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Datasheet for the decision of 1 September 2009

Case Number: T 0085/07 - 3.3.10

Application Number: 02706247.0

Publication Number: 1359953

IPC: A61L 31/14

Language of the proceedings: EN

Title of invention:
Bioabsorbable polymeric implants and a method of using the same to create occlusions

Applicant:
The Regents of The University of California

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes): - improvement made credible by comparative tests - solution not obvious"

Decisions cited:
-

Catchword:
-

Case Number: T 0085/07 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 1 September 2009

Appellant: The Regents of The University of California
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 9 August 2006 refusing European application No. 02706247.0 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: R. Freimuth
Members: P. Gryczka
D. S. Rogers

Summary of Facts and Submissions

I. The present appeal lies from the decision of the Examining Division posted on 9 August 2006 refusing the European patent application N° 02 706 247.0 published under the international publication N° WO 02/066091.

The Examining Division held that the amended claim 1 of the then pending main request did not comply with the requirements of Article 123 (2) EPC since it extended the claimed subject-matter beyond the content of the application as filed. Claims 1 to 13 of the then pending auxiliary request fulfilled that requirement and defined a clear and novel subject-matter. However, the claimed endovascular apparatus differed from that disclosed in document

(1) WO-A 00/44306

only by the specific molar ratio 90/10 of glycolic to L-lactic acid copolymers in the biocompatible and bioabsorbable polymer included in the apparatus. Since no surprising or advantageous effect was shown for this specific ratio the problem solved by the invention was merely to provide a further intraluminal implant. The claimed solution which was characterised by the specific ratio of copolymers was an arbitrary selection within the teaching of document (1). For these reasons, the claimed apparatus did not involve an inventive step.

II. At the oral proceedings which took place in front of the Board on 1 September 2009, the Appellant (Applicant) replaced all previously filed sets of claims by one set of 7 claims filed as sole request.

Claim 1 of said request reads as follows:

"1. An endovascular apparatus for developing an inflammatory response in a body cavity with cellular manipulation, which apparatus comprises a separable implant comprised at least in part of at least one biocompatible and bioabsorbable polymer, and an endovascular placement device associated with the separable implant adapted to dispose the implant into the body cavity, the biocompatible and bioabsorbable polymer being a polyglycolic/poly-L-lactic acid copolymer (PLGA) containing a 90/10 molar ratio of glycolic to L-lactic acid."

III. The Appellant argued that the problem underlying the present invention when considering document (1) as representing the closest prior art was to provide an endovascular apparatus improving the healing of aneurysms without occlusion of the blood vessels. This problem was effectively solved by the claimed apparatus comprising an implant containing a bioabsorbable polymer with a 90/10 molar ratio of glycolic

to L-lactic acid as shown by comparing the results described in the following documents:

(5) Slides of a lecture presentation at VIII Congress of WFITN, October 19-22, Venice, concerning the results observed by the inventors of the claimed device, F. Vinuela and Y. Murayama and co-wokers; and

(6) Y. Marayama et al., "Cellular Responses of Bioabsorbable Polymeric Material and Guglielmi Detachable Coil in Experimental Aneurysms", Stroke, April 2002, 1120 to 1128.

Since no prior art suggested that if the apparatus comprised a polymer with the specific molar ratio 90/10 of glycolic to L-lactic acid, then the healing of aneurysm was improved without generating occlusions of the blood vessels, the claimed subject-matter involved an inventive step.

IV. The Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 7 filed at the oral proceedings on 1 September 2009.

V. At the end of the oral proceedings, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

Claim 1 was amended by specifying that the biocompatible and bioabsorbable polymer is a polyglycolic/poly-L-lactic acid copolymer (PLGA) containing a 90/10 molar ratio of glycolic to L-lactic acid as disclosed in claim 34 as filed.

Dependent claim 2 is based on claim 4 as filed.

Dependent claim 3 is based on claims 35, 36 and 39 as filed.

Dependent claim 4 is based on page 3, lines 4 and 5 of the application as filed.

Dependent claim 5 is based on page 3, lines 6 to 8 of the application as filed.

Dependent claim 6 is based on the three last lines of the second paragraph of page 11 of the application as filed.

Dependent claim 7 is based on page 22, lines 21 and 22 of the application as filed.

Thus, the amended claims find a basis in the application as filed (Articles 123(2) EPC).

3. *Novelty*

It was acknowledged in the decision under appeal that the claims of the then pending auxiliary request defined a novel subject-matter since the specific molar ratio 90/10 of glycolic to L-lactic acid was not disclosed in document (1). The Board sees no reason to challenge these findings. Since the present claims also define an apparatus characterised by this specific molar ratio, the claimed subject-matter is novel (Article 54 EPC).

4. *Inventive step*

4.1 The present application is directed to an endovascular apparatus comprising a separable implant comprised at least in part of a biocompatible and bioabsorbable polyglycolic/poly-L-lactic acid copolymer (PLGA). Endovascular apparatuses containing an implant comprising also PLGA polymers are disclosed in document (1), which was considered in the decision under appeal as representing the closest prior art. The Board considers, in agreement with the Appellant, that this document represents the closest state of the art and, hence, takes it as the starting point for assessing inventive step.

Document (1) discloses an endovascular apparatus which comprises a separable coil comprised at least in part of at least one biocompatible and bioabsorbable polymer, and an endovascular placement device associated with the separable coil adapted to dispose the implant into a selected body cavity (page 6, lines 9 to 13; claim 1). The biocompatible and bioabsorbable polymer is selected from a group of polymers comprising, *inter alia*, a polyglycolic/poly-L-lactic acid copolymer (PLGA) (page 7, line 1; claim 6). The biocompatible and absorbable polymer promotes an intra-aneurismal inflammatory response and the healing of aneurisms (page 6, lines 13 to 15).

4.2 Having regard to this prior art, the Appellant submitted that the technical problem underlying the present application was to provide an endovascular apparatus improving the healing of aneurisms without causing occlusion of the blood vessels.

4.3 As the solution to this problem, the present application proposes the endovascular apparatus according to claim 1 which is characterized in that the polyglycolic/poly-L-lactic acid copolymer (PLGA) contains a 90/10 molar ratio of glycolic to L-lactic acid.

4.4 In order to demonstrate that the technical problem as defined above has effectively been solved by the claimed apparatus the Appellant relied on the results observed when treating aneurisms with three endovascular apparatus differing in that the implant comprised a polyglycolic/poly-L-lactic acid copolymer (PLGA) containing respectively a 15/85, a 50/50 or the claimed 90/10 molar ratio of glycolic to L-lactic acid. These results are described in documents (5) and (6). The comparative tests show that 14 days after embolization with an implant containing a polymer with a 15/85 molar ratio of glycolic to L-lactic acid remnant of the aneurism was observed, whereas a 50/50 molar ratio healed the aneurism but induced a parent artery stenosis (respectively figures 2E and 2D at page 1121 of document (6), the 15/85 molar ratio of glycolic to L-lactic acid being described as a 85/15 PLGA in document (6)). However, after 14 days, healing of the aneurism was observed without arterial stenosis when treating the aneurism with an implant containing a polymer with the claimed 90/10 molar ratio of glycolic to L-lactic acid (document (5), slide 22 in the section "Phase II-B (results)" with the title "Polysorb implanted aneurisms", "Polysorb" designating a commercial PLGA co-polymer with a 90/10 molar ratio of glycolic to L-lactic acid).

Thus, the claimed apparatus comprising an implant with a polyglycolic/poly-L-lactic acid copolymer (PLGA) in which the molar ratio of glycolic to L-lactic acid is 90/10 improves the healing of aneurisms without inducing occlusion of blood vessels. The alleged improvement over the closest prior art is thus adequately supported by the comparative experiments filed during the appeal proceedings. The Board is thus satisfied that the technical problem as defined above is effectively solved by the claimed endovascular apparatus.

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

4.6 Whereas document (1) generally describes that an endovascular apparatus for treating aneurisms can comprise an implant made of a biocompatible and bioabsorbable polyglycolic/poly-L-lactic acid copolymer, it does not give any information with regard to the molar ratio of glycolic to L-lactic acid in the polymer and thus, cannot teach that the particular ratio of 90/10 characterizing the presently claimed apparatus improves the healing of aneurisms without inducing occlusion of blood vessels.

The Examining Division did not rely on any further documents in the decision under appeal to challenge obviousness. The Board is not aware of any further relevant document and is, thus, satisfied that the state of the art addressed in the proceedings does not render the claimed invention obvious.

5. The Board concludes from the above that the subject-matter of claim 1 and, consequently that of dependent claims 2 to 7 of the sole request involves an inventive step within the meaning of Articles 52 (1) and 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of claims 1 to 7 received during the oral proceedings of 1 September 2009 and a description yet to be adapted thereto.

The Registrar: The Chairman:

C. Rodríguez Rodríguez R. Freimuth