**Internal distribution code:**

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

# Datasheet for the decision of 3 May 2019

**Case Number:** T 1026/15 - 3.2.08

**Application Number:** 10715009.6

**Publication Number:** 2416812

**IPC:** A61L27/04, A61L31/02, A61L31/14

**Language of the proceedings:** EN

**Title of invention:**
BIOERODIBLE, IMPLANTABLE MEDICAL DEVICES INCORPORATING SUPERSATURATED MAGNESIUM ALLOYS

**Patent Proprietor:**
Boston Scientific Scimed, Inc.

**Opponent:**
BIOTRONIK AG

**Headword:**

**Relevant legal provisions:**
RPBA Art. 13(1), 12(4)
EPC Art. 56

**Keyword:**
Late-filed auxiliary requests - admitted (yes)
Inventive step - (no)

**Decisions cited:**

**Catchword:**

Europäisches Patentamt
European Patent Office
Office européen des brevets

**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

**Case Number: T 1026/15 - 3.2.08**

# D E C I S I O N
# of Technical Board of Appeal 3.2.08
# of 3 May 2019

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | Boston Scientific Scimed, Inc.<br>One Scimed Place<br>Maple Grove, MN 55311-1566 (US) |
| **Representative:** | Peterreins Schley<br>Patent- und Rechtsanwälte<br>Hermann-Sack-Strasse 3<br>80331 München (DE) |
| **Respondent:** (Opponent) | BIOTRONIK AG<br>Ackerstrasse 6<br>8180 Bülach (CH) |
| **Representative:** | Keil & Schaafhausen<br>Patent- und Rechtsanwälte PartGmbB<br>Friedrichstraße 2-6<br>60323 Frankfurt am Main (DE) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted on 19 March 2015 revoking European patent No. 2416812 pursuant to Article 101(3)(b) EPC.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairwoman** | P. Acton |
| **Members:** | A. Björklund |
| | Y. Podbielski |

## Summary of Facts and Submissions

I. The appeal is directed against the decision of the opposition division posted on 19 March 2015 revoking European patent No. EP 2 416 812.

II. The patent proprietor (appellant) filed an appeal against this decision.

III. Oral proceedings before the Board took place on 3 May 2019.

IV. At the end of the oral proceedings the requests of the parties were as follows:

The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained according to the main request filed on 23 July 2018, or, as an auxiliary measure, according to one of:
- auxiliary requests 1 to 4 filed on 23 July 2018,
- auxiliary request 4A filed during the oral proceedings before the Board,
- auxiliary requests 5 to 8, and 11 to 13, filed on 16 July 2015 as main request, auxiliary requests 1 to 3, and 4 to 6, or
- auxiliary requests 9 and 10, filed on 1 March 2017 as auxiliary requests 3A and 3B.

The respondent (opponent) requested that the appeal be dismissed. It also requested that neither the requests filed on 23 July 2018, nor auxiliary requests 7 and 11, nor auxiliary requests 9 and 10 be admitted into the proceedings.

V. The following documents are referred to in the decision:

D1: WO 2008/035948

D3: WO 2007/107286

D12: US 6,908,516 B2

D15: "Microstructure, biocorrosion and cytotoxicity evaluations of rapid solidified Mg-3Ca alloy ribbons as a biodegradable material", X N Gu *et al*, Biomed. Mater. 5, 27 May 2010

FW1ges: "Magnesium Taschenbuch", Aluminium-Verlag Düsseldorf, 1. Auflage, 2000, ISBN 3-87017-264-9

VI. Independent claims

Claim 1 of the **main request** reads:

"A bio-erodible, implantable stent comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C;
wherein the stent includes a structural member and
wherein the supersaturated magnesium alloy forms at least a portion of the structural member;
wherein the alloying element is selected from the group consisting of lanthanum, cerium, dysprosium, gadolinium, tungsten, molybdenum, niobium, tantalum, rhenium, zirconium, chromium, hafnium, and calcium;
wherein the at least one alloying element is distributed substantially homogeneously throughout the body of the alloy; and

wherein the supersaturated magnesium alloy has a microstructure characterized by an average grain size less than 10 µm."

Claim 1 of **auxiliary request 1** reads:

"A bio-erodible, implantable stent comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C;
wherein the stent includes a structural member and
wherein the supersaturated magnesium alloy forms at least a portion of the structural member;
wherein the alloying element is selected from the group consisting of lanthanum, cerium, dysprosium, gadolinium, tungsten, molybdenum, niobium, tantalum, rhenium, zirconium, chromium, hafnium, and calcium;
wherein the at least one alloying element is distributed homogeneously throughout the body of the alloy; and
wherein the supersaturated magnesium alloy has a microstructure characterized by an average grain size less than 10 µm."

Claim 1 of **auxiliary request 2** reads:

"A bio-erodible, implantable stent comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C;

wherein the stent includes a structural member and
wherein the supersaturated magnesium alloy forms at least a portion of the structural member;
wherein the alloying element is selected from the group consisting of lanthanum, cerium, dysprosium, gadolinium, tungsten, molybdenum, niobium, tantalum, rhenium, zirconium, chromium, hafnium, and calcium,
wherein the alloying element is present in supersaturation in the magnesium matrix;
wherein the at least one alloying element is distributed substantially homogeneously throughout the body of the alloy; and
wherein the supersaturated magnesium alloy has a microstructure characterized by an average grain size less than 10 µm."

Claim 1 of **auxiliary request 3** reads:

"A bio-erodible, implantable stent comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C;
wherein the stent includes a structural member and
wherein the supersaturated magnesium alloy forms at least a portion of the structural member;
wherein the alloying element is selected from the group consisting of lanthanum, cerium, dysprosium, gadolinium, tungsten, molybdenum, niobium, tantalum, rhenium, zirconium, chromium, hafnium, and calcium,
wherein the alloying element is present in supersaturation in the magnesium matrix;
wherein the at least one alloying element is distributed homogeneously throughout the body of the alloy; and

wherein the supersaturated magnesium alloy has a microstructure characterized by an average grain size less than 10 µm."

Claim 1 of **auxiliary request 4** reads:

"A bio-erodible, implantable stent comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C;
wherein the stent includes a structural member and
wherein the supersaturated magnesium alloy forms at least a portion of the structural member;
wherein the alloying element is selected from the group consisting of lanthanum, cerium, dysprosium, gadolinium, tungsten, molybdenum, niobium, tantalum, rhenium, zirconium, chromium, hafnium, and calcium;
wherein the at least one alloying element is distributed homogeneously throughout the body of the alloy; and
wherein the supersaturated magnesium alloy has a microstructure characterized by an average grain size less than 10 µm; and
wherein the supersaturated magnesium alloy is obtainable by rapid solidification processes."

Claim 1 of **auxiliary request 4A** reads:

"A bio-erodible, implantable stent comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C;

wherein the stent includes a structural member and wherein the supersaturated magnesium alloy forms at least a portion of the structural member;
wherein the alloying element is selected from the group consisting of lanthanum, cerium, dysprosium, gadolinium, tungsten, molybdenum, niobium, tantalum, rhenium, zirconium, chromium, hafnium, and calcium;
wherein the at least one alloying element is distributed substantially homogeneously throughout the body of the alloy; and
wherein the supersaturated magnesium alloy has a microstructure characterized by an average grain size less than 10 µm; and
wherein the supersaturated magnesium alloy is obtainable by rapid solidification processes."

Claim 1 of the **auxiliary request 5** reads:

"A bio-erodible, implantable medical device comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C, wherein the supersaturated magnesium alloy is obtainable by rapid solidification processes."

Claim 1 of **auxiliary request 6** reads:

"A bio-erodible, implantable medical device comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C, wherein the supersaturated magnesium alloy is obtainable by rapid

solidification processes and wherein the implantable medical device is a stent."

Claim 1 of **auxiliary request 7** reads:

"A bio-erodible, implantable medical device comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C, wherein the supersaturated magnesium alloy is obtainable by rapid solidification processes and wherein the alloying element is selected from the group consisting of lanthanum, cerium, dysprosium, gadolinium, and combinations thereof; or a refractory metal selected from the group consisting of tungsten, molybdenum, niobium, tantalum, rhenium, and combinations thereof; or calcium."

Claim 1 of **auxiliary request 8** reads:

"A bio-erodible, implantable medical device comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C, wherein the supersaturated magnesium alloy is obtainable by rapid solidification processes and wherein the alloying element is selected from the group consisting of lanthanum, cerium, dysprosium, gadolinium, and combinations thereof; or a refractory metal selected from the group consisting of tungsten, molybdenum, niobium, tantalum, rhenium, and combinations thereof;

or calcium; and wherein the implantable medical device is a stent."

Claim 1 of **auxiliary request 9** reads:

"A bio-erodible, implantable medical device comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying clement in hexagonal close-packed magnesium at 25°C;
wherein the alloying element is selected from the group consisting of lanthanum, cerium, dysprosium, gadolinium, tungsten, molybdenum, niobium, tantalum, rhenium, zirconium, chromium, hafnium, and calcium;
wherein the supersaturated magnesium alloy has a microstructure characterized by an average grain size less than 10 µm;
wherein the alloying element is homogeneously distributed throughout the body of the alloy, wherein the alloying element is present in supersaturation in the magnesium matrix; and
wherein the implantable medical device is a stent."

Claim 1 of **auxiliary request 10** reads:

"A bio-erodible, implantable medical device comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C;
wherein the alloying element is selected from the group consisting of lanthanum, cerium, dysprosium, gadolinium, tungsten, molybdenum, niobium, tantalum, rhenium, zirconium, chromium, hafnium, and calcium;

wherein the supersaturated magnesium alloy is obtainable by rapid solidification processes, the supersaturated magnesium alloy has a microstructure characterized by an average grain size less than 10 µm, the alloying clement is homogeneously distributed throughout the body of the alloy and is present in supersaturation in the magnesium matrix; and wherein the implantable medical device is a stent."

Claim 1 of **auxiliary request 11** reads:

"A bio-erodible, implantable medical device comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C, wherein the supersaturated magnesium alloy is obtainable by rapid solidification processes and wherein the alloying element is calcium."

Claim 1 of **auxiliary request 12** reads:

"A bio-erodible, implantable medical device comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C, wherein the supersaturated magnesium alloy is obtainable by rapid solidification processes and wherein the alloying element is calcium, and wherein the implantable medical device is a stent."

Claim 1 of **auxiliary request 13** reads:

"A bio-erodible, implantable medical device comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C, wherein the supersaturated magnesium alloy is obtainable by rapid solidification processes and wherein the alloying element is calcium, wherein the implantable medical device is a stent; and wherein the supersaturated magnesium alloy has a microstructure characterized by an average grain size less than 10 µm, and includes no more than 0.0015 wt.% iron, no more than 0.001 wt.% nickel, and no more than 0.001 wt.% Cu."

VII. The appellant argued essentially as follows:

*Admissibility of requests*

The newly filed main request and auxiliary requests 1 to 4 were a reaction to the communication of the board. They did not change the scope of the appeal proceedings, but merely contained explicit definitions of the alloy characteristics inherently resulting from rapid solidification processing. This applied also to the requests 9 to 10, which addressed the respondent's objections to the product-by-process definition "obtainable by rapid solidification processing". The requests were legitimate reactions to the course of the proceedings and contained simple amendments. They should therefore be admitted into the proceedings.

Auxiliary requests 7 and 11 addressed the impugned decision and should therefore be admitted into the proceedings as well.

*Main request*

The subject-matter of claim 1 of the main request was novel. It differed from the bioerodible implants disclosed in D1 in that it was a stent, in that the alloying element of the supersaturated magnesium alloy was distributed substantially homogeneously throughout the body of the alloy and in that the alloy had an average grain size less than 10 µm.

D1 was not suitable as the closest prior art since it did not disclose stents. But even if the implants of D1 were regarded as the closest prior art, the subject-matter of claim 1 involved an inventive step.

In view of page 4, lines 11 to 14 of the application as originally filed, the skilled person would understand that the claimed microstructure of the supersaturated magnesium alloy resulted in a more homogenous corrosion and therefore a reduced risk of pitting corrosion. The influence of the claimed microstructure on the homogeneity of corrosion was corroborated by D15, page 3, right column. Thus, the risk of breakage of the filigree stent struts was reduced.

Consequently, the problem solved by the subject-matter of claim 1 was to provide a safer bioerodible stent.

While the prior art described the influence of alloy properties on the global corrosion rate, it did not describe that a more homogenous and finer grained alloy reduced the risk of pitting corrosion. The claimed solution to the problem posed was therefore not obvious to the skilled person.

Thus, the subject-matter of claim 1 involved an inventive step.

*Auxiliary request 2*

Claim 1 of auxiliary request 2 explicitly defined that the alloying element was present in supersaturation in the magnesium matrix. This required that the major portion of the alloying element was present in the magnesium matrix and differed from the slight supersaturation with a few atoms which could result from the quenching disclosed in D1. This was a further differing feature which required a rapid solidification processing with cooling rates of 1000 $Ks^{-1}$, as described in paragraph 2 on page 642 of FW1ges.

As with the main request, the problem to be solved was to provide a safer bioerodible stent.

The skilled person would not have had any incentive to use rapid solidification processing in order to provide a safer bioerodible stent. D1 taught the use of extrusion to achieve a fine and uniform microstructure which reduced the global corrosion rate. Should the corrosion rate be optimized, the skilled person would rather change the extrusion parameters or the amount of the alloying element calcium than use rapid solidification processing.

The claimed solution to the problem posed was therefore not obvious to the skilled person. Consequently, the subject-matter of claim 1 of auxiliary request 2 involved an inventive step.

*Auxiliary requests 1 and 3 to 4, 4A and 5 to 13*

It was acknowledged that the reasoning with respect to auxiliary request 2 applied also to auxiliary requests 1 and 3 to 4, 4A and 5 to 12.

Regarding auxiliary request 13 the appellant referred to the written submissions.

VIII. The respondent argued essentially as follows:

*Admissibility of requests*

The new main request and auxiliary requests 1 to 4 and 9 to 10 were late filed without valid reasons. Furthermore, most requests changed the scope of the proceedings since a rapid solidification processing was no longer claimed. They also had no relation to the appealed decision. The late filed requests should therefore not be admitted into the proceedings.

The auxiliary requests 7 and 11 should also not be admitted into the proceedings since they were diverging.

*Main request*

D1 disclosed bioerodible implants made of magnesium alloys supersaturated with calcium. As described on page 11, lines 16 to 18, the implants were for example vascular implants and the skilled person would understand these as stents. The alloying element calcium was distributed substantially homogeneously throughout the body of the alloy, and the average grain size was in the order of magnitude of 10 µm, as could be seen on Figure 8 of D1.

The subject-matter of claim 1 of the main request was therefore not new.

Should D1 not be regarded to disclose a stent, it would have been trivial for the skilled person to make a bioerodible implant in the form of a stent since they were one of the most common types of vascular implants.

Should the distribution of the alloying element and the grain size also be seen as differing features, they would solve the problem of providing a stent with a reduced corrosion rate. The problem formulated by the appellant was incorrect since an increased safety due to reduced pitting corrosion was neither mentioned in, nor was it deducible for the skilled person from the application as filed. D15 was published after the priority date of the patent and did not corroborate any synergetic effect of grain size and homogeneity of the distribution of the alloying elements. It was therefore not relevant for the formulation of the problem.

D1, page 26, lines 7 to 11, described that a fine and uniform microstructure reduced the corrosion rate. As evidenced by FW1ges, page 642, paragraph 2, it also belonged to the common general knowledge of the skilled person that a fine microstructure and homogenous distribution of alloying elements reduced the corrosion rate.

Consequently, it would have been obvious to the skilled person to reduce the grain size and provide for a substantially homogeneous distribution of the alloying elements in order to reduce the corrosion rate. The specific average grain size below 10 µm was too close to the grain sizes already known from D1 to solve a technical problem and therefore represented nothing

more than an arbitrarily selected value which had no particular surprising effect.

The subject-matter of claim 1 of the main request did therefore not involve an inventive step.

*Auxiliary request 2*

Claim 1 of auxiliary request 2 differed from claim 1 of the main request only in that it stated that the alloying element was present in supersaturation in the magnesium matrix.

The amount of supersaturation was not quantified and already the alloys of D1 were supersaturated with calcium in the magnesium matrix. Should this be seen as a further differing feature, it did not involve an inventive step.

It was common general knowledge, as evidenced by FW1ges, page 642, paragraph 2, that rapid solidification processing reduced the corrosion rate. It would therefore have been obvious for the skilled person to use rapid solidification processing in order to reduce the corrosion rate of a bioerodible stent. According to the contested patent, rapid solidification processing inherently led to the claimed characteristics of the supersaturated magnesium alloy. Thus, using rapid solidification processing in the production of stents made of the alloys of D1 would inherently result in a stent according to claim 1 of auxiliary request 2.

The subject-matter of claim 1 of auxiliary request 2 did therefore not involve an inventive step.

*Auxiliary requests 1 and 3 to 4, 4A and 5 to 13*

The subject-matter of claim 1 of the auxiliary requests 1 and 3 to 4, 4A and 5 to 13 did not involve an inventive step either.

As already set out with respect to auxiliary request 2, it would have been obvious to the skilled person to use rapid solidification processing in the production of stents made of the supersaturated alloys of D1 in order to reduce the corrosion rates. When doing so, the skilled person would have arrived at the subject-matter of claim 1 of the auxiliary requests 1 and 3 to 4, 4A and 5 to 12 without any inventive activity.

Claim 1 of auxiliary request 13 further defined specific purity limits for nickel, iron and copper. However, already D1 described the influence of impurities on the corrosion rate, and the specific values of the impurities defined in the claim were commonly known in the field of magnesium alloys, as shown in D3 or D12. Therefore, the selection of the claimed values was obvious in order to further reduce the corrosion rate of the bioerodible stent.

The subject-matter of claim 1 of auxiliary request 13 did therefore not involve an inventive step.

## Reasons for the Decision

1. Admissibility of requests

The respondent argued that the main request and auxiliary requests 1 to 4 filed with the submission of 23 July 2018 as well as the auxiliary requests 9 and 10 filed with the submission of 1 March 2017 should not be

admitted into the appeal proceedings since they were late filed and changed the scope of the proceedings. The respondent also argued that auxiliary requests 7 and 11 filed with the grounds of appeal should not be admitted since they diverged from the respective higher ranking request.

It is true that the new main request and auxiliary requests 1 to 4 and 9 to 10 are late filed. However, the newly filed requests address objections raised by the respondent and remarks in the communication of the Board. This is seen as a normal reaction of a party to the proceedings. Furthermore, the amendments made in these requests are not complex. The Board therefore decided to admit the requests into the proceedings (Rule 13(1) RPBA).

Auxiliary requests 7 and 11 were filed with the grounds of appeal. While the order of these requests formally makes them diverging from their respective previous request, they address the appealed decision. The Board saw therefore no reason to exercise its discretion not to admit them into the proceedings (Rule 12(4) RPBA).

2. Main request

2.1 Novelty in view of D1

2.1.1 D1 discloses biodegradable implants made of magnesium-calcium alloys. Example 2 discloses magnesium-calcium alloy compositions used for the biodegradable implants, where the concentration of calcium is 0.8, 5, 10.5, 22.5 or 33 % by weight.

The solubility of calcium in magnesium at room temperature is very low, and according to FW1ges, page

115, "Bild 6.3.5", it is practically zero at room temperature. Apart from the value of 0.8%, the concentrations of calcium of the alloys used in D1 are well above the solubility limit in magnesium at 25°C.

As described on page 13, lines 7 to 11, the molten alloy is moulded to an implant, and the alloy can be solidified by rapid quenching. This prevents precipitation of all of the calcium present in the liquid alloy, and therefore more than an insignificant amount of calcium will remain in the magnesium-matrix. Consequently, the alloy of the implants of D1 is supersaturated. This has not been contested by the appellant.

2.1.2 Document D1 undisputedly discloses:

A bio-erodible, vascular implant (page 11, lines 16 to 18) comprising a supersaturated magnesium alloy that includes magnesium and at least one alloying element present in a concentration in excess of the equilibrium solid solubility concentration of the alloying element in hexagonal close-packed magnesium at 25°C (calcium in Example 2);
wherein the implant includes a structural member, and wherein the supersaturated magnesium alloy forms at least a portion of the structural member (it is implicit that the cardiovascular implant made of the alloy has a structural member);
wherein the alloying element is calcium (Example 2).

2.1.3 The respondent argued that D1, page 11, lines 16 to 18 implicitly disclosed stents, and also that figure 8 disclosed a magnesium alloy with 33 % calcium which was distributed substantially homogeneously throughout the

body of the alloy and had an average grain size of less than 10 µm.

It is true that stents are common vascular implants. However, in line with the established case law (Case Law of the Boards of Appeal, 8th Edition 2016, I.C. 5.2.6), the generic disclosure of a vascular implant in D1 does not destroy the novelty of a specific vascular implant in the form of a stent.

Furthermore, although Figure 8 seems to show grains with sizes in the order of magnitude of 10 µm, this is not a direct and unambiguous disclosure of an average grain size of less than 10 µm.

Nor does D1 disclose that the calcium is distributed substantially homogeneously throughout the body of the alloy. The distribution of calcium in the alloy can neither be deduced from the figures, nor is it described in the text. A substantially homogenous distribution of calcium throughout the body of the alloy would also not be an intrinsic result of the casting and extrusion used in the manufacturing of the implants of D1.

2.1.4 The subject-matter of claim 1 therefore differs from the vascular implant disclosed in D1 in that:
- the vascular implant is a stent,
- the at least one alloying element is distributed substantially homogeneously throughout the body of the alloy,
- the supersaturated magnesium alloy has a microstructure characterized by an average grain size less than 10 µm.

Thus, the subject-matter of claim 1 is new.

2.2 Inventive step

2.2.1 Closest prior art

The appellant argued that D1 cannot be regarded as the closest prior art since it does not disclose a stent and therefore would not be a suitable starting point for arriving at the subject-matter of claim 1.

It is true that D1 puts most focus on bioerodible implants for osseous tissue. However, page 11, lines 16 to 18, discloses that the implants of D1 also can be vascular implants and stents are amongst the most common vascular implants. The skilled person concerned with the development of bioerodible stents would therefore consider document D1. Thus, the vascular implant disclosed therein is a suitable starting point for the assessment of inventive step of claim 1 of the main request.

2.2.2 Technical Effect – Problem solved

The subject-matter of claim 1 differs from the implant disclosed in D1 in the features set out in point 2.1.4.

The appellant argued that the skilled person would understand from page 4, lines 11 to 14 of the original application that the differing features would lead to a stent which is less susceptible to pitting corrosion and therefore safer. Consequently, the problem to be solved was to provide a safer bioerodible stent.

However, neither this passage, nor any other passage of the original application mentions that the claimed characteristics of the microstructure of the magnesium

alloy have an influence on pitting corrosion or on the uniformity of corrosion. It is only explained that the small average grain size and a substantially homogenous distribution of the alloying elements "minimise creation of microgalvanic cells which enhance corrosion rates", that is, they reduce the global corrosion rate. The effect the appellant relies on when formulating the technical problem is therefore not deducible for the skilled person from the application as filed. D15 is a research paper which was published after the priority date of the disputed patent. It cannot establish the common general knowledge of the skilled person at the priority date of the disputed patent and is therefore not relevant for the formulation of the objective technical problem.

Consequently, the assessment of inventive step is based on the problem formulated by the respondent, namely to provide a biodegradable stent with a reduced corrosion rate.

2.2.3 Solution

D1 does not describe any specific vascular implant, but stents together with filters, grafts and coils are common vascular implants. Therefore, it is obvious for the skilled person to apply the teaching of D1 to a stent.

The other differing features of claim 1, namely the substantially homogenous distribution of the alloying element and the average grain size of less than 10 µm also do not involve an inventive step for the reasons set out below.

D1, page 26, lines 7 to 8 describes that "the microstructure became fine and uniform by extrusion, thereby greatly reducing the corrosion rate". The appellant submitted that this taught the skilled person that extrusion leads to a reduced corrosion rate. While it is correct that the microstructure is mentioned as a result of extrusion, the teaching to the skilled person is that the resulting fine and uniform microstructure reduces the corrosion rate irrespective of the method by which it has been achieved. Already from this passage in D1, the skilled person is directed towards a fine and uniform microstructure in order to reduce the corrosion rate.

Furthermore, as evidenced by FW1ges, page 642, paragraph 2, it belongs to the common general knowledge that a more homogenous distribution of alloying elements and a finer grain size lead to a higher chemical resistance, i.e. a lower corrosion rate.

It would therefore have been obvious to the skilled person aiming at reducing the corrosion rate of a bioerodible stent comprising a magnesium-alloy that a more homogenous distribution of the alloying element, i.e. a "substantially homogenous distribution", and a smaller grain size would be a solution to the problem posed.

The appellant has not put forward any reasons as to why an average grain size less than the specific value of 10 µm provides any surprising advantage. Moreover, the claimed grain size is also in the same order of magnitude as the grain sizes disclosed in D1, Figure 8. The selection of the specific value "less than" 10 µm is therefore an arbitrary selection which does not involve any inventive activity.

The subject-matter of claim 1 of the main request does therefore not involve an inventive step.

2.2.4 It is noted that in the event that the skilled person in view of common general knowledge had understood from the application as filed that the claimed microstructure leads to reduced pitting corrosion, it would also have been obvious that the claimed microstructure would be a means to reduce the risk of pitting corrosion. Consequently, even on the basis of the problem formulated by the appellant, the subject-matter of claim 1 would not involve an inventive step.

3. Auxiliary request 2

Claim 1 of auxiliary request 2 explicitly defines that the alloying element is present in supersaturation in the magnesium matrix.

According to the appellant, this is a result of the rapid solidification processing mentioned on page 4, line 29 to page 5, line 2 of the application as originally filed. A true supersaturation of the magnesium matrix would require a cooling rate of at least 1000 $Ks^{-1}$, as described in paragraph 2 on page 642 of FW1ges. It would not be an inherent feature of the implants of D1 since the cooling rate during the moulding and quenching in D1 would not be sufficiently high to achieve a true supersaturation of the magnesium-matrix.

It is true that D1 does not disclose the cooling rates achieved by the “rapid quenching”. However, as admitted by the appellant, it will not be so slow that the calcium will precipitate to such an amount that it is

below the solubility limit in the magnesium-matrix at 25°C. Whether this would be a supersaturation of the magnesium-matrix in the sense of the contested patent is disputed, but can be left undecided since it has no influence on the outcome of the inventive step analysis of the subject-matter of claim 1.

The appellant has not provided any convincing reasons as to why the supersaturation in the magnesium-matrix would have an effect on the uniformity of the corrosion, nor is this mentioned in the original application. Consequently, even under the assumption that the supersaturation in the magnesium-matrix is a further differing feature, the problem to be solved by the differing features remains to provide a biodegradable stent with a reduced corrosion rate.

As evidenced by FW1ges, page 642, paragraph 2, it belongs to the common general knowledge of the skilled person that rapid solidification processing of magnesium-alloys leads to an improved chemical resistance, i.e. a lower corrosion rate. Consequently, it would be obvious for the skilled person to use rapid solidification processing in the manufacturing of a stent made of the supersaturated magnesium-calcium alloy of D1.

According to the patent, rapid solidification processing leads to the claimed microstructure of the magnesium alloy. The use of such processing in the manufacturing of a stent with the alloys of D1 would thus inevitably lead to a stent according to claim 1 of auxiliary request 2.

The subject-matter of claim 1 of auxiliary request 2 does therefore not involve an inventive step.

4. Auxiliary requests 1, 3 to 4, 4A and 5 to 12

As acknowledged by the appellant, the reasoning with respect to auxiliary request 2 applies mutatis mutandis to auxiliary requests 1, 3 to 4, 4A and 5 to 12.

For the reasons set out above, it would be obvious for the skilled person to use rapid solidification processing in the manufacturing of a bioerodible implant in the form of a stent made of the supersaturated magnesium-calcium alloys of D1. Doing so would inevitably lead to the stents of claim 1 of auxiliary requests 1, 3 to 4, 4A, 6, 8 to 10 and 12 and the medical devices of claim 1 of auxiliary requests 5, 7 and 11.

The subject-matter of claim 1 of these requests does therefore not involve an inventive step.

5. Auxiliary request 13

Claim 1 of auxiliary request 13 contains the further differing feature that the alloy does not include more than 0.0015 wt.% iron, 0.001 wt.% nickel and 0.001 wt.% Cu [sic].

During the oral proceedings, the appellant referred to its written submissions regarding auxiliary request 13. However, these do not contain any arguments as to why the choice of these specific values involves an inventive step, but merely explain where this feature was disclosed in the application as originally filed.

It is common general knowledge that impurities have a negative influence on corrosion, and this is also

mentioned in D1, page 26, line 10. Reducing the amount of impurities to limit the rate of corrosion is therefore obvious to the person skilled in the art. The specific values in claim 1 of auxiliary request 13 are within ranges known to the skilled person, see D3, page 10, lines 32 to 36 or claim 3, or D12, column 174, lines 60 to 67.

The selection of the specific values of claim 1 of auxiliary request 13 does therefore not involve any inventive activity.

Consequently, the subject-matter of claim 1 of auxiliary request 13 does not involve an inventive step.

## Order

## For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated