Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 28 March 2017

Case Number: T 1312/15 - 3.3.10

Application Number: 08831224.4

Publication Number: 2197510

IPC: A61L31/10, A61L31/16

Language of the proceedings: EN

Title of invention:
MEDICAL DEVICES HAVING BIOERODABLE LAYERS FOR THE RELEASE OF THERAPEUTIC AGENTS

Applicant:
Boston Scientific Scimed, Inc.

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)

Decisions cited:
T 0020/81

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1312/15 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 28 March 2017

Appellant: (Applicant)	Boston Scientific Scimed, Inc. One Scimed Place Maple Grove, MN 55311-1566 (US)
Representative:	Peterreins Schley Patent- und Rechtsanwälte Hermann-Sack-Strasse 3 80331 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 10 February 2015 refusing European patent application No. 08831224.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	P. Gryczka
Members:	R. Pérez Carlón
	F. Blumer

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal against the decision of the examining division to refuse European patent application No. 08 831 224.4.

II. The documents forming part of the examination proceedings included the following:

D1: US 2006/0041102 A1
D3: WO 00/43579
D4: Makadia *et al.* Poly Lactic-co-Glycolic Acid (PLGA) as Biodegradable Controlled Drug Delivery Carrier, *Polymers* **2011**, *3*, 1377-1397

III. The examining division concluded that claim 1 of the main request then pending was not inventive. Document D1 was the closest prior art, the problem underlying the claimed invention was to provide a medical device comprising a layer having a poly(lactic acid-co-glycolic acid) (PLGA), a therapeutic agent and a plasticiser alternative to that of D1. The claimed solution, which was a medical device characterised in that it comprised a plasticiser selected from glycolic acid, an oligomer comprising glycolic acid, and combinations thereof, was obvious having regard to D3.

IV. The board informed the appellant in a communication dated 25 November 2016 that it was minded to consider document D1 to be the closest prior art. The problem formulated by the appellant, which was to provide a medical device which allowed sustained-release properties so that initial drug release was reduced while subsequent drug release was increased, could not be considered solved in the absence of any experimental data involving the plasticisers required by claim 1 of

the main request then pending. For that reason, the problem should be reformulated as providing an alternative medical device containing a therapeutic agent and a bioerodable polymeric layer.

V. With a letter dated 25 January 2017, the appellant filed a new main request, whose sole claim reads as follows:

"A medical device comprising (a) a substrate and (b) a bioerodable polymeric layer over the substrate that comprises (i) poly(lactic acid-co-glycolic acid) as biodegradable polymer, (ii) a therapeutic agent, and (iii) glycolic acid monomer as plasticizer."

VI. The arguments of the appellant relevant for the present decision were the following:

Document D1, which was the closest prior art, did not disclose a medical device having glycolic acid as plasticiser. The problem underlying the claimed invention was to provide a medical device capable of modulating sustained release so that initial drug release was reduced while subsequent drug release was increased. This problem was solved by the claimed medical device, characterised by having glycolic acid as plasticiser. Glycolic acid modulated the diffusion-governed release phase and the subsequent biodegradation-governed phase. The strategy used was completely different from that of D1, since it relied on the hydrophilicity of the plasticiser. As the prior art did not hint towards the claimed solution, the medical device of claim 1 was inventive.

VII. The appellant informed the board that it would not be attending the oral proceedings, which took place on

28 March 2017.

VIII. 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 (one claim) as filed with letter dated 25 January 2017.

IX. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Inventive step

2. Claim 1 of the sole request on file is directed to a medical device comprising a substrate and a bioerodable polymeric layer over it. Said polymeric layer comprises poly(lactic acid-co-glycolic acid) (PLGA), a therapeutic agent and glycolic acid monomer as plasticiser.

3. Closest prior art

The appellant did not challenge the finding of the examining division that document D1 was the closest prior art, and the board sees no reason to differ.

It has not been disputed that document D1 discloses a medical device such as a stent coated with a polymer [0009] which can be PLGA [0045]. Said coating may contain a therapeutic agent, which can be released due to gradual disappearance of the polymer [0080]. Di-lactide acid monomer is disclosed as a suitable plasticiser [0061] for polylactate [0052].

Nor has it been disputed that a plasticiser is a substance that changes a polymer in one or more ways relative to the same polymeric component without the plasticiser (see [0021] of the application), such as by increasing bioerosion [0036].

4. Technical problem underlying the invention

In the statement of grounds of appeal, the appellant defined the technical problem underlying the claimed invention as being to provide a medical device which allowed modulated sustained release, so that initial drug release was reduced and subsequent drug release increased.

5. Solution

The solution to this technical problem is the claimed medical device having a substrate and a bioerodable layer comprising PLGA and a therapeutic agent, characterised in that said bioerodable layer contains glycolic acid monomer as plasticiser.

6. Success

The application contains three examples. The first relates to lactic acid as plasticiser; the second and third to mixtures of PLGA polymers having different molecular weights.

Thus, none of the examples relates specifically to the effect of glycolic acid. No comparison with the closest prior art D1 is hence provided.

The appellant relied on document D4 for proving that, nevertheless, said problem had been credibly solved. However, D4 (see page 1387, paragraph 4.2.1) merely refers to the degradation rate of PLGA as a function of the relative amount of glycolic acid as PLGA constituent, i.e. polymerised. Thus, document D4 does not provide proof of the alleged effect, as it does not refer to the effect of unpolymerised glycolic acid monomer on PLGA degradation.

The appellant has argued that the alleged drug-release modulation was due to the difference in hydrophobicity and hydrophilicity of di-lactic and glycolic acids, and that this effect was not known in the art. Glycolic acid had a higher polarity than di-lactic acid monomer and would be more prone to leach, so that the drug release rate would be higher. Thus, PLGA containing glycolic acid had a bioerosion and drug-release profile different from PLGA containing di-lactic acid.

However, the application merely mentions in [0047] that plasticisers of varying hydrophilicity and hydrophobicity may be employed. No effect is linked to any of these plasticiser's groups, and no data relative to glycolic acid is provided. Thus, the appellant's arguments are merely assertions relying on a hypothetical mechanism, unsupported by any experimental evidence.

For these reasons, it is concluded that the problem as defined by the appellant cannot be considered credibly solved by the medical device of claim 1.

7. Reformulation of the technical problem

7.1 It is established case law of the boards of appeal that alleged but unsupported advantages cannot be taken into consideration in determining the problem underlying the invention (see e.g. decision T 20/81, OJ EPO 1982, 217, Reasons 3, last paragraph). As the alleged improvement in terms of modulated sustained release, enabling initial drug release to be reduced while subsequent drug release is increased, lacks the required support, the technical problem as defined above needs to be reformulated as being to provide an alternative medical device having a substrate and a bioerodable layer containing PLGA and a therapeutical agent, which is suitable for drug release.

It is not disputed that this technical problem has been solved by the medical device subject-matter of claim 1, characterised by containing glycolic acid as plasticiser in the bioerodable layer.

8. It thus remains to be decided whether or not the proposed solution to the objective problem defined above is obvious in view of the state of the art.

The skilled person trying to obtain a further medical device would consider using glycolic acid as part of the composition and thus arrive at the claimed solution without using inventive skills. Glycolic acid is one of the reaction products resulting from PLGA hydrolysis and, hence, will unavoidably be obtained during bioerosion; it is also biocompatible and bound to promote PLGA biodegradation due to autocatalysis (D1, [0020]), and document D1 hints at using plasticisers for modulating absorption rates [0061].

For these reasons, the medical device of claim 1 of the main request is not inventive, as required by Article 56 EPC, with the consequence that the sole request on file is not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated