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Datasheet for the decision of 11 January 2023

Case Number: T 1073/19 - 3.2.08

Application Number: 14177702.9

Publication Number: 2796112

IPC: A61F2/82, A61F2/91, A61F2/06, A61F2/07, A61F2/02

Language of the proceedings: EN

Title of invention:
Degradable implantable medical devices

Patent Proprietor:
Elixir Medical Corporation

Opponent:
BIOTRONIK AG

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 13(2)

Keyword:
Inventive step - common general knowledge
Amendment after summons - exceptional circumstances (yes)

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Case Number: T 1073/19 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 11 January 2023

Appellant: (Opponent)	BIOTRONIK AG Ackerstrasse 6 8180 Bülach (CH)
Representative:	Biotronik Corporate Services SE Corporate Intellectual Property Sieversufer 7-9 12359 Berlin (DE)
Respondent: (Patent Proprietor)	Elixir Medical Corporation 920 N. McCarthy Boulevard Milpitas, CA 95035 (US)
Representative:	Clark, Jane Anne Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 14 February 2019 concerning maintenance of the European Patent No. 2796112 in amended form.**

Composition of the Board:

Chairwoman	P. Acton
Members:	G. Buchmann
	Y. Podbielski

Summary of Facts and Submissions

I. The opposition division decided that European patent No. 2 796 112 in amended form fulfilled the requirements of the EPC.

The opposition division found that the subject-matter of the then valid auxiliary request 7 was disclosed in a manner sufficiently clear and complete to be carried out, and that the subject-matter of claim 1 involved an inventive step.

II. The opponent filed an appeal against that decision.

III. Oral proceedings took place before the Board on 11.01.2023.

IV. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked. They also requested that the first auxiliary request filed with letter dated 9 December 2022 not be admitted into the proceedings.

V. At the end of the oral proceedings the respondent's (patent proprietor's) request was that the patent be maintained on the basis of the first auxiliary request filed on 9 December 2022 (hereinafter "the request").

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

D3 EP 0 966 979 A2

D7 EP 1 389 471 A1

D13 "Effects of porosity and pore size on in vitro degradation of three-dimensional porous poly(D,L-lactide-co-glycolide)scaffolds for tissue engineering"; Linbo Wu, Jiandong Ding, 2005 Wiley Periodicals, Inc.

D14 "Porosity and Pore Size Regulate the Degradation Product Profile of Polylactide"; Karin Odelius et al., **2011** American Chemical Society p. 1250 - 1258

D15 "The Effects of Porosity on in Vitro Degradation of Polylactic Acid-Polyglycolic Acid Implants Used in Repair of Articular Cartilage"; K.A. ATHANASIOU, Ph.D., P.E. et al., TISSUE ENGINEERING Volume 4, Number 1, 1998 Mary Ann Liebert, Inc.

VII. Claim 1 of the request reads:

"A degradable, implantable stent comprising:

an implantable body comprising a metal, a metal alloy or a combination thereof, wherein said body has at least one corrosion enhancing and/or resisting element;

and a protective layer covering at least a portion of the body, wherein the protective layer comprises a polymer and wherein the protective layer is porous;

wherein the stent has corroded and has corroded by less than 5% by mass or less than 10% of the surface area prior to implantation, and wherein the implanted stent substantially degrades in about one month to about five years."

VIII. **The arguments of the respondent can be summarised as follows:**

Admittance of the request

The request had been filed in reply to an objection first raised in the communication of the Board. Therefore, it could not have been filed earlier. Since it overcame this objection, it should be admitted into the proceedings.

Inventive step

When starting from D3, the combination with D7 resulted in a stent having a non-porous coating. Moreover, the provision of a porous coating was not rendered obvious by the teaching of D13 or D15.

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

Admittance of the request

The respondent had not provided cogent reasons which justified exceptional circumstances for admittance of the request. The request could and should have been filed earlier, and it caused new problems under the EPC.

Inventive step

The subject-matter of claim 1 did not involve an inventive step with respect to D3 in combination with D7 and the common general knowledge which was represented by D13-D15. Furthermore, the subject-matter

of claim 1 was not inventive with respect to D3 in combination with D13 or D15.

Reasons for the Decision

1. Admittance of the request

1.1 The request was filed on 9 December 2022, i.e. after notification of the summons to oral proceedings. Its admittance is therefore subject to Article 13(2) RPBA 2020.

1.2 The appellant requested not to admit the request because the respondent had not justified any exceptional circumstances with cogent reasons (Article 13(2) RPBA 2020).

1.3 The respondent submitted that the request had been filed as a response to the objection raised in the Board's preliminary opinion according to which the subject-matter of claim 10 was not disclosed in a manner sufficiently clear and complete to be carried out by a person skilled in the art. The Board had raised doubts as to whether a stent having a polymeric coating with a thickness of 0.1 nm could be produced.

1.4 In the letter of 9 December 2022, the respondent referred to this objection (points 1 and 2, first sentence, respectively), presented arguments and documents against this objection, and filed as an auxiliary measure the present request in order to overcome this objection. The Board understands this as a justification in the sense of Article 13(2) RPBA 2020, even if this was not explicitly mentioned.

The respondent could not be expected to have filed this request at an earlier stage because the objection against the coating thickness of 0.1 nm had not been raised earlier in the appeal proceedings than with the communication of the Board. Even though this point was discussed in the decision of the opposition division (point 14), it was decided in favour of the respondent, and this point had not been raised by the appellant in the statement of grounds of appeal. The appellant had only raised the objection that it was not possible to provide pores in a layer having a thickness of 0.1 nm (statement of the grounds of appeal, point 3.1).

Therefore, before receiving the Board's communication, the respondent had no reason to assume that this objection could arise during the appeal proceedings.

These circumstances are regarded as exceptional in the sense of Article 13(2) RPBA 2020.

1.5 Additionally, the request does not, as argued by the appellant, create new problems under the EPC. In claim 10 of the request, two of five alternative features were deleted. Contrary to the appellant's opinion, this deletion of alternatives does not have the potential to create problems in view of added subject-matter (Article 123(2) EPC) or of clarity (Article 84 EPC).

1.6 For the above reasons, the request was admitted into the proceedings.

2. Inventive step - Article 56 EPC

2.1 Starting from D3 in combination with D7 and the common general knowledge

2.1.1 The appellant submitted that claim 1 did not involve an inventive step with respect to D3 in combination with D7 and the common general knowledge.

2.1.2 D3 discloses a bio-degradable metallic stent.

It is undisputed that the subject-matter of claim 1 differs from the stent of D3 in that the stent comprises "a protective layer covering at least a portion of the body wherein the protective layer comprises a polymer and wherein the protective layer is porous".

2.1.3 According to the appellant, the problem to be solved is the provision of a degradable stent which includes features to protect the tissue of the vessel wall. This formulation of the problem is based on paragraphs [0012] and [0085] of the patent. These paragraphs mention the risk of re-stenosis and inflammation which was overcome by the coating according to the patent.

2.1.4 Further according to the appellant, the problem to be solved was also mentioned in D7, paragraph [0017] which referred to inflammation and re-stenosis. The solution provided by D7 was a polymeric coating of the stent. Therefore, the skilled person would apply the teaching of D7 to the stent according to D3 and apply a polymeric coating on that stent.

Up to this point, the Board agrees with the appellant's

argumentation.

2.1.5 Since the polymeric layer of D7 is not disclosed as being porous, the appellant further argued that in view of the common general knowledge it was obvious to make the polymer coating porous. It was well known in the art (D13, D14, D15) that the porosity had an influence on the degradation. Moreover, D7 and D13-D15 used the same materials to be degraded (PLA, PLGA, PGA). Therefore, the skilled person would use and vary the parameter of porosity for designing the stent coating according to their needs, without performing an inventive step.

However, D13-D15 are scientific articles which are, according to established case law, not regarded as representing the common general knowledge. The appellant argued that for the skilled person in the field of stents, the scientific literature was commonly known and therefore represented common knowledge. However, three scientific articles are no sufficient evidence to confirm this allegation.

The appellant could also not convince the Board that the knowledge provided by D13 - D15 about the degradation of scaffolds which are used as a bulk material in tissue engineering, would be regarded as relevant by the skilled person for the improvement of the coating of a stent. To the contrary, the two technical fields appear to be remote from each other.

2.1.6 Additionally, it is noted that D14 was published in 2011 and does therefore not belong to the prior art. The mere mentioning in D14 that "it is well-known that the porosity greatly influences the rate of degradation, with a lower porosity leading to a faster

degradation rate" (page 1250, second column), does not prove that this is common general knowledge. The Board notes in his respect that the older documents which were cited in D14 in order to confirm this allegation (citations [18]-[20]) had not been provided by the appellant.

2.1.7 Therefore, applying the teaching of D7 in combination with the common general knowledge to the stent of D3 does not lead to the subject-matter of claim 1 in an obvious manner.

2.2 Starting from D3 in combination with D13, D14 or D15

2.2.1 The appellant had raised an objection regarding inventive step based on D3 in combination with D13, D14 or D15.

However, since D14 does not form part of the prior art, this document is not used for the assessment of inventive step in combination with D3.

2.2.2 D13 and D15 investigate the degradation rate of PLA, PGA or PLGA scaffolds, depending on the porosity and pore size.

They do not treat the influence of a porous polymeric coating on the degradation rate of a metallic implant (as alleged by the appellant). The documents do not even contain any reference to a stent or the coating of a stent.

Therefore, the skilled person would not have had any incentive to combine the teaching of D13 or D15 with the degradable metallic stent of D3.

2.2.3 Hence, the subject-matter of claim 1 is not rendered obvious when starting from document D3, in combination with D13 or D15.

2.3 For the above reasons, the ground of opposition under Article 100(a) EPC in combination with Article 56 EPC does not stand against the maintenance of the patent.

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:

Claims 1-13
filed with letter dated 9 December 2022;

Description columns 1-2, 11-12, 15-20, 25-33
of the patent specification;

Description columns 3-10, 13-14 and 21-24
filed with letter dated 09 December 2022;

Figures 1-21
of the patent specification.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated