, even if the "device chamber" was considered to be delimited proximally by the "coil spring" 6. The coil spring acted as an abutment means for the stent (page 15, lines 20-26). When using a longer stent, the coil spring could be compressed and displaced further proximally as far as the retracted sheath, i.e. beyond the location of the flushing opening. Hence, the "device chamber", representing the maximum space available for the device, included the location of the opening. Therefore, the flushing openings in Figures 2a and 3b also fell within the terms of Feature 5.

Novelty - D10

D10 disclosed an intraluminal medical device delivery system with Features 1-4 (Figures 4, 11 and 12). Figure 12 also disclosed a plurality of "flush holes" 174 (page 15, lines 23-25) extending radially outward from the lumen (hollow space within "encapsulating layer" 172, Figure 12) to the device chamber (Feature 5). Accordingly, D10 disclosed all the features of claim 1.

Inventive step - starting from D9

Claim 1 differed from D9 by the axial location of the hydration channels from Feature 5 extending radially outward "to the device chamber". The objective technical problem solved could thus be seen in more effective, targeted flushing.

D6 disclosed that flushing openings could be provided "at any location", and D8 disclosed placing them "in the area" of the device chamber. D6 and D8 therefore suggested varying the axial location of the openings. To provide more direct, targeted flushing, it would have been obvious for the skilled person using their common general knowledge to place the openings within the device chamber.

Inventive step - D3+D7

D3 disclosed a balloon-based stent delivery system (Figure 1). The balloon disclosed axial lumina ("medication conduits" 25) with a plurality of perforations (21, Figures 2B and 2D) representing "hydration channels" (column 4, lines 1-5) extending radially outward from the lumen to the region of the stent.

D3 did not disclose an elongate tubular member (Feature 1) disposed around the balloon and stent and forming a "device chamber" (Features 3 and 4). This outer tubular member solved the objective technical problem of protecting the medical device and the body vessels during catheter placement.

The same problem was addressed and solved in D7 by providing an outer sheath (30, Figures 1, 2A and 3; column 2, lines 11-21; column 4, lines 6-8). It would thus have been obvious for the skilled person to implement an additional outer sheath in D3, thus arriving at the subject-matter of claim 1 without involving an inventive step.

Article 100(c) EPC

The application as filed did not disclose "dehydrated" materials as defined in claim 7 as granted. Likewise, a "bioactive that can be released from the intraluminal medical device upon hydration with a suitable fluid" as required in claim 8 was not originally disclosed.

IX. The respondent's arguments regarding the main request are summarised as follows.

Novelty - D6

The generic disclosure of side holes "at any location" in D6 did not anticipate the more specific feature that they extended radially outward "to the device chamber" required by claim 1.

Novelty - D8

The term "device chamber" was to be understood as the space suitable for holding the device. It was, thus, limited to the axial region of the "stent holder" distal of the tantalum marker 42 in Figures 1 and 7 of D8. The flushing openings 64 in D8, which could be considered "hydration channels", were, however, located in the proximal part of the inner tubular member (page 11, lines 10-11), proximal of the marker (Figure 7). The hydration channels shown in Figure 7 did thus not extend "radially outward [...] to the device chamber" as required by Feature 5. Page 21, lines 15-21, disclosed the openings "in the area" where the stent holder met the inner tubular member. This generic disclosure could also not anticipate the location defined in Feature 5. Hence, claim 1 was novel over D8.

Novelty - D9

The "device chamber" in D9 was delimited proximally by the coiled spring 6 and was thus restricted to the axial space between the marker bands 13. There was no disclosure in D9 that the spring was compressible or that the stent could extend proximally beyond the marker bands (13).

The position of the opening 14 shown within the marker bands 13 in the small overview Figures 1 and 2 was inconsistent with that in the remaining, more detailed figures (e.g. Figures 2a and 3b) showing the opening proximal of the marker bands, i.e. outside the device chamber. Since Figures 1, 2, 2a and 3b displayed different views of the same catheter (page 10, lines 8-30), the disclosure of the location of the opening in D9 was ambiguous.

Hence, D9 did not disclose hydration channels extending radially outward to the device chamber (Feature 5). Accordingly, the subject-matter of claim 1 was novel over D9.

Novelty - D10

D10 did not directly and unambiguously disclose the direction of extension of the "flush holes" 174 shown in Figure 12. It could not be derived from the figures or description that the holes extended radially outward from the lumen and to the device chamber. Therefore, D10 did not directly and unambiguously disclose Feature 5.

Inventive step - starting from D9

D9, D6 and D8 all referred to the flushing of a stent delivery device before insertion into a patient. None of these documents disclosed flushing openings at the location of the device chamber. This would also not have been obvious because providing the flushing openings within the device chamber created a dead space that was not properly flushed. Effective flushing required placement of the flushing openings proximal of the device chamber contrary to Feature 5. The subject-matter of claim 1 thus involved an inventive step.

Inventive step - D3+D7

Even if the skilled person had applied the teaching of D7 to the delivery system of D3, they would not have arrived at the subject-matter of claim 1. In the state where the stent was covered by an additional protective sheath, the balloon had to be wrapped tightly around

the catheter with the stent crimped on top (Figure 2). In this compressed configuration, the thin-walled conduits 25 and perforations 21 were collapsed so that they did not form "channels", and no fluid communication was possible. Hence, even if the skilled person had used a protective sheath for the stent according to D7, they would not have arrived at Feature 5. Consequently, the subject-matter of claim 1 involved an inventive step.

Article 100(c) EPC

Claims 7 and 8 as granted were based on paragraph [0073] of the application as filed. It disclosed materials that "can be hydrated" implying, in line with paragraph [0046], a "dehydrated" material as defined in claim 7. Paragraph [0073] also disclosed the release of bioactive agents upon hydration in the context of intraluminal medical devices as required in claim 8.

Reasons for the Decision

1. Main request

1.1 **Novelty - D6**

D6 discloses an intraluminal medical device delivery system comprising an outer tube (12) and an inner tube (10, Figure 3a, paragraph [0043]) that can be considered to represent, respectively, the elongate tubular member and dilator from **Features 1 and 2** of claim 1. A device chamber containing an intraluminal medical device (**Features 3 and 4**) may be seen in the annular space holding the device between the inner and outer tubes distal of the "retainer" (14, Figure 3a).

Paragraph [0053] of D6 mentions that "the inner and outer tubes 10 and 12 may have side holes at any location for flushing and/or for injection of fluids" (emphasis added). However, this generic disclosure does **not** directly and unambiguously disclose the more specific definition of **Feature 5** requiring a plurality of hydration channels extending radially outward from the lumen of the inner tube "to the device chamber".

Hence, the subject-matter of claim 1 is novel over D6.

1.2 **Novelty - D8**

1.2.1 D8 undisputedly discloses an intraluminal medical device delivery system with **Features 1-4**. A "stent holder" (40) is located between a proximal tantalum marker (42) and the distal tip assembly (41) of the dilator (Figure 1). In this axial region, a space is provided between the "inner tubular member" (21) (page 17, line 28, to page 18, line 9) and an "outer tubular member" (22). A stent is held within this space.

1.2.2 The appellant submits that the patent did not define the structure and the axial limits of the "device chamber". Thus, according to the appellant, the entire available space between the inner and outer tubular members should be considered to represent the "device chamber" from claim 1. In D8, this space extended *proximally* beyond the tantalum marker at least to the area where the flushing openings 64 were provided (Figure 7) so that flushing fluid could pass through to the stent (page 21, line 21, to page 22, line 5).

It is true that claim 1 does not specify the axial extension of the device chamber and merely requires

that it be formed between the dilator and the tubular member. It is also true that in D8 the space between the inner and outer tubular members extends proximally beyond the axial region of the "stent holder" to allow fluid flow. However, the term "device chamber" is to be understood as a chamber suitable or adapted for containing the intraluminal medical device to be deployed. In D8, this chamber is defined by the structurally delimited space *distally* of the tantalum marker 42. Accordingly, **Figure 7**, which shows a plurality of flushing openings (representing "hydration channels") proximally of the marker, does not disclose **Feature 5**.

1.2.3 On page 21, lines 15-21, D8 discloses a flushing system consisting of "openings 64 extending through the inner tubular member 21 in the area where the proximal portion of the stent holder 40 meets the distal portion of the inner tubular member (FIG. 7)" (emphasis added).

The appellant argues that the broad disclosure "in the area [...]" encompassed two alternative locations: either proximally of the tantalum marker 42 (where the inner tubular member 21 and the stent holder 40 meet at the tantalum marker) or distally of the marker (that is, within the device chamber). In the appellant's view, D8 thus disclosed, *inter alia*, openings extending radially outward "to the device chamber".

However, the above passage does not spell out two distinct alternatives; it discloses that a plurality of openings can be placed anywhere in a broadly defined "area". Hence, it does not disclose that a plurality of openings is located distally of the marker. Moreover, the passage specifically refers to Figure 7, where all openings are located proximally of the "stent holder".

Accordingly, **page 21, lines 15-21**, does also not disclose channels extending radially outward to the device chamber as required by **Feature 5**.

1.2.4 Finally, page 11, lines 7-13, discloses that the openings extend through the inner tubular member "where the proximal portion meets the distal portion of the inner member". This passage also does not spell out two distinct alternatives for the location of the holes. Moreover, the "distal portion" of the inner tubular member refers to second/inner layer 37 (page 10, lines 10-15; page 17, lines 1-7) that does not extend into the region of the stent holder 40 (see Figure 12). Accordingly, **page 11, lines 7-26**, does not disclose **Feature 5**, either.

Hence, the subject-matter of claim 1 is novel over D8.

1.3 **Novelty - D9**

D9 undisputedly discloses an intraluminal medical device delivery system with **Features 1-4** (Figures 1 and 2). A "reception space" for a stent (page 15, lines 1-3) is provided between the "inner core" 5 and the outer "sheath" 4 (Figures 1 and 2). As set out in more detail above, the term "device chamber" corresponds to that space which is suitable or adapted for containing the device to be deployed. In D9, the collapsed stent - and thus the "device chamber" - is restrained within the reception space (page 16, lines 12-15; page 19, lines 17-20) between the distal catheter "tip" 8 and a proximal abutment means in the form of a "coiled spring" 6 (page 15, lines 20-29).

1.3.1 In the appellant's view, the "coiled spring" was compressible and displaced further proximally than shown in the figures when using a longer stent. The available space suitable for accommodating the device between the coiled spring and the distal tip was thus variable and larger than shown in the figures.

However, as submitted by the respondent, not every "coiled spring" is compressible. D9 discloses neither that the spring is compressible (in fact it appears from Figure 2c that there are no appreciable spaces between the coils) nor that stents of different length could be deployed. Accordingly, D9 does not directly and unambiguously disclosure that the available space for the device could be larger than shown in the figures. Thus, D9 only discloses a "device chamber" extending between the positions of the marker bands 13 as shown in the figures.

1.3.2 D9 discloses a flushing opening for flushing the reception space (page 4, line 27, to page 5, line 4), which can be considered a "hydration channel".

Figures 1 and 2 of D9 show the flushing opening 14 at a position *between* the marker bands 13, whereas Figures 2a and 3b disclose a flushing opening located *proximal of* the marker bands. According to page 10, lines 8-30, these figures display different views of the *same* delivery catheter. Figures 1, 2, 2a and 3b thus cannot be considered to disclose alternative locations of the opening. This inconsistency leads to ambiguity in the actual disclosure of these figures regarding the location of the opening. As a consequence, Figures 1 and 2 do not clearly and unambiguously disclose the specific location of the hydration channel between the marker bands.

Hence, D9 does not disclose hydration channels extending "to the device chamber" as required by **Feature 5**. The subject-matter of claim 1 is thus novel over D9.

1.4 **Novelty - D10**

It is undisputed that D10 discloses an intraluminal medical device delivery system with **Features 1-4**.

A plurality of "flush holes" 174 are shown in Figure 12. It is non-controversial that the holes can be considered "hydration channels" and are depicted at an axial location within the "device chamber" in D10. However, neither Figure 12 nor the passage on page 15, lines 23-25 - the only disclosure in D10 on the structure of the holes - disclose or allow deriving information about the orientation and direction of them. Therefore, D10 does not directly and unambiguously disclose that the hydration channels extend in the radial direction (**Feature 5**).

Accordingly, the subject-matter of claim 1 is novel over D10.

1.5 **Inventive step** - starting from **D9**

Claim 1 differs from the system of D9 by Feature 5.

The channels in D9, D6 and D8 concern flushing. The parties thus concurred that, starting from D9, the objective technical problem solved by Feature 5 had to relate to improved flushing.

The appellant submitted that the axial location of flushing channels within the device chamber solved the problem of more effective, targeted flushing and that D6, D8 and the common general knowledge would have led the skilled person to the subject-matter of claim 1.

However, D6 and D8 do not disclose flushing openings at the location of the device chamber and thus could not have led the skilled person to the claimed solution of Feature 5.

Furthermore, as set out by the respondent, the purpose of flushing is to eliminate all air bubbles from the delivery system, in particular from regions exposed during device delivery such as the device chamber. The placement of the flushing openings within the device chamber would, however, create dead spaces at the end of the chamber that are not or are not sufficiently flushed. Effective flushing instead requires - according to the fluid path of Figure 3b of D9 - placing the channels proximally of the device chamber so that sufficient fluid flow is created across the entire device and device chamber to flush all air bubbles. It would therefore not have been obvious for the skilled person in view of their common general knowledge to relocate the flushing opening(s) axially in such a way that they extend radially outward from the lumen to the device chamber (Feature 5).

Accordingly, the subject-matter of claim 1 involves an inventive step when starting from D9.

1.6 **Inventive step - D3+D7**

1.6.1 D3 discloses a balloon catheter for delivering a stent. The balloon, which is considered to represent a

"dilator" with a distal end adapted for insertion into a body vessel, has "medication-dispensing conduits" (25) on or within its wall. Each of these lumina is "provided with one or more perforations (21) to enable entry of medications into the body passage" (column 4, lines 1-15; Figures 2A-2D). The perforations can thus be considered to represent "hydration channels". When the balloon is in its inflated configuration (Figure 1), the conduits (dashed lines in Figure 1) extend in the axial direction, and the "hydration channels" extend radially outward from the respective conduit to the space where the stent (30) is placed (Figures 2B and 2D).

D3 does not disclose an "elongate tubular element" (Feature 1) covering the stent which is thus not contained in a "device chamber" (Features 3 and 4).

Even if it had been obvious to provide an additional protective sheath as disclosed in D7 (30, Figures 1-4; column 3, lines 11-21, and column 4, lines 3-8), representing an "elongate tubular member", the skilled person would not have arrived at the subject-matter of claim 1 for the following reasons.

1.6.2 When the protective sheath is applied over the balloon catheter and the stent, the resulting device could be considered to fulfil Features 1, 3 and 4. However, in this configuration, the thin-walled balloon is in the collapsed and wrapped state (Figure 2; column 4, lines 50-54). Because the balloon is wound around the catheter, in this state, the medication conduits are not "formed in an axial direction" (Feature 2a), and the hydration channels do not extend in the radial direction (Feature 5). It is not even clear whether the collapsed and compressed conduits and perforations can

"provide fluid communication" and "facilitate hydration" (Feature 5). Therefore, even when applying a protective sheath over the catheter of D3, the resulting device does not disclose Features 2a and 5 in the collapsed configuration of the balloon.

1.6.3 As set out above, a dilator "having a lumen formed in an axial direction therein" and a plurality of hydration channels extending radially outward from the lumen to the device are disclosed in D3 when the balloon is inflated. In this configuration, however, the additional protective sheath is pulled back and no longer forms a "device chamber" (Feature 3) in which the stent is disposed (Feature 4). Hence, also in the inflated state of the balloon, the system at which the skilled person would have arrived by applying the teaching of D7 to the catheter of D3 does not disclose all features of claim 1.

1.6.4 Accordingly, the subject-matter of claim 1 involves an inventive step in view of the combination of D3 with D7.

1.7 **Article 100(c) EPC**

Claim 7 specifies that "the intraluminal medical device comprises a dehydrated material". Paragraph [0073] of the application as filed discloses that the "device" may include "materials" that "can be hydrated" to achieve certain effects. The term "hydrate" is explained in paragraph [0046] very broadly as the exposure of a surface to an unspecific fluid or liquid. The term "dehydrated" used in claim 7 refers to the structural properties resulting from the inverse process of "dehydrating". However, that a material "can be hydrated" does not generally imply that it has

previously undergone a process of removal of fluid or liquid. Furthermore, the disclosure of materials that "can be hydrated" *to achieve specified effects* does not amount to a disclosure of *any* "dehydrated" material. Hence, the subject-matter of claim 7 extends beyond the content of the application as filed.

Claim 8 requires that the intraluminal device includes a "bioactive [agent] that can be released" from the device "upon hydration with a suitable fluid". Paragraph [0073] discloses additional features of the intraluminal medical device including "coatings and materials" that "can be hydrated to effect [...] release of a bioactive agent". Accordingly, paragraph [0073] discloses that the device may include a material that can release a bioactive agent upon hydration (with a suitable fluid). However, the subject-matter of claim 8 is more general in that it omits the restriction of the release *from a material* upon hydration *of the material* but refers to a bioactive (agent) that can be released by *any other mechanism* "upon hydration". The subject-matter of claim 8, therefore, contains an unallowable intermediate generalisation of the disclosure of paragraph [0073] which extends beyond the content of the application as filed.

Consequently, the ground for opposition under Article 100(c) EPC prejudices the maintenance of the patent as granted (main request).

2. **Auxiliary request 1**

Auxiliary request 1 differs from the main request in that dependent claims 7 and 8 are deleted rendering moot the corresponding objections against the main request.

Claim 1 of auxiliary request 1 is identical to claim 1 of the main request which was found to be novel and to involve an inventive step.

The parties concurred that no adaptation of the description was necessary.

Hence, it is concluded that the patent in amended form in the version according to auxiliary request 1 meets the requirements of the EPC.

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 in the following version:

   - claims 1 to 6 of auxiliary request 1, filed with the letter dated 7 August 2018
   - description (columns 1 to 18) of the patent as granted
   - drawings (Figures 1 to 31) of the patent as granted

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated