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Datasheet for the decision of 8 September 2020

Case Number: T 2329/15 - 3.2.02

Application Number: 04754059.6

Publication Number: 1631195

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Language of the proceedings: EN

Title of invention:
SUBCUTANEOUS BIOPSY CAVITY MARKER DEVICE

Applicant:
Devicor Medical Products, Inc.

Headword:

Relevant legal provisions:
EPC Art. 54
RPBA 2020 Art. 13(2)

Keyword:
Novelty (no)
Admissibility of a new auxiliary request filed at oral proceedings (no)

Decisions cited:

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 2329/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 8 September 2020

Appellant: (Applicant)	Devicor Medical Products, Inc. 300 E Business Way Fifth Floor Cincinnati, OH 45241 (US)
Representative:	Vos, Derk Maiwald Patentanwalts- und Rechtsanwaltsgesellschaft mbH Elisenhof Elisenstraße 3 80335 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 13 July 2015 refusing European patent application No. 04754059.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	Y. Podbielski
Members:	M. Stern
	S. Dennler

Summary of Facts and Submissions

I. The applicant lodged an appeal against the decision of the Examining Division refusing European patent application No. 04 754 059.6. The application was refused on the grounds that the subject-matter of claim 1 of the main request lacked novelty over the following document:

D6: US-A-5 370 691,

and that the first and second auxiliary requests contravened Article 123(2) EPC.

II. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main request or one of the first or second auxiliary requests, all filed with the statement setting out the grounds of appeal dated 23 November 2015, or on the basis of the third auxiliary request filed with letter dated 31 August 2020.

In the course of the oral proceedings, held on 8 September 2020, the appellant filed a new second auxiliary request and changed the order of requests as follows: main request, third auxiliary request, new second auxiliary request (filed during the oral proceedings), first auxiliary request, second auxiliary request.

III. Claim 1 of the **main request** reads as follows:

"1. A biopsy cavity marking device for identifying a subcutaneous biopsy cavity comprising:

a first nonabsorbable marker element (118, 122, 126, 130) detectable by X-ray;
and
a second marker element (120, 124, 128, 132) detectable by ultrasound,
wherein said first marker element comprises a metal and said second nonabsorbable marker element comprises a polymer,
wherein the first marker element wraps around a portion of the second marker element, and characterised in that the second marker element is nonabsorbable."

Claim 1 of the **third auxiliary request** reads as follows (changes vis à vis claim 1 of the main request highlighted by the Board):

"1. A biopsy cavity marking device for identifying a subcutaneous biopsy cavity comprising:
a first nonabsorbable marker element (118, 122, 126, 130) detectable by X-ray;
and
a second marker element (120, 124, 128, 132) detectable by ultrasound but not detectable by X-ray,
wherein said first marker element comprises a metal and said second nonabsorbable marker element comprises a polymer,
wherein the first marker element wraps around a portion of the second marker element, and characterised in that the second marker element is nonabsorbable."

Claim 1 of the **new second auxiliary request** (filed during oral proceedings) reads as follows (changes vis à vis claim 1 of the main request highlighted by the Board):

"1. Composition of a ~~A biopsy cavity marking device for identifying a subcutaneous biopsy cavity comprising:~~
a first nonabsorbable marker element (118, 122, 126, 130) detectable by X-ray;
and
a second marker element (120, 124, 128, 132) detectable by ultrasound but not detectable by X-ray, for use in a biopsy cavity marking device for identifying a subcutaneous biopsy cavity and for long-term follow-up of the subcutaneous biopsy cavity,
wherein said first marker element comprises a metal and said second nonabsorbable marker element comprises a polymer,
wherein the first marker element wraps around a portion of the second marker element, and characterised in that the second marker element is nonabsorbable."

Claim 1 of the **first auxiliary request** reads as follows (changes vis à vis claim 1 of the main request highlighted by the Board):

"1. A biopsy cavity marking device for identifying a subcutaneous biopsy cavity comprising:
a first nonabsorbable marker element (118, 122, 126, 130) detectable by X-ray;
and
a second marker element (120, 124, 128, 132) detectable by ultrasound,
wherein said first marker element comprises a metal and said second nonabsorbable marker element comprises a polymer,
wherein the first marker element wraps around ~~a portion of~~ the second marker element, and characterised in that the second marker element is nonabsorbable."

Claim 1 of the **second auxiliary request** reads as follows (changes vis à vis claim 1 of the main request highlighted by the Board):

"1. A biopsy cavity marking device for identifying a subcutaneous biopsy cavity comprising:
a first nonabsorbable marker element (118, 122, 126, 130) detectable by X-ray;
and
a second marker element (120, 124, 128, 132) detectable by ultrasound but not detectable by X-ray,
wherein said first marker element comprises a metal and said second nonabsorbable marker element comprises a polymer,
wherein the first marker element wraps around ~~a portion of~~ the second marker element, and characterised in that the second marker element is nonabsorbable."

IV. The arguments of the appellant that are relevant for the present decision may be summarised as follows:

Main request

The subject-matter of claim 1 of the main request was novel over D6. There was nothing in D6 to disclose or suggest a biopsy cavity marking device having a second nonabsorbable marker element which was detectable by ultrasound. D6 did not disclose the use of a *nonabsorbable* polymer marker. Moreover, D6 was directed to stents and did not disclose or suggest a biopsy cavity marking device. It was not reasonable to consider a stent as a biopsy cavity marking device. Both instruments were clearly configured to meet different purposes and to be placed in different locations. No medical practitioner would consider a stent to be a type of biopsy cavity marking device. In

particular, the stent of D6 would not be suited for marking a biopsy cavity, especially the center of the cavity as explained on page 2, paragraphs 2 and 3 of the application. Moreover, after release of the compressive forces applied during breast biopsy procedures, the flexible, hollow tubular stent of Figure 1A of D6 would deform or move, so that the orientation and location of the margins of the cavity would be lost. Furthermore, placement of a hollow tubular stent in a biopsy cavity would hinder the regrowth of tissue within the cavity.

Third auxiliary request

The polymers mentioned in D6 were not disclosed as being "not detectable by X-ray", as additionally defined in claim 1 of the third auxiliary request.

New second auxiliary request

In order to remedy the raised novelty objection, claim 1 of the new second auxiliary request was formulated as a purpose-related product claim following Article 54(5) EPC specifying a medical use otherwise excluded from patentability under Article 53(c) EPC (use in a biopsy cavity marking device for identifying a subcutaneous biopsy cavity and for long-term follow-up of the subcutaneous biopsy cavity). It had not been possible to file the claim earlier since the representatives had been unable to contact the appellant for months.

First and second auxiliary requests

Claim 1 of these auxiliary requests corresponded to claim 1 of the main and third auxiliary requests save

for an amendment made to overcome an objection under Article 123(2) EPC made by the Examining Division. The device of claim 1 of these requests was thus novel for the reasons given for the main and third auxiliary requests.

Reasons for the Decision

1. *The invention*

The application relates to a biopsy cavity marker device comprising two nonabsorbable marker elements, one detectable by X-ray, the other by ultrasound. Such a marker device helps to identify a biopsy site in a subsequent examination of the site, in particular the location and orientation of the cavity (page 2, paragraph 2). The use of nonabsorbable marker elements allows to permanently mark the location of the cavity (page 3, paragraphs 4 and 5).

Claim 1 defines the ultrasound detectable second marker element as comprising a nonabsorbable polymer and the X-ray detectable first marker element as comprising a metal and to wrap around a portion of the second marker element (see Figures 1D-1G; page 8, lines 6 to 9; page 9, paragraph 2).

2. Main request

2.1 Document D6 is addressed at intraluminal stents or grafts suited for treatment of aneurysms and diseased blood vessels and other bodily lumen needing such a prosthesis (column 1, lines 57 to 60). D6 discloses in Figure 1A a stent having a polymeric tubing (102) ("second marker element" of the claim) (column 3,

lines 1 to 5) and a radiopaque metal marker (110) ("first marker element" of the claim) wrapped around a portion of the former (column 3, lines 12 to 17; Figure 1A). The polymeric tubing may comprise polypropylene (column 3, lines 25 to 28). It results from common general knowledge that the polymeric tubing (102) will be detectable by ultrasound depending, inter alia, on the acoustical impedance of the tissue surrounding the stent, and that the radiopaque metal marker (10) is detectable by X-ray.

The appellant asserted that D6 did not disclose a *nonabsorbable* polymer marker. While this property is indeed not explicitly mentioned in D6, it is inherent to the polypropylene stent tubing disclosed (in column 3, lines 25 to 28), since the application describes polypropylene as a nonabsorbable polymer (page 9, third paragraph, first sentence). Moreover, dependent claim 9 of the main request specifies polypropylene as a preferred embodiment of the nonabsorbable polymeric marker defined in claim 1.

2.2 Claim 1 is addressed at a "biopsy cavity marking device". Hence, the claim defines a device that is **suitable for** marking a cavity which may have originated from a biopsy.

It is established jurisprudence that a formulation such as "apparatus for" is to be interpreted as meaning an apparatus which is suitable for the stated use (Case Law of the Boards of Appeal, 9th edition, 2019, I.C. 8.1.5). Any prior art apparatus which, in addition to features expressly mentioned in the claim also possesses these implicit physical features and can thus **reasonably** be used for the stated purpose, will then take away novelty of the claimed apparatus. This is

irrespective of whether or not the prior art mentions the stated use or purpose or whether the stated use is obvious or not. This is because the claim is directed at the apparatus, not its use. Nor can stating a use that is new and not-obvious render an apparatus which is already known novel and inventive.

2.3 As indicated above, D6 is addressed at intraluminal stents or grafts suited for treatment of aneurysms and diseased blood vessels and other bodily lumen needing such a prosthesis. Given the physical properties of the stent depicted in Figure 1A of D6, the Board considers that it is likewise suited to be used for marking a cavity which may have originated from a biopsy, even if D6 does not mention this purpose or use.

2.4 None of the reasons presented by the appellant convinced the Board that it was not reasonable to consider the stent of D6 as being suitable for the claimed purpose.

2.4.1 The Board finds it undisputable that the stent of Figure 1A of D6, comprising two radiopaque metal markers (110), is designed for radiographically marking its position in the vasculature. If the stent was inserted into any other cavity of the body, the markers would still allow to determine its position. The appellant's argument that the stent would not allow marking the *center* of a biopsy cavity, as explained on page 2, paragraphs 2 and 3 of the application, is not relevant since this purpose is not defined in claim 1. Even if it was, it is noted that the two markers at each end of the stent would also allow to determine a center point between the markers.

2.4.2 The appellant argued, moreover, that no medical practitioner would consider using a stent for marking a biopsy cavity. It was argued that after release of the compressive forces applied during breast biopsy procedures, the flexible, hollow tubular stent of Figure 1A of D6 would deform or move, so that the orientation and location of the margins of the cavity would be lost. Furthermore, placement of a hollow tubular stent in a biopsy cavity would hinder the regrowth of tissue within the cavity.

The Board does not consider that the stent of D6 would necessarily deform or move when inserted into a cavity. Stents are designed to be fixedly positioned and secured within the vasculature and will normally not move once inserted. The application and release of compressive forces mentioned by the appellant in the particular context of breast biopsies is no general prerequisite for placing a marker in a biopsy cavity. The appellant's assertion that tissue would be hindered to regrow within the lumen of the stent does not appear to be a proven reason deterring the skilled person from using the stent within a cavity.

2.5 The Board therefore concludes that the device of claim 1 lacks novelty within the meaning of Article 54 EPC.

3. Third auxiliary request

3.1 In claim 1 of the third auxiliary request, the second marker element detectable by ultrasound is further specified as being *"not detectable by X-ray"*. The request was filed about one week prior to the oral proceedings. As the substance of the request

corresponds to that of the second auxiliary request, the Board admitted it into the proceedings.

3.2 As explained in the application on page 7, paragraph 3, the expression "not detectable" means that there is no significant visualisation of the second marker element by X-ray. The expression provides therefore a rather unspecific, qualitative indication about the insignificant visualisation of the second marker element using an (unspecified) X-ray detection system.

D6 discloses that tubing 102 (the "second marker element") is made of polypropylene (column 3, lines 25 to 28), one of the polymers listed in dependent claim 9 of the third auxiliary request as examples of a marker "not detectable by X-ray". Consequently, also the polypropylene tubing in D6 will be hardly visualised by X-ray (depending on the X-ray imaging modality), and therefore, "not detectable by X-ray".

3.3 The device of claim 1 of the third auxiliary request therefore lacks novelty.

4. *New second auxiliary request*

4.1 The appellant explained that in order to remedy the raised novelty objection, amended claim 1 filed during oral proceedings was formulated as a purpose-related product claim in the sense of Article 54(5) EPC specifying a medical use otherwise excluded from patentability under Article 53(c) EPC. Claim 1 was no longer addressed at a device, but at a "composition" of first and second marker elements for use in a biopsy cavity marking device for identifying a subcutaneous biopsy cavity and for long-term follow-up of the subcutaneous biopsy cavity.

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

4.3 When queried about the reasons justifying the late filing of the request during oral proceedings, the representatives explained that the request was filed in response to the novelty objections raised in the communication accompanying the summons to oral proceedings. It had not been possible to file it earlier since the representatives had been unable to contact the appellant for months.

4.4 The Board disagrees. The appellant's lack of involvement in the prosecution of the present case, as unusual as it may be, can in the current case not be regarded as "exceptional circumstances" which may lead the Board to admit the filing of the new second auxiliary request after notification of the summons to oral proceedings. "Exceptional circumstances" generally concern new or unforeseen developments of the appeal proceedings themselves, such as new objections raised by the Board (or another party). In the present case, however, the novelty objection in view of D6 had already been raised by the Examining Division and formed part of the reasons for the impugned decision. Thus, whether or not the appellant's representatives were unable to liaise with their clients in the period between notification of the summons and the oral proceedings is of no relevance to the issue of admittance of the request into the proceedings.

4.5 The Board, therefore, exercised its discretion under Article 13(2) RPBA 2020 not to admit the new second auxiliary request.

5. First and second auxiliary requests

5.1 Claim 1 of the first and second auxiliary requests corresponds to claim 1 of the main and third auxiliary requests, respectively, with the following amendment: "*the first marker element wraps around ~~a portion of~~ the second marker element*".

5.2 The subject-matter of claim 1 of the first and second auxiliary requests is thus a generalisation of the subject-matter of claim 1 of the main and third auxiliary requests, respectively.

5.3 As a consequence, the aforementioned objection of lack of novelty applies likewise to the first and second auxiliary requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

D. Hampe Y. Podbielski

Decision electronically authenticated