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# Datasheet for the decision of 15 January 2019

**Case Number:** T 2136/15 - 3.2.08

**Application Number:** 07837908.8

**Publication Number:** 2051748

**IPC:** A61F2/00

**Language of the proceedings:** EN

**Title of invention:**
INTRAMYOCARDIAL PATTERNING FOR GLOBAL CARDIAC RESIZING AND RESHAPING

**Applicant:**
CardioPolymers, Inc.

**Headword:**

**Relevant legal provisions:**
EPC Art. 54(5), 112(1)(a)
Vienna Convention on the Law of Treaties (1986) - Art. 31, 32

**Keyword:**
Novelty - (no) - novelty of use - second (or further) medical use
Referral to the Enlarged Board of Appeal - by the board of appeal - (no)

**Decisions cited:**
T 1758/15, T 2003/08, G 0005/83

**Catchword:**

Europäisches Patentamt
European Patent Office
Office européen des brevets

**Beschwerdekammern**

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**Case Number: T 2136/15 - 3.2.08**

# D E C I S I O N
# of Technical Board of Appeal 3.2.08
# of 15 January 2019

| | |
|---|---|
| **Appellant:** (Applicant) | CardioPolymers, Inc.<br>26051 Merit Circle, Suite 102<br>Laguna Hills, CA 92653 (US) |
| **Representative:** | Lucas, Brian Ronald<br>Lucas & Co.<br>135 Westhall Road<br>Warlingham, Surrey CR6 9HJ (GB) |
| **Decision under appeal:** | **Decision of the Examining Division of the European Patent Office posted on 2 April 2015 refusing European patent application No. 07837908.8 pursuant to Article 97(2) EPC.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairwoman** | P. Acton |
| **Members:** | C. Herberhold |
| | C. Schmidt |

## Summary of Facts and Submissions

I. By decision posted on 2 April 2015 the Examining Division refused European patent application No. 07837908.8 on the grounds of lack of novelty.

II. The appellant (applicant) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.

III. Oral proceedings before the Board were held on 15 January 2019.

At the end of the oral proceedings, the appellant requested that the decision under appeal be set aside and that the patent be granted on the basis of the main request, filed with a letter dated 31 December 2014. Alternatively, it requested to grant a patent on the basis of one of the auxiliary requests 1, 2 or 3 filed with the letter setting out the grounds of appeal dated 11 August 2015 (1st auxiliary request), a letter dated 20 November 2018 (2nd auxiliary request), or at the oral proceedings before the Board (3rd auxiliary request).

The appellant further requested to refer the following question to the Enlarged Board of Appeal:

"Is recognition of the novelty of a substance or composition for a new surgical and/or therapeutic application under Article 54(5) EPC precluded where the substance or composition after treatment brings about its therapeutic effect at least partly as a result of physical properties of the substance post-administration?"

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

"A self-gelling alginate for treating a dilated left ventricle of a heart of a patient suffering cardiomyopathy, said alginate

being for injection while undergoing gelling into a free myocardial wall of the dilated left ventricle in at least three injection sites respectively containing therapeutically effective amounts of the alginate for thickening the myocardial wall and reducing systolic volume of the left ventricle,

the sites for injection being spaced to have essentially no linkage and being circumferentially distributed in a therapeutically effective pattern across most of the ventricular free wall at or in proximity to the near widest part of the ventricle and along anterior, anterior lateral and posterior lateral surfaces of the heart for globally reducing stress in the free myocardial wall."

V. Claim 1 of auxiliary request 1 reads as follows (differences with the main request are underlined):

"A self-gelling alginate for treating a dilated left ventricle of a heart of a patient suffering cardiomyopathy, said alginate

being for injection while undergoing gelling into a free myocardial wall of the dilated left ventricle in at least three injection sites respectively containing therapeutically effective amounts of the alginate for thickening the myocardial wall and reducing systolic volume of the left ventricle,

the self-gelling alginate having a pre-gel viscosity suitable for injection, being non-contractile when in situ and having a post-gel stiffness in situ equal to or slightly greater than normal myocardium;

the sites for injection being spaced to have essentially no linkage and being circumferentially distributed in a therapeutically effective pattern across most of the ventricular free wall at or in proximity to the near widest part of the ventricle and along anterior, anterior lateral and posterior lateral surfaces of the heart for integration into and thickening at least part of the cardiac wall about the chamber so as to globally reduc~~ing~~e stress in the free myocardial wall, to stabilise or reduce chamber size and give rise to a sustainable therapeutic effect on cardiac function."

VI. Claim 1 of auxiliary request 2 reads as follows:

"A self-gelling alginate for use in the treatment by surgery of a dilated left ventricle of a heart of a patient suffering cardiomyopathy by injection while undergoing gelling into a free myocardial wall of the dilated left ventricle in at least three injection sites respectively containing therapeutically effective amounts of the alginate for thickening the myocardial wall and reducing systolic volume of the left ventricle, the self-gelling alginate having a pre-gel viscosity suitable for injection, being non-contractile when in situ and having a post-gel stiffness in situ equal to or slightly greater than normal myocardium, the sites for injection being spaced to have essentially no linkage and being circumferentially distributed in a therapeutically effective pattern across most of the ventricular free wall at or in

proximity to the near widest part of the ventricle and along anterior, anterior lateral and posterior lateral surfaces of the heart for integration into and thickening at least part of the cardiac wall about the chamber so as to globally reduce stress in the free myocardial wall, to stabilise or reduce chamber size and give rise to a sustainable therapeutic effect on cardiac function."

VII. Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 2 in the following amendment (underlined):

"A self-gelling alginate comprising as one component sodium alginate fully solubilized in an aqueous solution and as the other component a divalent cation dispersed or dissolved in solution for use in the treatment by surgery of a dilated left ventricle of a heart ...".

VIII. The essential arguments of the appellant can be summarised as follows:

*Novelty*

While it was true that the alginates defined in the claims of every request were known in the art per se, their use for treating a dilated left ventricle by injection into the heart in a therapeutically effective pattern was not. Since alginates clearly qualified as a substance or composition in accordance with Article 54 (5) EPC, this article imparted novelty to the claimed subject-matter.

Already taking the ordinary meaning of the term 'substance or composition', which in accordance with

Article 31(1) of the Vienna Convention on the Law of Treaties (hereafter "Vienna Convention") should be used for interpretation of a treaty and as in the present case of Article 54(5) EPC, the claimed alginate - a specific chemical - fell under the term substance or composition.

An interpretation which did not consider alginate a 'substance or composition' because it was not the active principle behind the therapeutic effect - such as in T 1758/15 - would lead to a result which was manifestly absurd and unreasonable and therefore contrary to an interpretation in accordance with Article 32(b) of the Vienna Convention.

The absurdity of such an interpretation of the term 'substance or composition' was further exemplified by the preparation Gaviscon, which mitigated the symptoms of oesophageal reflux by formation of a so-called 'raft' in the stomach. In this case, the 'active principle' would be regarded not as the composition of matter taken by the patient but as the raft which was a physical device.

Following the interpretation in T 1758/15 would lead to not considering the product Gaviscon as a "substance and composition" within the meaning of Article 54(5) EPC, a finding which would be contrary to the opinion of medical practitioners and the public, almost in their entirety, who would definitely regard the product as falling into the medical substance or composition category.

Not considering the claimed alginate a substance or composition was indeed absurd. The therapeutically effective pattern of alginate injections could in no

way be regarded as a device. All injection sites were isolated and, while their effect was a collective result, it was not a co-operative result, such that it was inappropriate to regard them as a "macrostructure" or "superstructure".

Moreover, the claims of the present main request and even more so of the present auxiliary requests, precisely defined a specific chemical with unique suitability for injection into the heart muscle. Alginate did not cause an inflammatory reaction, but only a fibrotic reaction which led to an encapsulation response. It did not interfere with the electric conductivity of the heart, such that no arrhythmias would arise, and it was further fine-tuned to a specific viscosity which allowed it to conform to the heart wall in a way that promoted reduction of wall tension. Lastly, alginate did not degrade which made the therapeutic effect permanent.

It was simply not credible that other materials likewise exhibited such favourable properties. While it was true that the description mentioned further possible materials and even devices for being implanted in the disclosed therapeutic pattern, the skilled reader would realise that the most relevant teaching of the invention was in the specific example and consequently focus on that information.

To conclude, the effect of the invention was a combination of biochemical and physical properties. While the specific injection pattern was important, the substance itself was equally important, such that the substance should be eligible for purpose-related product protection.

*Referral of a question to the Enlarged Board of Appeal*

If one accepted that Article 54(4), (5) EPC via interpretation of G 5/83 offered purpose-related product protection only for substances and compositions having an active principle, i.e. which qualify as the 'active ingredient', this clearly resulted in a gap in the law not acceptable from a policy point of view. The system for approval of both medicinal products and products of the pharmaceutical industry was equally hostile to the inventor. The same rationale underlying G 5/83 and the consequent introduction of Article 54(5) into the EPC should thus also be applied to such products, making second medical use protection for substances as the alginate of the present invention available. Indeed, it appeared that this would have been the intention of any legislator, who certainly did not want to exclude from patent protection an invention as the present one, which was highly beneficial to patients. The case should thus be referred to the Enlarged Board, to allow them to correct that undesirable gap in the law by answering the requested question.

## Reasons for the Decision

1. Novelty

1.1 The appellant admits that the substance "alginate" per se, as defined in all of the requests, was known in the prior art. This is in accordance with paragraph [0067] of the application which states that the alginate injectate was a commercially available self-gelling alginate formulation.

Thus, novelty of the claimed subject-matter could only be acknowledged by virtue of the purpose-related product claim form authorised for a further medical use of a substance or composition under Article 54(5) EPC.

However, said article imparts novelty only to substances or compositions. It thus has to be examined, whether the claimed self-gelling alginate can be considered a substance or composition within the meaning of Article 54(5) EPC or not.

1.2 Following the general rule of interpretation as advocated in Article 31 of the Vienna Convention on the Law of Treaties, regularly applied by the boards of appeal (see for example G 5/83, points 3 *et seq.*, OJ EPO 1985, 64 and G 1/07, point 3.1, OJ 2011, 134), the appellant was of the opinion that the alginates claimed clearly fell under the term 'substance or composition' in its ordinary meaning. The new uses defined in the respective independent claims thus imparted novelty on the alginates claimed.

1.3 Article 31(1) of the Vienna Convention states that a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

Thus, in addition to the ordinary meaning of the terms, due consideration is to be given to their context and to the object and purpose of the treaty.

According to Article 31(2) of the Vienna Convention, the context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:

(a) ...
(b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.

For a proper interpretation of the terms of Article 54(5) EPC following Article 31(1), (2) of the Vienna Convention, it is therefore necessary to take into account the legislative history of said article.

1.4 The final wording of Article 54(4) and (5) EPC 2000, accepted by the diplomatic conference held in Munich from 20 to 29 November 2000, goes back to a proposal of the Swiss delegation made in MR/18/00 dated 21 November 2000 (see MR/24/00, points 138-143). Thus, the object and purpose of Article 54(5) EPC has to be taken from MR/18/00.

The document states that the wording of Article 54(5) EPC was intended to match as closely as possible the scope of protection to the scope provided by a Swiss-type claim, i.e. see MR/24/00, point 139, without extending protection beyond the legal status quo.

In other words, the legislator intended the case law developed by the EPO Enlarged Board of Appeal (i.e. decision G 5/83) to be enshrined in the Convention (see MR/2/00; MR/18/00; and MR/24/00, points 138-143). This is accordingly reflected in the Synoptic presentation EPC 1973/2000 - Part 1: The Articles (Official Journal, Special Edition No. 4, 2007, page 54, point 4).

In view of the so-established context, object and purpose of the amended article, reference needs to be made to Enlarged Board of Appeal decision G 5/83 (OJ

EPO 1985, 64) in order to establish the required interpretation of the term "substance or composition".

An interpretation of Article 54(5) EPC following G 5/83 thus clearly corresponds to the explicitly declared intention of the legislator, even if the result were - in the subjective view of the appellant - manifestly absurd and unreasonable.

1.5 In T 2003/08, Board 3.3.04 had analysed Enlarged Board of Appeal decision G 5/83, (see T 2003/08, Reasons points 15-18) and came to the conclusion that G 5/83 endorsed the interpretation of the term substance or composition as being the active agent or ingredient of the particular specific medical use (see G 5/83, the term "active ingredient" is used synonymously with the term "substance or composition" for example in the Reasons points 20 and 23). The present Board concurs with this interpretation.

With this interpretation in mind, Board 3.3.04 developed an approach to determine whether or not "a substance or composition" is used in a treatment (Reasons point 18), an approach which was likewise used in T 1758/15 and which is also helpful in the present case.

In particular, it suggested establishing

(a) the means by which the therapeutic effect is achieved and

(b) whether that which achieves the therapeutic effect is a chemical entity or composition of chemical entities.

A typical example in which these conditions are fulfilled would be a pharmacologically active ingredient, such as the chemical substance 1,4-dihydro-2,6-dimethyl-4-(3'-nitrophenyl)-pyridin-3-ß-methoxyethylester-5-isopropylester active to treat pathologically decreased cerebral functions in T 17/81 of 30 May 1983, the referring decision of G 5/83.

1.6 In the present case, a particular "therapeutically effective pattern" is created by injecting the self-gelling alginate in at least three injection sites, the dose being effective for thickening the myocardial wall and reducing systolic volume of the left ventricle.

The alginate acts as a "space occupying agent" (application, paragraph [0048]), distributed in the myocardium in a suitable pattern. By its presence, the space-occupying agent with its pattern of distribution within the myocardium essentially cinches the baggy globe shaped chamber back to a conical shape that is the most effective pump (application, paragraph [0086]), thereby improving the cardiac function.

The therapeutic effect of the use is thus caused by the ensemble of "space-occupying" physical structures formed of the alginate positioned in particular patterns of distribution. These patterned 3D macrostructures do not, however, qualify as a 'chemical entity' or 'composition of chemical entities' within the meaning of G 5/83. As discussed in T 1758/15, Reasons 5.2.6 and 5.2.8, such a material qualifies as an initially viscous device rather than as a substance or composition.

1.7 The appellant argued that the therapeutically effective pattern of alginate injections could in no way be

regarded as a device because the injection sites were isolated and the effect was collective rather than co-operative. However, according to paragraph [0086], the improvements are believed to result from the action of the single circumferential line injections, which essentially cinch the baggy globe shaped chamber back to a conical shape that is the most effective pump. In 'cinching' the baggy globe shaped chamber to a conical shape, the gelled blobs of alginate arranged in the line pattern co-operate to reach the desired effect. Conversely, a collection of such gelled blobs of alginate arranged in a different pattern (e.g. multiple line pattern) reaches a weaker effect. Arranging all gelled blobs for instance in the apex of the heart would not have the effect of shaping the chamber back to a conical shape. The effect of the 'alginate injections circumferentially distributed in a therapeutically effective pattern' is thus not simply cumulative but co-operative. Anyhow, the superstructure in which the alginate injections co-operate cannot be considered a 'chemical' in the above-discussed sense.

1.8 The appellant further argued that while the injection pattern was important, the biochemical and physical properties of the alginate also played a decisive role, which justified eligibility for purpose-related product protection.

However, according to the application (paragraphs [0098] *et seq*.) many different types of biocompatible materials, some injectable and some implantable, are suitable and may be used. Paragraphs [0115] *et seq*. mention a myriad of possible such polymers; paragraphs [0124] *et seq*. further state that implantable mechanical devices such as particles, rods, spheres, expandable small balloons, and struts may also be used

as occupying agent. It thus has to be concluded that the beneficial effect of the created patterned superstructure is basically independent of the material from which the space-occupying elements in the pattern are made, as long the space-occupying elements are arranged in the particular therapeutically effective pattern and as long as they are biocompatible.

To put it differently, if the alginate is "active" then it is in building the 3D macro/superstructure. Conversely, it is not active in reshaping the heart chamber, this being the action of the 3D superstructure created. It is also not active in the surgical injections, it being rather the passive object thereof.

The Board further notes that not causing an inflammatory reaction but encapsulation is neither mentioned in the application, nor is part of said use defined in the claim.

The injectates and implants within the pattern not being pro-arrhythmic is mentioned in paragraph [0055], without, however, any link to the particular alginate. Rather, the effect is ascribed to any space-occupying agent within the suitable pattern as described in paragraph [0055] which belongs to the application's section dealing with "Patterns of distribution of Space-Occupying Agent", see paragraph [0053].

Furthermore, the particular stiffness of ionically cross-linked alginate hydrogels is disclosed as controllable "in various ways", including e.g. variation of the molecular weight distribution for controlling and decoupling the viscosity of the pre-gel solution from the post-gel stiffness (paragraph [0117]).

Moreover, the effects mentioned by the appellant are not effects of the alginate as the active agent when interacting with the body. The effects, rather, are in determining the mechanical or biological properties of the particular patterned blob-superstructure formed, just as the elasticity and the degree of tissue interaction of a hip implant depend on the titanium alloy used.

Consequently, the alginate cannot be considered the active ingredient or active principle and thus does not qualify as a "substance or composition" in accordance with Article 54(5) EPC.

1.9 As to the preparation Gaviscon mentioned by the appellant to demonstrate the - in its view - absurdity of interpreting "substance or composition" in the sense of "active ingredient", the Board notes the following:

As pointed out during the oral proceedings, according to its product information sheet, Gaviscon comprises as 'active ingredient' aluminium hydroxide and magnesium carbonate, and as 'inactive ingredients' (among others) alginic acid and sodium bicarbonate. Bicarbonate reacts with the stomach acid to form $CO_2$, such that in combination with the alginic acid a foam-like structure develops - the raft mentioned by the appellant. The terminology used in this product information sheet thus rather supports the Board's conclusion that the 'inactive ingredient' alginate, even though it is involved in the formation of the "raft", is not considered to be the 'active ingredient' of Gaviscon in the meaning of the term used in pharmacology, the field with which G5/83 was dealing.

Contrary to the present case, the antacids aluminium hydroxide and magnesium carbonate are 'active ingredients' within the meaning of G 5/83 and consequently within the meaning of Article 54(5) EPC, and they are thus generally eligible for purpose-related product protection if the other requirements of Article 54(5) are fulfilled.

The example of Gaviscon thus cannot change the Board's above evaluation.

1.10 To conclude, the alginate claimed in all requests does not qualify as a substance or composition within the meaning of Article 54(5) EPC. Claim 1 of all requests is thus not novel.

2. Referral of a question to the Enlarged Board of Appeal

As discussed above, the present case can be decided on the basis of the EPC, the settled Enlarged Board of Appeal case law and the travaux préparatoires. There is thus no need to refer the question posed. The Board can furthermore see no contradiction, in particular with decision T2003/08. Indeed, as can be seen from the reasoning above, the present decision exactly follows the approach developed therein.

During the oral proceedings, the appellant did not focus on why an answer to the formulated question by the Enlarged Board was required in order to decide the case. Rather, the argument was made that an invention as the present one should be patentable, for the benefit of innovation, patients and the society as a whole.

The Board notes that also Article 53(c) EPC is a compromise. It balances the wish to foster innovation by allowing inventors to gain profit from their ideas, with the wish not to inhibit the free choice of medical practitioners to choose the best available treatment for their patients. Necessarily, not allowing patent protection for surgical, therapeutic or diagnostic methods results in possibly highly beneficial inventions not being eligible for patent protection. There is thus no general principle underlying the EPC according to which every great and beneficial (medical) invention should be patentable.

It is true that for "active ingredients" G 5/83 introduced purpose-related product protection in a praetorian way, a development which was later integrated into the EPC 2000. The wish to have such an exception available also for other medicinal products is understandable. However, when deciding on the amendments in the EPC 2000 the legislator had the possibility to amend Article 54 EPC in order to also cover further exceptions. They did not only not do so, but furthermore clearly stated that the article was intended to match the scope of protection provided by a Swiss-type claim as closely as possible.

In view of this clear statement by the legislator, there is no room for further opening, in a praetorian way, patent protection for medicinal products which are not substances or compositions within the meaning of Article 54(5) EPC. This appears to be a desire which would rather need to be pursued in the political arena.

**Order**

**For these reasons it is decided that:**

1. The appeal is dismissed.

2. The request for a referral of the case to the Enlarged Board is rejected.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated