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Datasheet for the decision of 20 January 2022

Case Number: T 1138/18 - 3.2.08

Application Number: 09791656.3

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Language of the proceedings: EN

Title of invention:
INTRODUCER SHEATH WITH ENCAPSULATED REINFORCING MEMBER

Patent Proprietor:
Cook Medical Technologies LLC

Opponent:
Boston Scientific Corporation

Headword:

Relevant legal provisions:
EPC Art. 84, 52(1), 54, 56
RPBA Art. 12(4), 12(2)

Keyword:

Main request - clarity (no)
Auxiliary requests 1 to 5 - clarity (no)
Auxiliary request 6 - product-by-process features sufficiently substantiated (no) - admitted (no)
Auxiliary requests 7 to 9 - novelty (no)
Auxiliary request 10 - novelty (yes) - inventive step (yes)

Decisions cited:

G 0003/14

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Case Number: T 1138/18 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 20 January 2022

Appellant: (Patent Proprietor)	Cook Medical Technologies LLC 750 North Daniels Way Bloomington, IN 47404 (US)
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Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 19 March 2018 concerning maintenance of the European Patent No. 2352540 in amended form.**

Composition of the Board:

Chairman	C. Schmidt
Members:	M. Olapinski
	C. Vetter

Summary of Facts and Submissions

I. The appeal was filed by both parties against the opposition division's decision to maintain the patent in amended form according to auxiliary request 2 then on file.

II. Oral proceedings by videoconference took place before the Board on 20 January 2022.

III. Appellant 1 (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or auxiliary requests 1 to 12. The valid versions of these requests were filed on the following dates:

- main request and auxiliary requests 1 to 6: letter setting out the grounds of appeal dated 30 July 2018
- auxiliary requests 7 and 8: letter dated 20 December 2021
- auxiliary requests 9 to 12: letter dated 13 December 2018

IV. Appellant 2 (opponent) requested that the decision under appeal be set aside and that the patent be revoked in its entirety. It further requested that auxiliary requests 1 to 6 and 8 to 12 not be admitted into the proceedings.

V. Claim 1 of the main request reads (feature denominations added by the Board):

"(**A1**) An introducer sheath comprising:

(**A2**) a liner having a passageway extending longitudinally therethrough, said liner having an outer surface;
(**A3**) an inner jacket positioned longitudinally over said liner, said inner jacket having an inner surface and an outer surface, said inner surface engaged with said outer surface of said liner;
(**A4**) a reinforcing member,
(**A5**) an outer jacket positioned longitudinally over said inner jacket, said outer jacket having an inner surface bonded to said outer surface of said inner jacket;
(**A6**) wherein said reinforcing member is encapsulated in said inner jacket and said outer jacket; and
(**A7**) wherein the inner jacket and outer jacket have been at least partially melted and have thereby flowed into each other, so as to form a secure bond therebetween."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request by "engaged with" in Feature A3 being replaced with "bonded to".

Claim 1 of auxiliary request 2 differs from claim 1 of the main request by the additional feature: "wherein said outer surface of said inner liner is roughened, and said inner jacket is bonded to said roughened outer surface".

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 2 by the additional feature: "wherein said inner jacket and outer jacket comprise at least one of a polyether block amide, nylon, and polyurethane".

Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 3 by further specifying that "said liner comprises a lubricious fluoropolymer".

Claim 1 of auxiliary request 5 differs from claim 1 of auxiliary request 2 by the additional feature: "wherein said inner jacket has a wall thickness between 0.0025 and 0.025 mm (0.0001 and 0.001 inch)."

Claim 1 of auxiliary request 6 differs from claim 1 of the main request by Feature A7 being deleted and instead specifying:
"wherein the introducer sheath is obtainable by a method comprising:
providing said liner;
applying a solution comprising a polymer dissolved in a solvent to said outer surface of said liner;
evaporating the solvent, leaving a layer of the polymer on the outer surface of the liner, said layer comprising an inner polymer layer;
positioning the reinforcing member around the inner polymer layer;
applying an outer polymer layer over the reinforcing member; and
exposing an assembly comprising a mandrel and said liner, inner polymer layer, reinforcing member and outer polymer layer to sufficient heat to at least partially melt the inner polymer layer and outer polymer layer such that a bond is formed therebetween, and such that said inner polymer layer is bonded to said liner outer surface, said reinforcing member being encapsulated within said inner and outer polymer layers."

VI. Auxiliary request 7 corresponds to the request deemed allowable in the decision under appeal. It differs from

the main request by the apparatus claims being deleted. Claim 1 of auxiliary request 7 reads (feature denominations added by the Board):

"(**M1**) A method for forming an introducer sheath, comprising:
(**M2**) providing an inner liner, said inner liner having a passageway extending therethrough, and having an outer surface;
(**M3a**) applying a solution comprising a polymer dissolved in a solvent to said outer surface of said inner liner;
(**M3b**) evaporating the solvent, leaving a layer of the polymer on the outer surface of the inner liner, said layer comprising an inner polymer layer;
(**M4**) positioning a reinforcing member around the inner polymer layer;
(**M5**) applying an outer polymer layer over the reinforcing member; and
(**M6**) exposing an assembly comprising the mandrel, inner polymer layer, reinforcing member and outer polymer layer to sufficient heat to at least partially melt the inner polymer layer and outer polymer layer
(**M6a**) such that a bond is formed therebetween, and
(**M6b**) such that said inner polymer layer is bonded to said liner outer surface,
(**M6c**) said reinforcing member being encapsulated within said inner and outer polymer layers."

Claim 1 of auxiliary request 8 adds to Feature M2 of claim 1 of auxiliary request 7 that the outer surface of the inner liner is "roughened".

Claim 1 of auxiliary request 9 differs from claim 1 of auxiliary request 8 by the additional feature
"(**M7**) wherein each of said inner and outer polymer

layers comprises at least one of a polyether block amide, nylon, and polyurethane".

Claim 1 of auxiliary request 10 differs from claim 1 of auxiliary request 9 by specifying, in place of the addition of "roughened" to Feature M2, the following additional feature inserted before Feature M7:
"(**M8**) wherein said liner comprises a lubricious fluoropolymer having a roughened outer surface, and said inner polymer layer bonds with said roughened outer surface upon said exposure to heat; and".

VII. Appellant 2's arguments relevant for the present decision can be summarised as follows.

Main request

The subject-matter of claim 1 was not clear because of a contradiction between Features A5 and A7. Feature A5 specified an outer jacket "having an inner surface bonded to said outer surface of said inner jacket". Feature A7 required that the two jackets had been at least partially melted and thus "flowed into each other" to form a secure bond between them. This implied a dissolution of the boundary surfaces between the jackets. Feature A7 included the case of *completely* melting and flowing into each other. Claim 1 thus included embodiments in which - contrary to Feature A5 - no boundary surface between the jackets remained in the product resulting from Feature A7.

Auxiliary requests 1 to 5

Claim 1 of auxiliary requests 1 to 5 also contained the contradictory Features A5 and A7. Thus, the subject-matter of these requests was also not clear.

Auxiliary request 6

Auxiliary request 6 could and should have been filed during the first-instance proceedings and should thus not be admitted into the appeal proceedings.

Furthermore, auxiliary request 6 was not properly substantiated. Appellant 1 did not substantiate why the claimed product could not have been defined by structural features instead of product-by-process features. Nor did it substantiate the structural implications of the new product-by-process features. Moreover, claim 1 of auxiliary request 6 *prima facie* suffered from the same contradiction and lack of clarity as the main request and was divergent with respect to the higher-ranking requests. Hence, auxiliary request 6 should not be taken into account by the Board.

Auxiliary request 7

Claim 1 of auxiliary request 7 was not new in view of D8.

Column 7, lines 3 to 22 disclosed the application of an impregnating polymer layer from a polymer solution onto a liner. In view of the high porosity of the liner material in D8, the pores and the impregnating polymer covered most of the liner's outer surface. Claim 1 did not require a particular structure or quality of the inner polymer "layer". Hence, the impregnating polymer of D8 also qualified as a "layer", even if it was not smooth, complete or continuous. D8 thus disclosed Features M3a and M3b.

When fusing the outer polymer layer to the inner polymer layer locked in the pores of the liner, the interjacent reinforcing member became encapsulated within the inner and outer polymer layers (Feature M6c). According to granted claim 7 and paragraph [0035] of the patent, claim 1 did not require a "complete" encapsulation.

Hence, D8 disclosed all the features of claim 1, even if the inner polymer layer was not complete or continuous.

Auxiliary request 8

D8 disclosed expanded ultra-high molecular weight polyethylene ("UHMWPE") as a liner material which had a "roughened" outer surface due to its fabrication process. Hence, the subject-matter of claim 1 of auxiliary request 8 was also not new.

Auxiliary request 9

The material choice of Feature M7 was known from column 7, lines 8 to 10 of D8. Accordingly, the subject-matter of claim 1 of auxiliary request 9 was also not new.

Auxiliary request 10

Auxiliary request 10 should not be admitted because it could and should have been filed during first-instance proceedings and it diverged from the preceding requests.

Claim 1 differed from that of auxiliary request 9 in that the liner comprised a lubricious fluoropolymer. D8 disclosed PTFE (polytetrafluoroethylene) as a common

liner material (column 2, lines 18 to 25). Hence, claim 1 was not novel.

Claim 1 was at least not inventive in view of D8. As there was no technical benefit of PTFE in view of D8, the problem was merely to define an alternative liner material. The solution was obvious because PTFE was most commonly used as liner.

Claim 1 was also not inventive in view of D7, which disclosed a three-layered sheath. Its innermost layer could be considered an inner liner, in which case the skilled person would have added the inner polymer layer from D8 or any of D3 to D6 to improve the bonding. If, alternatively, the innermost layer from D7 was considered to represent the inner polymer layer from claim 1, the provision of an additional inner liner was commonly known and suggested by each of D3 to D6.

VIII. Appellant 1 argued essentially as follows.

Main request

Claim 1 did not express that the surfaces between the inner and outer jackets had dissolved. Feature A7 merely required that the jackets had been "partially melted". The bond between the jackets did not necessarily involve the entirety of their boundary surfaces. For example, Feature A7 encompassed localised spot welds, leaving the remaining surfaces between the jackets unchanged. This was a reasonable interpretation of Feature A7 that was not contradictory with Feature A5. In contrast, embodiments leading to contradictions would be ruled out as illogical by the skilled person. The subject-matter of claim 1 was thus clear.

Auxiliary requests 1 to 5

Claim 1 of auxiliary requests 1 to 5 was clear for the same reasons as set out for the main request.

Auxiliary request 6

Claim 1 of auxiliary request 6 was filed in response to objections raised only at the first-instance oral proceedings and reasoned in the decision under appeal. It could thus not have been filed earlier.

Auxiliary request 6 did not create a fresh case but aimed at essentially the same subject-matter as the previous requests and merely combined the subject-matter of the granted independent claims. Hence, there was no divergence with respect to the main request. However, by avoiding the wording "flowed into each other" of Feature A7 that was seen as contradictory to Feature A5, claim 1 of auxiliary request 6 was clear.

Claim 1 specified the inner polymer layer applied by solution casting, which was impossible to define in structural terms alone. Hence, the product of claim 1 could not have been defined other than in terms of a process of its manufacture.

Accordingly, auxiliary request 6 represented a genuine attempt to overcome the objections raised against the main request and should be admitted into the proceedings.

Auxiliary request 7

D8 disclosed that the polymer applied by solution casting was impregnated "into" the liner and remained

mechanically locked "within" the pores. Hence, the polymer was not applied on the liner's "outer" surface. Nor did D8 disclose that the impregnating polymer formed a "layer". This term was generally understood to relate to a complete, continuous film of appreciable thickness. This also derived from the context of the patent. It required that the inner polymer layer "shields or otherwise covers" the liner (paragraph [0019]) and that it not be "too thin to accomplish the objectives of the invention" (paragraph [0028]). The impregnated polymer from D8 did not fulfil these requirements. Hence, D8 did not disclose the formation of an inner polymer layer as required by Feature M3b. As a consequence, D8 did also not disclose a reinforcing member encapsulated within the inner and outer polymer layers as required by Feature M6c.

Auxiliary request 8

D8 disclosed an inherently rough liner material but not that its outer surface was "roughened", i.e. made by a process of roughening. Hence, claim 1 was novel.

Auxiliary request 9

As D8 did not disclose an inner polymer layer at all, claim 1 of auxiliary request 9 was novel.

Auxiliary request 10

Auxiliary request 10 was filed in response to the new objections against auxiliary request 7 in view of D8 raised by appellant 2 in its grounds of appeal. It was convergent with respect to auxiliary request 7 and its subsequent requests. Auxiliary request 10 should thus be admitted.

D8 mentioned a conventional PTFE liner only in its discussion of the prior art, whereas the liner according to its invention was made from expanded UHMWPE. The subject-matter of claim 1 was thus novel.

It differed from D8 in that the liner comprised a lubricious fluoropolymer having a roughened outer surface. D8 taught away from PTFE and described the solution casting of the inner polymer layer only in conjunction with microporous expanded UHMWPE. It would thus not have been obvious for the skilled person starting from D8 to arrive at the subject-matter of claim 1.

It would also not have been obvious to arrive at claim 1 when starting from D7.

If the innermost layer represented an inner liner, claim 1 differed at least by the solution casting of an additional inner polymer layer. D8 disclosed this only in combination with a liner made from expanded UHMWPE, which led away from claim 1. D3 to D6 did not disclose solution casting of an intermediate polymer layer onto the outer surface of an inner liner.

If the innermost layer was considered to represent an "inner polymer layer", claim 1 differed at least by providing an inner liner on which the inner polymer layer was applied. However, D7 was directed to providing an inner lumen with a coating layer (paragraph [0003]), which could provide a lubricious inner surface (paragraph [0020]). Hence, D7 hinted at making the innermost layer 12 from PTFE (paragraph [0023]). In contrast, solution casting of layer 12 as an intermediate layer onto an additional inner liner

would go against the teaching of D7 and was not hinted at by D3 to D6, either.

Accordingly, the skilled person would not have been led to the subject-matter of claim 1 in an obvious manner when starting from D7.

Reasons for the Decision

1. Main request - Article 84 EPC

The subject-matter of claim 1 is not clear because of a contradiction between Features A5 and A7.

Claim 1 defines an introducer sheath comprising a liner, an inner jacket, a reinforcing member and an outer jacket. Feature A3 defines an inner jacket having "an outer surface". According to Feature A5, the outer jacket has "an inner surface bonded to said outer surface of said inner jacket". Accordingly, claim 1 requires a bond between recognisable opposing boundary surfaces of the inner and outer jackets.

Product-by-process Feature A7 specifies that "the inner jacket and outer jacket have been at least partially melted and have thereby flowed into each other, so as to form a secure bond therebetween". The formation of such a bond by melting and "flowing into each other" involves diffusion of molecules of the compositions of both jackets across their boundary surfaces and, hence, the dissolution of these surfaces at the location of bonding.

In the case of *complete* melting, which is encompassed by Feature A7, the jackets have "flowed into each other" at every location where they have come into

contact during heat bonding, and no recognisable boundary surfaces are left between them. Accordingly, claim 1 encompasses a product obtained from the product-by-process Feature A7 that contradicts Feature A5.

Appellant 1 argued that Feature A7 only required *partial* melting. It thus encompassed "spot welds" that did not necessarily occupy the entirety of the boundary surfaces between both jackets. In that case, recognisable surfaces between the jackets remained, and no contradiction between Features A5 and A7 arose. Hence, a non-contradictory understanding of claim 1 was available, and the skilled person would rule out the embodiments that led to a contradiction.

However, by emphasising that the jackets must have been "at least" *partially* melted, Feature A7 expressly includes the case that the jackets have been *more than* "partially" melted, that is, *completely* melted. In fact, bonding across the entire available contact surface is particularly preferable in view of the patent's objective to provide secure bonding (e.g. paragraphs [0021], [0023] and [0034]). It is thus not a meaningless or illogical interpretation which the skilled person would rule out. As an expressly emphasised and particularly meaningful embodiment of Feature A7, the option of completely melting and flowing into each other cannot be disregarded.

Accordingly, the product-by-process Feature A7 covers embodiments that are contradictory to the structural properties required by Feature A5. Hence, the subject-matter of claim 1 of the main request is unclear and thus does not fulfil the requirements of Article 84 EPC.

2. Auxiliary requests 1 to 5 - Article 84 EPC

Claim 1 of each of auxiliary requests 1 to 5 also comprises the contradictory Features A5 and A7. The additional limitations of these requests are not related to and have no impact on the contradictory subject-matter. Hence, auxiliary requests 1 to 5 also do not fulfil the requirements of Article 84 EPC for the same reasons as set out for the main request.

3. Auxiliary request 6 - Admittance

3.1 According to the main clause of Article 12(4) RPBA 2007, the parties' submissions filed with the notice or statement of grounds of appeal or replies under Article 12(1) RPBA 2007 are only taken into account if and to the extent that they meet the requirements of a complete, clear, concise and express substantiation of their case as set out in Article 12(2) RPBA 2007.

3.2 Auxiliary request 6 - filed by appellant 1 for the first time together with its statement of grounds of appeal - combines the subject-matter of two previously independent claims. Claim 1 of this request specifies the apparatus of granted claim 1 as being "obtainable" by the steps of granted method claim 8. Claim 1 of auxiliary request 6 thus differs from claim 1 of the main request by replacing Feature A7 with product-by-process features corresponding to all the steps of method claim 8. The complexity of this amendment requires at least a detailed substantiation as to why it was not possible to define the claimed product other than in terms of product-by-process features (Case Law of the Boards of Appeal, 9th edition, 2019, II.A.7.1 and 7.3).

3.3 In its grounds of appeal, appellant 1 did not provide any substantiation in this respect. This was objected to by appellant 2 in its written reply of 29 November 2018. Appellant 1 did not react to this objection until the oral proceedings. There, it stated that the solution casting of the inner polymer layer could only be expressed by reference to the process of its formation.

Irrespective of the lateness and persuasiveness of this submission, it could at best justify only the product-by-process features corresponding to steps M2 to M3b of the method (see the feature denominations of auxiliary request 7).

Hence, appellant 1 did not provide the necessary substantiation for admitting the product-by-process claims 1 of point i) above. For this reason, auxiliary request 6 cannot be taken into account.

3.4 Apart from this, in the case at hand, it is of particular relevance whether and to what extent the product-by-process features corresponding to steps M6, M6a and M6c (see the feature denominations of auxiliary request 7) differ from Feature A7 of the main request, which they replace.

Appellant 2 submitted in its reply of 29 November 2018 that claim 1 of auxiliary request 6 should not be admitted because it *prima facie* lacked clarity and was not convergent with the higher-ranking requests. The lack of clarity was due to the same contradiction as between Features A5 and A7 in the main request. This assumes that the features replacing Feature A7 in auxiliary request 6, in spite of their different

wording, still imply that the jackets have "flowed into each other". If, on the other hand, there was a difference in content, this would have a bearing on the question of lack of convergence.

These issues were endorsed in the Board's preliminary opinion set out in a communication under Article 15(1) RPBA 2020, in particular since G3/14 was not considered to exclude an objection of lack of clarity in the current case.

Appellant 1 only reacted to these objections in its letter of 20 December 2021, after notification of the summons. It submitted that auxiliary request 6 did not create a fresh case nor fundamentally change the character of the claimed apparatus compared to the first-instance proceedings. Hence, there was no divergence of auxiliary request 6 from the main request. It could have been inferred from these statements that there was no appreciable difference between the subject-matter of Feature A7 and the corresponding product-by-process features in claim 1 of auxiliary request 6, in which case, *prima facie*, the same lack of clarity as set out against the main request arose.

At the oral proceedings, however, appellant 1 argued that auxiliary request 6 was to be understood as a reaction to the objection of the lack of clarity against the main request by avoiding the wording "flowed into each other". If this was understood as a substantive change of subject-matter to overcome the clarity objection against the main request, it would mean that auxiliary request 6 indeed diverges from the subject-matter of the main request.

Accordingly, depending on whether and which of the late submissions of appellant 1 are taken into account and agreed with, additional reasons for not admitting auxiliary request 6 are evident either in the initial failure to properly substantiate the meaning and purpose of the product-by-process features in the statement of grounds of appeal, in the *prima facie* lack of clarity of the subject-matter of claim 1 or in the divergence of auxiliary request 6 from the main request.

3.5 In summary, auxiliary request 6 is not taken into account pursuant to Article 12(4) RPBA 2007.

4. Auxiliary request 7 - Novelty, D8

4.1 D8 undisputedly discloses a method for forming an introducer sheet which comprises the steps of providing an inner liner (Features **M1** and **M2**), providing a reinforcing structure between the inner liner and an outer polymer jacket, bonding the inner liner to the outer polymer jacket, and fusing the reinforcing structure between them (claim 16 and Figure 1).

4.2 In column 7, lines 3 to 22, D8 discloses optionally "impregnating" the inner liner with a polymer compatible with the outer jacket material (lines 3 to 8) prior to fusion bonding. This process comprises the steps of applying a solution comprising a polymer dissolved in a solvent (for example, PEBAX® in THF, lines 8 to 11) to the outer surface of the inner liner (for example, by "brushing the solution on the outer surface", lines 14 to 15) and subsequently evaporating the solvent (lines 15 to 17). After evaporation, the polymer "remains mechanically locked within the porous structure of the inner liner" (lines 17 to 19). During

the following bonding step, the polymer of the outer jacket "fuses to the compatible impregnated polymer" in the inner liner, "thus securing the inner liner and polymeric outer jacket together" (lines 19 to 22).

4.3 The inner liner in D8 is formed from expanded ultra-high molecular weight polyethylene ("UHMWPE"): a microporous material that has a node and fibril microstructure and a porosity of about 20% to about 90% (column 2, lines 56 to 66 and claims 1, 2 and 6). Porosity is defined as the percentage of void space in a material. Although it applies to volume, not surface, at 90% porosity, most of the liner's surface is also occupied by pores. The pores on the surface are open to the outside so that their "inner" surface also forms part of the "outer surface" of the inner liner. Impregnating these pores with polymer thus results in considerable coverage of the outer surface of the inner liner with impregnating polymer. In the Board's view, this can be considered an inner polymer "layer" according to claim 1.

4.4 Appellant 1 submitted that the term "layer" was to be understood as a complete, continuous film of appreciable thickness. The patent specification disclosed a protective function of the inner polymer layer of shielding or covering the liner (paragraph [0019]) which required a certain quality and thickness (paragraph [0028]).

4.5 With respect to appellant 1's reference to the patent specification, the Board notes that, for the purpose of assessing novelty and inventive step, it is not

permissible to read additional limitations into a claim which are only derivable from the description but not included in the claim (Case Law, 9th edition, 2019, II.A.6.3.4).

Claim 1 of auxiliary request 7 does not explicitly specify a particular quality, completeness or thickness of the inner polymer layer. Such properties can also not be implicitly inferred from claim 1 owing to the fact that it does not specify the materials for the liner, the inner polymer layer or the solvent; the surface quality of the inner liner; or the technique for the application of the solution or the evaporation of the solvent.

4.6 Other than submitted by appellant 1, the context and overall teaching of the patent also does not suggest or require that the skilled person adopt a more restrictive understanding of the term "layer" in terms of a particular quality, thickness or completeness that would distinguish the subject-matter of claim 1 from that of D8.

On the contrary, the patent discloses that the liner be preferably "roughened in any conventional manner" to facilitate bonding (paragraph [0020]) and that the polymer must fill the cavities thus obtained (paragraph [0028]). Hence, the layer need not be even or have homogeneous thickness. Moreover, paragraph [0035] de-emphasises the function of shielding and covering of paragraph [0019] by defining that a "minor amount of contact between the coil and the lubricious layer", i.e. a certain number of defects in the inner polymer layer, was "permissible". A "complete" encapsulation of the reinforcing member was thus not required.

Accordingly, the patent itself considers that the inner polymer "layer" is not necessarily smooth or continuous.

Also with respect to thickness, the patent does not provide definitive information on which thicknesses are envisaged (see paragraph [0030], last sentence). This is quite similar to D8, in which the impregnated polymer layer must be thick enough to provide sufficient basis for fusing with the outer polymer jacket. Hence, no specific difference in thickness between the layer according to the patent and the layer of D8 can be established.

4.7 It must thus be concluded that the requirements on the inner polymer "layer" of claim 1 do not go beyond what is disclosed in D8. Hence, D8 discloses the manufacturing steps **M3a** and **M3b**.

4.8 It was undisputed that, with the additional impregnated inner polymer layer, D8 also discloses Features **M4 to M6b**.

4.9 During the heat shrinking and fusion bonding step in D8, the polymeric "outer jacket material flows through the spaces in the [...] reinforcing structure" and "fuses to" the impregnated polymer layer (column 6, lines 56 to 63 and column 7, lines 19 to 22). The molten polymer thus fills voids in the inner polymer layer and flows underneath the reinforcing member. Hence, after the heat bonding step, the reinforcing member is *largely* encapsulated within the inner and outer polymer layers.

As the inner polymer layer in D8 is not necessarily a closed layer, a small amount of contact between the

rough inner liner and the reinforcing structure may persist. The reinforcing member is thus not necessarily "completely" encapsulated.

However, as correctly pointed out by appellant 2 in its letter of 5 January 2022, Feature M6c does not require a "complete" encapsulation, especially in view of granted claim 7, which explicitly specifies "completely encapsulated", and in view of paragraph [0035], according to which a "minor amount of contact" between the reinforcing structure and the liner was "permissible".

With this understanding, the reinforcing member of D8 is "encapsulated within the inner and outer polymer layers" after heat fusing as required by Feature **M6c**.

4.10 Accordingly, D8 discloses all the features of claim 1 of auxiliary request 7. Hence, the subject-matter of claim 1 does not fulfil the requirement of novelty of Articles 52(1) and 54 EPC.

5. Auxiliary request 8 - Novelty, D8

Claim 1 of auxiliary request 8 differs from claim 1 of auxiliary request 7 by further specifying that the liner has a "roughened" outer surface. Irrespective of whether this term refers to a product-by-process feature (i.e. that the surface has been made rough by an unspecific process of roughening) or merely to the property of being rough, it is also known from D8. The "expanded" UHMWPE from D8 is "roughened" due to the process of expanding UHMWPE.

Hence, the subject-matter of claim 1 of auxiliary request 8 is not novel over D8.

6. Auxiliary request 9 - Novelty, D8

D8 discloses that the inner and outer polymer layers (the polymeric outer jacket and the impregnating polymer) can both be formed of polyether block amide (PEBAX®, column 7, lines 8 to 10). Accordingly, D8 also discloses the additional feature **M7** of claim 1 of auxiliary request 9, the subject-matter of which is thus not novel.

7. Auxiliary request 10

7.1 Admittance

In its grounds of appeal, appellant 2 raised for the first time an objection of lack of novelty against auxiliary request 7 in view of new facts identified in D8. Auxiliary request 10 was filed with the reply to appellant 2's grounds of appeal. As submitted by appellant 1, it thus represents a timely response to this change of subject with respect to the opposition proceedings. Furthermore, claim 1 of auxiliary request 10 is part of a convergent development of successively further limited requests from auxiliary request 7 onwards. Therefore, auxiliary request 10 is admitted into the appeal proceedings.

7.2 Novelty, D8

Claim 1 of auxiliary request 10 differs from claim 1 of auxiliary request 9 by specifying that the inner liner "comprises a lubricious fluoropolymer" having a roughened outer surface (Feature **M8**).

D8 mentions conventional PTFE (polytetrafluoroethylene) liners with chemically etched surfaces (i.e. with a roughened outer surface) and the disadvantages to these in its background section. According to the invention of D8, however, expanded UHMWPE, which is not a fluoropolymer, is used for the liner.

Hence, the embodiments disclosed in D8 do not disclose all the features of claim 1 of auxiliary request 10 in combination. The subject-matter of claim 1 thus fulfils the requirement of novelty in accordance with Articles 52(1) and 54 EPC.

7.3 Inventive step starting from D8

Appellant 2 submitted that the only difference between the subject-matter of claim 1 and the method of D8 resided in the lubricious fluoropolymer material of the liner. In view of the disadvantages of this material disclosed in D8, no technical effect could be established for the different material choice, so that the objective technical problem to be solved was merely the provision of an alternative liner material.

As lubricious fluoropolymers were the most common materials for liners as disclosed in several prior-art documents as well as paragraph [0020] of the patent, no inventive step could be seen in the subject-matter of claim 1.

However, by emphasising the disadvantages of conventional PTFE liners, D8 teaches away from using a lubricious fluoropolymer for the liner. In addition, the invention D8 discloses specifically and exclusively applies to expanded UHMWPE and its microporous structure. Therefore, it would not have been obvious

for the skilled person to apply the method of D8 to another liner material, and in particular not to a commonly used lubricious fluoropolymer liner. The skilled person would thus not have arrived at the subject-matter of claim 1 in an obvious manner.

The subject-matter of claim 1 thus involves an inventive step within the meaning of Articles 52(1) and 56 EPC in view of D8.

7.4 Inventive step starting from D7

D7 discloses a method for forming an introducer sheath (catheter, Figure 6) with three layers:
- an "inner polymer layer member" (12) formed by applying a polymer solution onto a mandrel and subsequent evaporation of the solvent (paragraphs [0012] and [0020] to [0028])
- a reinforcing member (14, paragraph [0029])
- a polymeric "outer tubular member" (16, paragraph [0037])

7.4.1 If the innermost layer 12 from D7 is considered to represent a liner according to Feature M2, claim 1 differs from the method of D7 at least by solution casting of an additional inner polymer layer according to steps **M3a** and **M3b**.

According to appellant 2, the skilled person would have added an inner polymer layer as disclosed in D8 or any of D3 to D6 to improve the bonding.

However, D3 to D6 do not disclose formation of an inner polymer layer by applying a polymer solution onto an inner liner as reasoned in the decision under appeal.

This finding, and its repetition in the Board's communication, was not challenged by appellant 2.

D8 discloses solution casting of an inner polymer layer. However, this technique is only disclosed in conjunction with a liner from expanded UHMWPE and could thus not have led the skilled person to the subject-matter of claim 1 requiring a fluoropolymer liner (Feature M8).

7.4.2 If, alternatively, the innermost layer 12 from D7 is considered to equate to the "inner polymer layer", the subject-matter of claim 1 differs at least by providing an inner liner from a lubricious fluoropolymer (Features **M2** and **M8**) on which layer 12 is to be applied.

The objective technical problem solved by these features is "to ease insertion and/or withdrawal" of instruments through the passageway (paragraph [0020] of the patent).

Appellant 2 submitted that it would have been obvious for the skilled person to add an inner liner made from PTFE because four-layer structures and PTFE liners were well known, e.g. from D3 to D6.

However, the invention of D7 resides in a method for making a catheter having a "polymer coated inner lumen" (paragraph [0003]). This is achieved by solution casting of layer 12 directly onto a mandrel as the sheath's innermost functional layer (paragraphs [0012] and [0020] to [0028] and claim 1). D7 discloses making the layer "of polymer that has the desired characteristics for use as the inner lumen", for example "a low coefficient of friction" (paragraph

[0020]), such as PTFE (paragraph [0023]). Hence, the skilled person would have solved the objective technical problem by making the inner polymer layer 12 from PTFE as proposed in D7.

In contrast, providing a separate inner liner would go against the teaching of D7, and D3 to D6 do not suggest the solution casting of an intermediate polymer layer onto a separate liner, either. Hence, the skilled person would not have arrived at a step of providing a separate inner liner according to Feature M2 in an obvious manner.

7.4.3 Accordingly, the subject-matter of claim 1 involves an inventive step over D7 within the meaning of Articles 52(1) and 56 EPC.

7.5 Adapted description

The Board is satisfied that the amended description filed during the oral proceedings fulfils the requirements of the EPC. Appellant 2 had no objections.

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 a patent in the following version:

   - Claims 1 to 5 of auxiliary request 10 filed with the letter dated 13 December 2018
   - Description: columns 1 to 5 as filed during the oral proceedings before the Board and columns 6 to 9 of the patent as granted
   - Figures 1 to 3 of the patent as granted

The Registrar: The Chairman:

S. Lichtenvort C. Schmidt

Decision electronically authenticated