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Datasheet for the decision of 24 May 2023

Case Number: T 2442/19 - 3.2.08

Application Number: 12075021.1

Publication Number: 2460491

IPC: A61F2/01, A61F2/915

Language of the proceedings: EN

Title of invention:
A vascular filter

Patent Proprietor:
Novate Medical Ltd.

Opponent:
Cook Medical Technologies LLC

Relevant legal provisions:
EPC Art. 54(2), 56, 76(1), 83
RPBA 2020 Art. 13(2)
EPC R. 115(2)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Divisional application - added subject-matter (no)
Sufficiency of disclosure - (yes)

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2442/19 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 24 May 2023

Appellant 1: (Patent Proprietor)	Novate Medical Ltd. First Floor Fitzwilton House Wilton Place Dublin 2 (IE)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstraße 4 81675 München (DE)
Appellant 2: (Opponent)	Cook Medical Technologies LLC 750 North Daniels Way Bloomington, IN 47404 (US)
Representative:	Williams Powell 5 Chancery Lane London WC2A 1LG (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 3 July 2019 concerning maintenance of the European Patent No. 2460491 in amended form.**

Composition of the Board:

Chairwoman	P. Acton
Members:	G. Buchmann
	F. Bostedt

Summary of Facts and Submissions

I. With the decision posted on 3 July 2019 the opposition division decided that European patent No. 2 460 491 in amended form fulfilled the requirements of the EPC.

II. Both parties filed an appeal against that decision.

III. Oral proceedings took place before the Board on 24 May 2023.

IV. At the end of the oral proceedings, appellant 1 (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request as filed during the oral proceedings.

V. Appellant 2 (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

VI. In the present decision, reference is made to the following documents:

D1 WO2008010197 A2
D2 US20060058836 A1
D3 US20070112372 A1
D5 US5383887 A
D6 WO2005023149 A2
D9 US6214025 B1
D10 US2003/0176914 A1

VII. Claim 1 of the **main request** reads as follows (with added feature numbering and showing the amendments over the granted version):

1.1
"A vascular filter (1) comprising:
1.2
capture members (6) for capturing thrombus passing through a blood vessel,
1.3
wherein the capture members (6) are movable from a capturing configuration to an open configuration, in the capturing configuration the capture members being configured to capture thrombus passing through a blood vessel, in the open configuration the capture members being configured to facilitate unrestricted blood flow;
1.4
support members (3, 4, 5) for supporting the capture members relative to a wall of the blood vessel, and being movable between a delivery configuration and a deployed configuration;
1.5
and wherein the support members comprise a proximal hoop in a wave pattern,
1.6
a distal hoop in a wave pattern,
1.7
and struts extending longitudinally along the wall of a blood vessel interconnecting the proximal and distal hoops;
1.8
wherein the proximal and distal hoops each comprises a plurality of connector elements (4, 10), each connector element connecting a peak of the wave pattern to an adjacent peak of the wave pattern;
1.9
wherein the capture members are connected to the support member at or adjacent to a distal peak of the proximal hoop; characterized in that,

1.10
the proximal hoop comprises ~~eight or less~~ seven, or six, or five, or four, or three proximal peaks and ~~eight or less~~ seven, or six, or five, or four, or three distal peaks, and the distal hoop comprises ~~eight or less~~ seven, or six, or five, or four, or three proximal peaks and ~~eight or less~~ seven, or six, or five, or four, or three distal peaks."

Dependent claims 2, 5 and 8-12 as granted have been deleted.

VIII. **The arguments of appellant 1 can be summarised as follows:**

Amendments - Article 76 EPC

Feature 1.10 did not go beyond the content of the earlier application.

Sufficiency of disclosure - Article 83 EPC

The technical features of the subject-matter of claim 1 were disclosed in a manner sufficient to be carried out by a person skilled in the art.

Novelty - Article 54(2) EPC

The subject-matter of claim 1 was novel over D1 because Figures 26(a)-(h) and 52(a)-(n) showed filters with support hoops having at least eight proximal and distal peaks, contrary to Feature 1.10.

D2 did not disclose at least Feature 1.9, according to which "the capture members are connected to the support member at or adjacent to a distal peak of the proximal

hoop."

The subject-matter of claim 1 was novel over D3 because D3 did not disclose at least Features 1.5, 1.6, 1.7 and 1.9.

Inventive step - Article 56 EPC

The subject-matter of claim 1 differed from the prior art disclosed in D1 in that the proximal and distal hoops have seven, six, five, four or three proximal or distal peaks (Feature 1.10). None of the documents D6, D9 and D10 taught the skilled person to modify the number of peaks of the filter shown in D1, when looking for a solution to the problem of improving the buckling resistance of the filter. Therefore, the subject-matter of claim 1 involved an inventive step starting from D1 in combination with any of D6, D9 and D10.

Furthermore, the subject-matter of claim 1 involved an inventive step over each of D3 and D5 when taken alone.

IX. **The arguments of appellant 2 can be summarised as follows:**

Amendments - Article 76 EPC

The introduction of the exact number of peaks into claim 1 constituted an unallowable intermediate generalisation of the disclosure of the earlier application.

Additionally, Feature 1.10 went beyond the earlier application because it allowed differing numbers of peaks within a single support hoop or, alternatively,

differing numbers of peaks between the two support hoops.

Sufficiency of disclosure - Article 83 EPC

The alleged effect of the claimed filter was not supported by the patent. Therefore, the invention as claimed was not disclosed in a manner sufficiently clear and complete to be carried out by a person skilled in the art.

Novelty - Article 54(2) EPC

Document D1 disclosed all of the features of claim 1, in particular Feature 1.10, which also included support hoops having more than eight proximal and distal peaks.

Furthermore, the subject-matter of claim 1 was not novel over D2 and D3.

Inventive step - Article 56 EPC

The subject-matter of claim 1 differed from the prior art disclosed by D1 in that the number of proximal and distal peaks was selected to be seven, six, five, four or three. The problem to be solved was to put the filter shown in Figure 52(a)-(n) into practice. This was obvious in view of the disclosure of either D6, D9 or D10.

Furthermore, the subject-matter of claim 1 was obvious in view of the disclosures of D3 or D5 when taken alone.

Reasons for the Decision

1. Absence of appellant 2

As indicated in its letter dated 20 April 2023, appellant 2 did not attend the oral proceedings. According to Rule 115(2) EPC, the proceedings were continued without this party and, pursuant to Article 15(3) RPBA 2020, appellant 2 was treated as relying solely on its written case.

2. Admittance of the main request

2.1 The main request of appellant 1 was filed during the oral proceedings before the Board. Its admittance had to be assessed in view of Article 13(2) RPBA 2020.

2.2 The main request is based on auxiliary request 5 as filed with the statement of the grounds of appeal. The only amendment compared to auxiliary request 5 was that dependent claims 2 and 7-11 of auxiliary request 5 had been deleted.

Said auxiliary request 5 was first filed during the opposition proceedings on 7 March 2019, and was then re-filed with the statement of the grounds of appeal. Hence, auxiliary request 5 was already in the proceedings (see Article 12(4) RPBA 2007).

In the present case, the deletion of the dependent claims is not regarded by the Board as being an amendment of appellant 1's case.

Therefore, the requirement of Article 13(2) RPBA 2020

to provide cogent reasons for the presence of exceptional circumstances does not apply. Hence, the main request has been admitted into the proceedings.

2.3 Even if the deletion of the dependent claims were to be considered an amendment of the appeal case, the Board is of the opinion that the deletion did not change the factual and legal framework of the appeal and that the request has to be admitted into the proceedings.

3. Amendments - Article 76 EPC

3.1 Appellant 2 argued that the introduction of the specific number of peaks into claim 1 constituted an intermediate generalisation of the disclosure of the earlier application. Since the number of peaks have the effect of improving the resistance to buckling, all other features contributing to this effect should also be included in claim 1. Examples of these features were the enlarged element at each peak, the wall thickness of the support hoop and the barrel shape of the filter.

According to page 6, lines 12-19, of the earlier application, the enlarged element at each peak of the wave pattern minimises the probability of buckling. This passage does not, however, mention any functional relationship between the enlarged element and the number of peaks of the support hoops.

The wall thickness of the support hoop and its effect on buckling is described on page 6, lines 19-26. This passage does not mention any functional relationship between the thickness of the support hoops and the number of peaks either.

The barrel shape of the filter is also said to improve

buckling resistance (in the sentence bridging pages 10 and 11). Again, no functional relationship between the barrel shape and the number of peaks is mentioned.

Additionally, from a structural point of view, the number of peaks can be selected without any influence by, or influence on, the enlarged element at each peak, the wall thickness of the support hoop or the barrel shape of the filter.

Consequently, the number of peaks of the proximal and distal hoops is structurally and functionally independent of the other features and can be taken in isolation from the description.

Therefore, the addition of the number of peaks to claim 1 does not constitute an intermediate generalisation of the disclosure of the earlier application, and Article 76(1) EPC has not been violated.

3.2 Appellant 2 raised a further objection against the definition of the numbers of peaks in Feature 1.10. According to appellant 2, Feature 1.10 allowed for different numbers of peaks within a single support hoop or, alternatively, different numbers of peaks between the two support hoops. In contrast, the description of the earlier application was restricted to support hoops having the same number of peaks. Therefore, Feature 1.10 went beyond the content of the earlier application.

Feature 1.10 reads as follows:
"The proximal hoop comprises seven, or six, or five, or four, or three proximal peaks and seven, or six, or five, or four, or three distal peaks, and the distal hoop comprises seven, or six, or five, or four, or

three proximal peaks and seven, or six, or five, or four, or three distal peaks."

Semantically, this means that within the limits of the given numbers,
a) each of the two hoops can have a different number of peaks and
b) in each hoop, the number of proximal and distal peaks may differ.

The wording on page 11, line 30, - page 12, line 7, of the earlier application is different from the wording of the claim. It says that "the proximal support hoop 3 and/or the distal support hoop 4 may comprise any suitable number of distal peaks and proximal peaks."

Regarding point a), the Board agrees with appellant 2 that the claim wording includes situations in which the two hoops have two different numbers of peaks. However, the Board does not agree with appellant 2's argument that the wording of the description mentioned only one single "number" which must be the same for the proximal hoop and the distal hoop. Instead, the Board understands said passage such that any of the two hoops can have any number of peaks, i.e. the number of peaks may be the same or different for the two hoops.

Regarding point b), the Board agrees with the opposition division that, technically, it does not make sense to have a different number of proximal and distal peaks in a hoop having a wave pattern (see Features 1.5 and 1.6). Therefore, for the skilled reader the claim does not include hoops having a different number of proximal and distal peaks in a single hoop.

Therefore, specifying the number of peaks in Feature

1.10 does not contravene Article 76(1) EPC.

4. Sufficiency of disclosure - Article 83 EPC

Appellant 2 argued that the alleged effect of the claimed filter was not supported by the patent. In particular, Figure 9 showed a higher resisting force for the 12-peak support hoop than for the support hoops having a lower number of peaks. From this, appellant 2 concluded that the invention as claimed was not disclosed in a manner sufficiently clear and complete to be carried out by a person skilled in the art.

However, the alleged technical effect is not included in the wording of the claim. Therefore, in order to fulfil Article 83 EPC, it is sufficient that the technical features of the claim can be carried out. This was not contested, however.

Therefore, the requirements of Article 83 EPC are fulfilled.

5. Novelty - Article 54(2) EPC

5.1 Novelty over D1

5.1.1 D1 discloses (see Figure 26h and page 24, line 13, - page 28, line 4)
1.1
a vascular filter (300) comprising:
1.2
capture members (3) for capturing thrombus passing through a blood vessel,
(1.3)
wherein the capture members (3) are biodegradable from a capturing configuration to an open configuration,

1.4
support members (302, 303, 312) for supporting the capture members relative to a wall of the blood vessel, and being movable between a delivery configuration and a deployed configuration;
1.5
and wherein the support members comprise a proximal hoop (302) in a wave pattern,
1.6
a distal hoop (312) in a wave pattern,
1.7
and struts (303) extending longitudinally along the wall of a blood vessel interconnecting the proximal and distal hoops;
1.8
wherein the proximal and distal hoops each comprises a plurality of connector elements (5), each connector element connecting a peak of the wave pattern to an adjacent peak of the wave pattern;
1.9
wherein the capture members are connected to the support member at or adjacent to a distal peak of the proximal hoop (Figure 26(h)).

5.1.2 Regarding the number of proximal and distal peaks of the hoops (Feature 1.10), Figures 26(a) and (b) show two perspectives of a support member which allow twelve peaks to be recognised. From the comparison of Figures 26(b) and 26(h), it has to be concluded that the support member of Figure 26(h) has (at least) eight peaks.

5.1.3 Regarding the meaning of Feature 1.10, the Board notes the following:

The formulation according to which "the proximal hoop comprises [for example] seven proximal peaks" means that the hoop can comprise various technical features, one of these features being that the hoop has exactly seven proximal peaks. It is correct that the term "comprises" leaves open whether there are more features present in the hoop. In the present case, however, the possible numbers of peaks are listed in detail, and therefore the term "comprises" does not mean that there may also be a higher number of peaks.

5.1.4 Since, as stated in section 5.1.2 above, Figure 26(h) discloses eight or more peaks, it does not disclose Feature 1.10, which requires seven, six, five, four or three peaks.

5.2 Novelty over D2

5.2.1 Document D2 discloses a system for removing a thromboembolism from a cerebral artery (paragraph [0004]). Appellant 2 argued that this system could also be regarded as a vascular filter.

5.2.2 Even if this argument is accepted, D2 shows the following structure (Figure 8a-c). A support member comprises a proximal and a distal hoop (171a, 171b) and struts (162b) extending longitudinally along the wall of a blood vessel, interconnecting the proximal and distal hoops (Features 1.4-1.7). Some members (160b) of the distal hoop (171a) function as engagement members (170b) for capturing the thrombus (paragraphs [0064]-[0066]). These members (160b) are not, however, connected to a distal peak of the proximal hoop; rather, they are attached to the struts (162b) close to a distal cuff (152b).

5.2.3 Therefore, D2 does not disclose at least Feature 1.9, according to which "the capture members are connected to the support member at or adjacent to a distal peak of the proximal hoop."

5.2.4 Hence, the subject-matter of claim 1 is novel over D2.

5.3 Novelty over D3

5.3.1 Document D3 discloses a vascular filter comprising proximal and distal nitinol struts (311, 312) having a helical shape (Figure 5). A (biodegradable) PLGA matrix (313) is used to trap emboli when the struts are in their expanded configuration.

5.3.2 Appellant 2 argued that the helical coil of Figure 5 represented a wave pattern. When viewed laterally, the helical configuration showed peaks at the top and at the bottom (Figure 5).

The helical struts of D3 (Figure 5) are not, however, hoops forming a wave pattern (Features 1.5 and 1.6). No distal peaks can be identified at the proximal helical strut, to which capture elements (PLGA matrix) would be connected (Feature 1.9). Furthermore, no struts are present in D3 which extend longitudinally along the wall of a blood vessel and interconnect the proximal and distal hoops (Feature 1.7).

5.3.3 Thus, D3 does not disclose at least Features 1.5, 1.6, 1.7 and 1.9, and therefore the subject-matter of claim 1 is novel over D3.

6. Inventive step - Article 56 EPC

6.1 Starting from document D1 in combination with D6 and D9

6.1.1 Appellant 2 raised an objection of a lack of inventive step starting from the embodiment shown in Figures 52(a)-(n) of D1.

Figures 52(a)-(n) of D1 disclose (see page 35, line 16, - page 39, line 5)
1.1
a vascular filter (340) comprising:
1.2
capture members (121) for capturing thrombus passing through a blood vessel,
1.3
wherein the capture members (121) are movable from a capturing configuration to an open configuration (page 37, lines 13-29),
1.4
support members (302, 303, 312) for supporting the capture members relative to a wall of the blood vessel, and being movable between a delivery configuration and a deployed configuration;
1.5
and wherein the support members comprise a proximal hoop (302) in a wave pattern,
1.6
a distal hoop (312) in a wave pattern,
1.7
and struts (303) extending longitudinally along the wall of a blood vessel interconnecting the proximal and distal hoops;
1.8
wherein the proximal and distal hoops each comprises a plurality of connector elements (5), each connector

element connecting a peak of the wave pattern to an adjacent peak of the wave pattern;
1.9
wherein the capture members are connected to the support member at or adjacent to a distal peak of the proximal hoop (Figure 52(a)); wherein
(1.10)
the proximal hoop comprises twelve proximal peaks and twelve distal peaks, and the distal hoop comprises twelve proximal peaks and twelve distal peaks.

6.1.2 The subject-matter of claim 1 therefore differs from the prior art in that the proximal and distal hoops have seven, six, five, four or three proximal or distal peaks (Feature 1.10).

6.1.3 Starting from the assumption that the number of peaks was not unambiguously disclosed in D1, appellant 2 formulated the problem to be solved as putting the embodiment of Figures 52(a)-(n) into practice by selecting a suitable number of peaks. This assumption, however, is incorrect because the number of peaks of the embodiments shown in Figure 26(h) and Figures 52(a)-(n) is unambiguously derivable from said Figures. Hence, there is no question as to the number of peaks when putting this embodiment into practice, and the problem to be solved must therefore be formulated differently.

6.1.4 Appellant 1 convincingly pointed out that the effect achieved by the reduced number of peaks is that the vascular filter is more resistant against buckling. This is all the more convincing since it is consistent with the description of the earlier application (page 2, lines 10-11, and page 12, lines 9-19, and Figure 9).

Therefore, the problem to be solved is the provision of a vascular filter with improved resistance against buckling.

6.1.5 Appellant 2 argued that both D6 and D9 illustrated that the number of six peaks was routine for the skilled person when adapting a support structure to the size of the vessel in which the implant is to be used.

Document D6 discloses (page 16, line 18, - page 17, line 3) that the number of apices of a stent is dependent upon the diameter of the vessel in which the stent graft is to be implanted. D6 does not, however, mention the problem of buckling in the context of a vascular filter. When starting from document D1 and in view of the problem posed, D6 therefore does not lead the skilled person to the solution of a reduced number of seven, six, five, four or three peaks.

Document D9 shows a vascular filter having cells around its circumference, i.e. having a support member with six peaks (Figure 1 and 1a). It states that the number of cells may be varied in accordance with the size of the blood vessel (column 7, lines 5-14). D9 does not mention the problem of buckling in the context of a vascular filter either. When starting from document D1 and in view of the problem posed, D6 therefore does not lead the skilled person to the solution of a reduced number of seven, six, five, four or three peaks.

6.1.6 For these reasons, the subject-matter of claim 1 involves an inventive step when starting from D1 in combination with either D6 or D9.

6.2 Starting from document D1 in combination with D10

6.2.1 Appellant 2's arguments were once again based on Figures 52(a)-(n) of D1. It argued that D10, paragraph [0091], taught that the radial forces of a stent increased as the angle between the struts increased. However, this passage also states that the angle is preferably 35-65°, "depending on the diameter of the stent in its expanded configuration, the desired radial force, the number of peaks in each annular ring, and the thickness of the struts."

6.2.2 This teaches the skilled person to provide peaks having an angle of 35-65° between the connector elements (which connect the proximal and distal peaks of the wave pattern of the support member). It does not teach the provision of a particular number of peaks. On the contrary, the number of peaks is left open as one of a number of variables which may be used to achieve the selected angle.

6.2.3 Therefore, the subject-matter of claim 1 involves an inventive step when starting from D1 in combination with D10.

6.3 Starting from document D3

6.3.1 Regarding document D3, appellant 2 argued that the hoops shown in Figure 3 could be combined with the filter shown in Figure 5 of the same document.

Figure 3 shows a hoop having eight proximal peaks and eight distal peaks and the filter of Figure 5 does not show hoops having a waveform with peaks.

Therefore, the combination of Figures 3 and 5 of D3

does not result in a filter having hoops with seven, six, five, four or three proximal and distal peaks.

6.3.2 Therefore, the subject-matter of claim 1 involves an inventive step over D3.

6.4 Starting from document D5

6.4.1 Document D5 discloses a vascular filter which does not have two wave-form hoops to which the capture elements are connected. The filter of D5 consists of one wave-form hoop, some of the peaks of which are tied together to form the capture elements (Figures 1-4).

Therefore, the filter of D5 does not comprise two hoops in a wave pattern which are connected by longitudinally extending struts (features 1.5-1.8). Additionally, the capture members are not connected to the only hoop present (Feature 1.9).

6.4.2 There is no teaching in D5 which could lead the skilled person to modify the filter so as to arrive at a filter according to claim 1.

6.4.3 Therefore, the subject-matter of claim 1 involves an inventive step over D5.

6.5 Dependent claims

All of the dependent claims against which appellant 2 had raised objections have been deleted in the present main request.

Order

For these reasons it is decided that:

The decision under appeal is set aside. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:

Description:
Columns 1 to 6 of the patent specification
Column 7 filed during the oral proceedings of 24 May 2023

Claims:
1 to 5 filed during the oral proceedings of 24 May 2023

Drawings:
Figures 1 to 10 of the patent specification

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated