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Datasheet for the decision of 25 September 2020

Case Number: T 0950/16 - 3.2.08

Application Number: 09820051.2

Publication Number: 2340075

IPC: A61M25/088, A61M25/04, A61F2/24

Language of the proceedings: EN

Title of invention:
MEDICAL DEVICES AND DELIVERY SYSTEMS FOR DELIVERING MEDICAL DEVICES

Patent Proprietor:
Boston Scientific Scimed Inc.

Opponent:
Stolmár, Matthias

Headword:

Relevant legal provisions:
EPC Art. 100(a), 52(1), 54, 56
RPBA 2020 Art. 25(3)
RPBA Art. 13(3)

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Keyword:
Novelty - (yes)
Inventive step - (yes)
Late-filed documents - amendments after arrangement of oral proceedings - justification for late filing (no) - admitted (no)

Decisions cited:

Catchword:
see reasons 3.2

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Case Number: T 0950/16 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 25 September 2020

Appellant: (Opponent)	Stolmár, Matthias Blumenstrasse 17 80331 München (DE)
Representative:	Trinks, Ole Meissner Bolte Patentanwälte Rechtsanwälte Partnerschaft mbB Postfach 10 26 05 86016 Augsburg (DE)
Respondent: (Patent Proprietor)	Boston Scientific Scimed Inc. One Scimed Place Maple Grove, Minnesota 55311 (US)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 February 2016 rejecting the opposition filed against European patent No. 2340075 pursuant to Article 101(2) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The opponent (appellant) filed an appeal against the decision of the opposition division to reject the opposition.

II. Oral proceedings took place before the Board on 25 September 2020.

III. At the end of the oral proceedings, the relevant requests were as follows.

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked. It further requested that the following documents be admitted into the proceedings:

E1: US 2007/0112358 A1
E2: US 2006/0173524 A1
E3: US 2007/0255390 A1
E4: US 2006/0229700 A1
E5: US 4 665 918
E6: US 5 571 135

submitted by letter dated 24 August 2020, or at least that document E2 be admitted into the proceedings.

The respondent (patent proprietor) requested that the appeal be dismissed. It further requested that documents E1-E6 not be admitted into the proceedings.

IV. Independent claim 1 of the patent as granted reads (with the feature designations used by the parties):

"(M1.1) A medical device system, including:

(M1.2) a delivery system (370, 600) comprising a housing (452, 620) disposed external to a subject,

(M1.3) wherein the housing (452, 620) comprises an actuator (372, 456, 624),

characterized in that

(M1.4) the delivery system (370, 600) is configured and arranged such that the actuator (372, 456, 624) is adapted to move a first delivery system component independently of a second delivery system component,

(M1.5) and wherein the delivery system (370, 600) is further configured and arranged such that the actuator (372, 456, 624) is also adapted to move the second delivery system component independently of the first delivery system component."

V. The following additional document is relevant for the decision:

D14: US 2003/0191516 A1

VI. The appellant argued essentially as follows.

(a) Novelty

Document D14 disclosed the preamble of claim 1.

Figure 5 disclosed a "clutch mechanism" able to disengage one (claim 49) or both (paragraph [0053]) pinions (38, 39) from their respective racks (34, 36). Depending on which pinion was engaged, the actuator

(dial 48 or crank 49, Figures 3A and 3B) was adapted to move either of the components independently of the other as required by features M1.4 and M1.5.

Moreover, Figure 6 disclosed a "lag system" in which a portion 602 of rack 634 was without teeth so that pinion 38 was not engaged and both components could be moved independently of each other in the same way as features M1.4 and M1.5.

Finally, a combination of the clutch mechanism and the lag system was disclosed as well since D14 generally taught the application of the invention to different types of implants (paragraph [0050]) requiring different combinations of movements.

(b) Inventive step

D14 was not limited to the specific embodiments shown in the figures. It related generally to mechanisms for the deployment of different implants (paragraph [0050]) and concepts of decoupling the movement of delivery system components (paragraphs [0015] and [0019]), which the skilled person would have applied, modified and combined as desired to adapt the delivery system of D14 to different implants. If a further independent movement of a component was needed for the delivery scheme of a specific implant, it would have been obvious for the skilled person to add a second portion without teeth on rack 36 of the lag mechanism of Figure 6 to arrive at a delivery system having feature M1.5 as well.

(c) Admittance of documents E1-E6

Documents E1-E6 were identified from the opposition proceedings against EP 3 238 661, a family member of the patent under appeal, only after change of representation in this case. The documents should be admitted due to their *prima facie* high relevance for novelty of the patent as apparent just from the figures.

For example, Figure 12 of E2 showed a rotary actuator (1206) connected to a drum with two guide grooves (1212, 1214) for conveying movement to distal components. As both grooves exhibited sections of zero pitch at different positions, the actuator was adapted to move each component while the other component remained stationary.

As claim 1 was not complex, and E1-E6 and their content were known to the proprietor, no postponement of the oral proceedings was to be expected.

VII. The respondent argued essentially as follows.

(a) Novelty

While D14 admittedly disclosed the preamble of claim 1, it did not disclose features M1.4 and M1.5.

As disclosed in [0053] and claim 49, in the clutch mechanism of Figure 5, both pinions were pushed out of engagement. In this state, the components could not be moved independently of each other by the same actuator as required by feature M1.5.

Likewise, in the disengaged state shown in the embodiment of Figure 6, none of the actuators (dial 48 or crank 49, Figure 3A or 3B; slide 46 or handle 122, Figure 2B) could move both components mutually independently as required by feature M1.5.

Finally, a combination of the mechanisms of Figures 5 and 6 was neither disclosed in D14, nor would such a combination reveal features M1.4 and M1.5.

(b) Inventive step

Feature M1.5 required that the same actuator be adapted to move both components independently of each other. Using the same actuator for a sequence of steps simplified the deployment procedure as stated in paragraph [0004] of the patent.

D14 neither related to simplifying the actuation of the deployment procedure; nor did it disclose the solution of using the same actuator for moving different components independently of each other.

The skilled person would have found no specific prompt for adding a second lag mechanism to rack 36 in Figure 6 of D14. However, even if a second portion free of teeth were foreseen on rack 36 in the embodiment of Figure 6, a further actuator would have been necessary for moving the pusher independently of the sheath, contrary to the requirements of feature M1.5.

(c) Admittance of documents E1-E6

The degree of lateness of the submission of E1-E6 only on 24 August 2020 could not be explained by the change of representative in May 2020 and the appearance of the

documents in the opposition against EP 3 238 661 in February 2020. Furthermore, E5 and E6 were not even cited in this opposition case.

Moreover, E1-E6 were not *prima facie* relevant, certainly not just from the figures. For example, the grooves shown in Figure 12 of E2 implied a synchronised, and hence not independent, movement of both components (paragraph [0051]).

Reasons for the Decision

1. Novelty

1.1 Document D14 undisputedly discloses:

(M1.1) A medical device system, including:

(M1.2) a delivery system (for endoluminal devices, paragraph [0001]) comprising a housing ("casing", paragraph [0013]; 502 in Figure 5, paragraph [0053]) disposed external to a subject (in view of the hand-operated elements in Figures 2 and 5),

(M1.3) wherein the housing comprises an actuator (e.g. handle 122, slide 46 (Figure 2B), dial 48 or crank 49 (Figures 3A and 3B); paragraph [0039]).

1.2 D14 further discloses two delivery system components (outer sheath 28 and pusher 27) connected to respective racks (34, 36) linked by pinions (38, 39) to be simultaneously movable (Figures 2A-2C). Undisputedly, such a movement is not independent.

However, D14 further discloses two mechanisms to temporarily disengage the linkage between the racks and

pinions. This renders both components mutually independently movable.

1.2.1 Figure 5 discloses a "clutch mechanism" to "push both pinions out of engagement with the racks" (paragraph [0053]). Claim 49 relates to this clutch mechanism and discloses "a second member movable to engage one or more of the pinions". However, contrary to the appellant's submission, claim 49 further describes that the second member acts to "disengage the pinions [plural] from the racks". Hence, claim 49 does not disclose an independent disengagement of only one of the pinions. Therefore, the clutch mechanism of Figure 5 discloses that either both or none of the pinions is engaged with the racks.

1.2.2 Figure 6 discloses a "lag system" in which rack 634 of the sheath is provided with a portion (602) without teeth to prevent the linkage between the two delivery system components. D14 explicitly discloses in paragraph [0055] referring to Figure 6 that, "when rack 634 attached to outer sheath 28 is retracted over portion 602, [...] neither pinion 39 or 38 rotate", so that the pusher remains stationary.

1.2.3 Accordingly, in both embodiments of Figures 5 and 6, the delivery system of D14 is configured and arranged such that the actuator (handle 122, Figure 2B) is adapted to move a first delivery system component (outer sheath 28) independently of a second delivery system component (pusher 27), thus disclosing feature M1.4.

1.3 It is correct that, in both embodiments, at the same time the second component (pusher 27) is also movable independently of the first component (outer sheath 28).

However, feature M1.5 does not only require an independent movement of both components but also that these independent movements are executable by "the [same] actuator".

In fact, none of the actuators in D14 is adapted to move both components mutually independently of each other when the linkage between the racks is disabled. Handle 122 and slider 46 (Figure 2B), which are attached to one of the racks, respectively, can only move the component attached to the respective rack. Dial 48 and crank 49 can only move the component whose rack is engaged with the pinions. According to Figure 5, where both pinions are disengaged from both racks, the dial and crank cannot move any of the components. In the embodiment of Figure 6, they can only actuate the pusher.

1.4 The embodiments of Figures 5 and 6 are presented as separate alternatives in D14 (see, for example, paragraphs [0015] and [0056]). They are thus not directly and unambiguously disclosed in combination. However, for the same reasons as in 1.3, not even a combination of the mechanisms of Figures 5 and 6 would disclose the same actuator adapted to move both components independently.

1.5 Accordingly, the invention defined in claim 1 is novel over the delivery system of document D14.

2. Inventive step

2.1 The subject-matter of claim 1 differs from the delivery system of Figure 6 of D14 by feature M1.5. This feature does not only foresee a movement of the second delivery system independently of the first but also that one and

the same actuator is adapted to move the first and second delivery system components independently of each other.

2.2 This difference solves the problem of simplifying the actuation of the deployment procedure (see [0004] of the patent in suit).

2.3 D14 does not disclose the solution of using the same actuator for different independent movements (see point 1.3 above). It is thus not apparent how D14 could have led the skilled person to the subject-matter of claim 1.

2.4 The appellant suggests that the skilled person while adapting the delivery system to different implants and their specific deployment procedures would have modified the embodiment of Figure 6 by providing a further portion without teeth on rack 36 connected with the pusher. In this way, the dial 48 or crank 49 shown in Figures 3A and 3B would be adapted to actuate movement of the outer sheath 28 and of the pusher 27 independently of each other.

However, the appellant failed to submit which specific implant or deployment procedure would have required or prompted the proposed modification. It is, however, considered that the skilled person would only have undertaken a particular modification based on a specific motivation.

In addition, the proposed modification would have led to a mechanism that did not work properly. While the dial or crank are in theory adapted to move the components independently, when the pinions are engaged with the respective rack, there is no mechanism that

brings the racks back into engagement with the pinions once disengaged at a toothless portion of the rack. A further actuator would thus be needed for pulling the racks back into engagement with the pinions and switching between the independent movements. As this is not seen as an improvement but rather as a complication of the actuation, the skilled person would not have considered the proposed modification as a proper solution for adapting the delivery system to a specific deployment procedure.

The skilled person would therefore not have modified the lag mechanism of Figure 6 in the way submitted by the appellant.

2.5 Accordingly, document D14 neither discloses nor suggests the distinguishing feature M1.5 and, starting from this document, the invention of claim 1 thus involves an inventive step.

3. Admittance of documents E1-E6

3.1 Documents E1-E6 were submitted with the appellant's letter of 24 August 2020, only about one month before the date of the oral proceedings.

3.2 Applicable provision of the RPBA

According to the transitional provisions of Article 25(3) RPBA 2020, Article 13 RPBA 2007 is applicable instead of Article 13(2) RPBA 2020 "where the summons to oral proceedings [...] has been notified before the date of the entry into force" of the revised version of the RPBA.

3.2.1 In the case at hand, a first summons to oral proceedings, issued on 16 December 2019, was notified before entry into force of the revised version of the RPBA. However, following a request for postponement, the oral proceedings were cancelled, and a new summons was issued on 7 February 2020.

The Board thus had to establish which of the summonses qualified as "the summons" in Article 25(3) RPBA 2020, to determine whether Article 13(2) RPBA 2020 or Article 13 RPBA 2007 is applicable with respect to the admittance of late filed documents E1-E6. The parties did not wish to comment on this point.

3.2.2 According to the "Explanatory remarks" on Article 25(1) RPBA 2020 (OJ EPO 2020, supplementary publication 2, page 71), the transitional provisions of Article 25 RPBA 2020 intend to protect the "legitimate expectations which parties may have had at the time of filing" their submissions. Indeed, the reasons for a further summons are diverse and not in every case caused by the parties. It would thus be undue to make the applicability of the law dependent on the date of a later summons.

Hence, in the current case, the admittance of documents E1-E6 is not subject to the criteria of Article 13(2) RPBA 2020 but is governed by Article 13 RPBA 2007.

3.3 In exercise of the discretion granted by Article 114(2) EPC and 13(3) RPBA 2007, the Board decided not to admit documents E1-E6 into the proceedings.

The appellant's justifications for the late submission of these documents, namely that these documents were identified from the opposition proceedings against a

family member of the patent only after a change of representative in this case, does not excuse their lateness. In addition, as the notice of opposition in the parallel case had been filed in February 2020 and the change of representative took place in May 2020, the reasons given cannot explain the documents being submitted as late as 24 August 2020.

The alleged *prima facie* high relevance of E2 for the novelty of the subject-matter of claim 1 could not be established.

Figure 12 of E2 shows a rotary actuator (1206) connected to a drum with two guide grooves (1212, 1214). Upon rotation, the pitch of the rotating guide grooves is converted into an axial movement of respective transmission elements (1216, 1218) engaged within the grooves and further transmitted to distal delivery system components. Sections without pitch in one of the grooves would mean that one component remained stationary while the other was moved, i.e. an independent movement of the two components. However, the exact orientation of the guide grooves, in particular a purely vertical, zero pitch alignment, is not unambiguously derivable from the schematic figure. In fact, the middle section of groove 1214 rather appears to be slightly inclined.

From documents E1, E3-E6 and the written submission of 24 August 2020, the Board could also not *prima facie* recognise a disclosure of the same actuator adapted to move different delivery system components mutually independently from each other, and the appellant did not wish to further elaborate on this point at the oral proceedings.

E1-E6 are thus not considered to be *prima facie* highly relevant for the assessment of novelty of the subject-matter of claim 1.

For these reasons, documents E1-E6 are not admitted into the proceedings.

4. In summary, none of the grounds of opposition under Article 100 EPC submitted by the appellant prejudices the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

D. Magliano P. Acton

Decision electronically authenticated