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Datasheet for the decision of 19 December 2017

Case Number: T 0549/13 - 3.2.02

Application Number: 03733880.3

Publication Number: 1572006

IPC: A61B17/08, A61B19/00

Language of the proceedings: EN

Title of invention:
BIODEGRADABLE POLYMER FOR MARKING TISSUE AND SEALING TRACTS

Applicant:
MED-Genesis, LLC

Headword:

Relevant legal provisions:
EPC Art. 56
EPC R. 115(2)
RPBA Art. 13(1), 15(3)

Keyword:
Oral proceedings - held in absence of appellant
Inventive step - main request (no)
Late-filed auxiliary request - admitted (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0549/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 19 December 2017

Appellant: (Applicant)	MED-Genesis, LLC 4900 Creekside Drive, Suite C Clearwater, FL 33760 (US)
Representative:	Heinze, Ekkehard Meissner Bolte Patentanwälte Rechtsanwälte Partnerschaft mbB Postfach 10 26 05 86016 Augsburg (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 19 October 2012 refusing European patent application No. 03733880.3 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairman	E. Dufrasne
Members:	D. Ceccarelli
	M. Stern

Summary of Facts and Submissions

I. The applicant has appealed the Examining Division's decision, dispatched on 19 October 2012, to refuse European patent application No. 07 733 880.3.

II. The Examining Division held that the subject-matter of claim 1 of the only request on file lacked novelty.

III. Notice of appeal was received on 27 December 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 25 February 2013.

IV. The Board summoned the appellant to oral proceedings. In the communication accompanying the summons the Board expressed its preliminary opinion that the subject-matter of claim 1 of the only request on file lacked an inventive step over the combination of the following documents, considered by the appellant in the statement of grounds:

D1: WO-A-01/08578;
D7: "Hydrogels for Biomedical applications", Hoffman A S, Annals New York Academy of Sciences, 2001, pages 62 to 73.

It also expressly reminded the appellant that the admission of any further submission was subject to the provisions of Article 114(2) EPC and Articles 12 and 13 RPBA.

V. By letter dated 27 October 2017 the appellant informed the Board that it would not attend the oral proceedings. With that letter it filed an auxiliary request, but did not provide any arguments addressing

the Board's preliminary opinion.

VI. Oral proceedings took place on 19 December 2017 in the appellant's absence.

VII. The appellant had requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with letter dated 16 December 2011 or, in the alternative, of the auxiliary request filed with letter dated 27 October 2017.

VIII. Claim 1 of the main request reads as follows:

"A combination tissue marker polymer (10) and sealant (12), wherein said tissue marker polymer (10) is formed of a biodegradable polymer, wherein said sealant (12) encapsulates the tissue marker polymer (10) and is adapted to anchor the tissue marker polymer (10) against migration,

characterized in that said sealant (12) is a hydrogel that can be delivered to a site in dehydrated form and that can be hydrated by moisture inherent in tissue at said site so that no in situ curing is required, said sealant (12) being adapted to expand when hydrated."

Claim 1 of the auxiliary request further comprises the following wording at the end of the claim:

"wherein the tissue marker polymer (10) is 75/25 poly(DL-lactide-co-ε-caprolactone) copolymer, or wherein the tissue marker polymer (10) is a copolymer consisting of 75/25 poly(DL-lactide-co-glycolide)".

IX. The appellant's arguments, as far as they are relevant for the present decision, may be summarised as follows:

D1 disclosed a remotely detectable tissue marker comprising a biocompatible covering. The covering included biologically inert metals and their alloys, collagen or fibrous material and various thermoplastic materials. D1 did not disclose a sealant made of a dehydrated hydrogel that expanded upon contact with natural body moisture, as defined in claim 1 of the main request. More particularly, collagen, disclosed in D1, was not a hydrogel. That was made clear by the disclosure of D7.

Hydrogel as a sealant for the tissue marker, while showing other characteristics of collagen, enabled much better sealing of openings in the body and much better anchoring against migration.

It followed that the subject-matter of claim 1 of the main request was novel and inventive over D1 and D7, even if they were combined with each other.

The auxiliary request differed from the main request in that independent claim 1 comprised features defined in claims 12 and 13 as originally filed which were also present in the main request. Article 123(2) EPC was complied with. The filing of the auxiliary request was an amendment to the appellant's case after it had filed its grounds of appeal, the admission of which was at the Board's discretion under Article 13(1) RPBA. However, since the additional features incorporated into independent claim 1 were already part of the claims of the main request, no issues were raised which the Board could not reasonably be expected to deal with without adjournment of the oral proceedings. It

followed that the auxiliary request should be admitted into the proceedings. The subject-matter of its claim 1 was novel and inventive because the prior art cited during the examination proceedings failed to disclose the specific combination of the claimed features.

Reasons for the Decision

1. The appeal is admissible.

2. Although having been duly summoned by communication dated 7 September 2017, the appellant was not present at the oral proceedings, as announced by letter dated 27 October 2017. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without the appellant, which is treated as relying only on its written case.

3. The invention

The claimed invention relates to a biodegradable tissue marker. More particularly, it concerns a polymeric tissue marker encapsulated in a hydrogel sealant.

Tissue markers are implanted in a patient's body, at selected sites to be kept under observation for further diagnostic or intervention procedures. They have the property that they can easily be seen under X-ray or other imaging means. It is important that such markers keep that property and their position for an extended period of time.

According to the invention, the presence of the hydrogel sealant prevents migration of the marker and provides a soft interface between the marker and the

surrounding tissue (page 5, lines 19 to 22, of the application as originally filed).

4. Main request

The main request comprises a single independent claim 1, the subject-matter of which is based on claims 1 and 10 and page 6, lines 10 to 12, of the application as originally filed.

In the impugned decision, the Examining Division held that that subject-matter was not novel over D1.

D1 discloses a combination of a tissue marker biodegradable polymer (150, figure 1A and page 50, lines 1 to 3) and a sealant (102, figure 1A and page 40, lines 27 and 28). The sealant encapsulates the tissue marker and is adapted to anchor the tissue marker polymer against migration (page 37, lines 3 to 5, and page 40, lines 30 and 31). The sealant can be delivered to a site in dehydrated form and can be hydrated by moisture inherent in tissue at said site so that no in situ curing is required (page 16, lines 19 to 20 and 23 to 26).

The appellant argued that D1 did not disclose that the sealant was in the form of hydrogel, as further required by claim 1.

The Board notes that D1 discloses a wide variety of materials suitable for the sealant (page 43, lines 9 to 30). More particularly, it specifically discloses "expanding gelatinous bioabsorbable materials", possibly made of "synthetic polymers", and mentions that they expand up to 30 times their compressed volume upon hydration (page 43, lines 30 to 32) and could be

in the form of a gel (page 40, lines 25 to 26, and page 41, lines 24 to 28).

Even if it were accepted that this does not amount to a direct and unambiguous implicit disclosure of a sealant material in the form of hydrogel, this would be the only feature of the subject-matter of claim 1 of the main request that distinguished it over D1.

In the Board's view, the objective technical problem solved by this distinguishing feature could only be the provision of an alternative material for the sealant of D1.

The appellant's argument that the use of hydrogel as a sealant enables much better sealing of openings in the body and much better anchoring against migration is not convincing. More particularly, in the Board's view this cannot be the case compared to the specific materials, disclosed in D1, that can expand up to 30 times their compressed volume upon hydration (page 43, lines 30 to 32).

As explained above, D1 discloses a wide variety of materials suitable for the sealant (page 43, lines 9 to 14). Hydrogel clearly fits into that variety, as it is a particular "expanding gelatinous bioabsorbable material", possibly made of "synthetic polymers". Moreover, the good suitability of hydrogels for biomedical applications is taught by D7 (page 62, first paragraph). In view of the teaching of D7 and the objective technical problem, the skilled person would provide the sealant of D1 in the form of hydrogel depending on circumstances, without any inventive activity.

It follows that the subject-matter of claim 1 of the main request does not involve an inventive step (Article 56 EPC).

5. Auxiliary request

The auxiliary request constitutes an amendment to the appellant's case, filed after the statement of grounds of appeal. Under Article 13(1) RPBA its admission into the appeal proceedings is at the Board's discretion, which is to be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy. A further relevant criterion, according to the established jurisprudence of the boards of appeal, is the *prima facie* relevance of the amendment.

The Board notes that the auxiliary request was filed at a very late stage of the proceedings. In view of the fact that the appellant decided not to attend the oral proceedings, this was in fact the last possible moment. Furthermore, it is to be noted that the appellant chose to provide no substantial arguments as to why the subject-matter of claim 1 of the auxiliary request should involve an inventive step: in its letter dated 27 October 2017 it merely stated that the prior art cited during the examination proceedings failed to disclose the combination of the claimed features, without formulating any technical problem addressed by those features, and announced that it would not attend the oral proceedings. Finally, *prima facie*, the copolymers defined in the claim do not appear to have any specific advantage or effect over any generally known biodegradable polymers suitable for the tissue marker and do not appear to have any interrelation with

the technical effects of the hydrogel sealant, on the exclusive basis of which the appellant argued its previous case. In other words, the amendments are not *prima facie* relevant to inventive step. In this context it is irrelevant that the additional features incorporated into claim 1 were already part of dependent claims of the main request, as argued by the appellant.

For these reasons the Board decides not to admit the auxiliary request into the appeal proceedings under Article 13(1) RPBA.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated