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Datasheet for the decision of 14 January 2014

Case Number: T 2316/11 - 3.3.10

Application Number: 07798666.9

Publication Number: 2027729

IPC: H04Q7/20

Language of the proceedings: EN

Title of invention:
EMBOLIZATION DEVICE CONSTRUCTED FROM EXPANSIBLE POLYMER

Applicant:
MicroVention, Inc.

Headword:

Relevant legal provisions:
EPC Art. 84, 113(1)

Keyword:
Claims - clarity (no)
No unequivocal generally accepted meaning for the feature "responsive when exposed to body fluids"
Right to be heard - non-attendance at oral proceedings

Decisions cited:
T 0341/92, T 0337/95, T 0728/98, T 0560/09

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

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Case Number: T 2316/11 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 14 January 2014

Appellant: (Applicant)	MicroVention, Inc. 75 Columbia, Suite A Aliso Viejo, CA 92656 (US)
Representative:	Green, Mark Charles Urquhart-Dykes & Lord LLP 3rd Floor 33 Glasshouse Street London W1B 5DG (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 24 June 2011 refusing European patent application No. 07798666.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: P. Gryczka
Members: J. Mercey
C. Schmidt

Summary of Facts and Submissions

I. The present appeal lies from the decision of the Examining Division refusing European patent application No. 07 798 666.9.

II. The Examining Division held *inter alia* that claim 1 of both the main request and the auxiliary request contained subject-matter which extended beyond the content of the application as filed, contrary to the provisions of Article 123(2) EPC.

III. With the Statement of Grounds of Appeal dated 27 October 2011, the Appellant (Applicant) submitted a main request and an auxiliary request.

IV. In a communication annexed to the summons to oral proceedings dated 10 September 2013, the Board indicated *inter alia* that the term "environmentally-responsive" appeared to be unclear, since said term did not appear to have a well-recognised meaning in the art, such that the skilled person could not clearly distinguish hydrogels that fell under the claim from those that did not.

V. With letter dated 13 December 2013, the Appellant filed a new main request and an auxiliary request. Claim 1 of the main request reads as follows:

"A device for implantation in an animal comprising: a hydrogel having ionizable functional groups wherein said hydrogel comprises at least one non-ionic macromer, further wherein said hydrogel is responsive when exposed to body fluids, and further wherein said hydrogel has an unexpanded bending resistance of 0.1 mg to about 85 mg under test using a Gurley 417ER tubular

sample stiffness tester with a 5g counterweight and a sample length of 2.54 cm and wherein said hydrogel is provided in continuous elongated form, characterised in that said hydrogel is arranged substantially co-axially within a carrier member."

Claim 1 of the auxiliary request differs from claim 1 of the main request in that the non-ionic macromer is selected from the group comprising poly(ethylene glycol) di-acrylamide, poly(ethylene glycol) di-acrylate, poly(ethylene glycol) dimethacrylate, derivatives thereof, or combinations thereof.

The Appellant provided no arguments as to why the term "responsive when exposed to body fluids" which had replaced the term "environmentally-responsive" in claim 1 of each of the newly filed requests should now be considered to fulfil the requirements of Article 84 EPC.

VI. With letter dated 19 December 2013, the Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or the auxiliary request, both requests filed with letter dated 13 December 2013.

VII. Oral proceedings were held on 14 January 2014 in the absence of the Appellant, who, after having been duly summoned, informed the Board in its letter dated 13 December 2013 that it would not attend. At the end of the oral proceedings, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request and auxiliary request

Article 84 EPC

2. It is established jurisprudence of the Boards of Appeal of the EPO that, in order to ensure legal certainty, a claim must clearly define the subject-matter for which protection is sought (see T 728/98, OJ EPO 2001, 319, point 3.1 of the reasons as well as T 337/95, OJ EPO 1996, 628, points 2.2 to 2.5 of the reasons). This requirement serves the purpose of ensuring that the public is not left in any doubt as to which subject-matter is covered by a particular claim and which is not.

2.1 In the present case, claim 1 of both requests is directed to a device for implantation comprising a hydrogel, wherein said hydrogel is defined *inter alia* in terms of functional features, one of which is that it is "responsive when exposed to body fluids".

2.2 Technical features may under certain circumstances be expressed in general functional terms. However, the function must be able to be verified by tests or procedures adequately specified in the description or known to the skilled person. That means not only that a feature in the claim must be comprehensible, but must also be non-ambiguous in the sense of it can be determined without any ambiguity whether the claimed functional requirement is satisfied of not. Hence, means of distinction are mandatory in order to allow a definition by a function instead of by a structure in a

claim (see T 560/09, not published in OJ EPO, point 2 of the reasons).

2.3 Therefore, the requirement of clarity of a claim requires clear identification of the meaning of the functional technical feature "responsive when exposed to body fluids" in order to establish without any doubt the subject-matter covered by that claim. Hence, there must be an unambiguous distinction between hydrogels having the claimed function and hydrogels not having this function.

2.4 However, it is not apparent which **type** of response of the hydrogel when it is exposed to body fluids qualifies as "responsive", the Appellant having neither alleged, let alone provided any evidence of, an unequivocal generally accepted meaning (see T 728/98, *loc. cit.*, point 3.3 of the reasons) of the expression "responsive when exposed to body fluids" in any context, let alone in the context of a hydrogel comprised in a device for implantation in an animal, nor is the Board aware of any.

2.5 In paragraph [0020] of the application as filed, which is the part of the description to which the Appellant refers as providing a basis for this feature, already different definitions of "environmentally sensitive" are provided, namely that the expansile element exhibits delayed expansion when exposed to body fluids, or expands quickly upon contact with body fluid, or comprises a porous or reticulated structure that may form a surface or scaffold for cellular growth. It could, however, also mean, for example, that the hydrogel biodegrades, partly or completely, upon contact with body fluid (see last line of paragraph [0053]). Furthermore, in paragraph [0033] of the

application as filed, a more general definition of the term "environmentally-responsive", including at physiological conditions, is given, namely a hydrogel that is sensitive to changes in environment including but not limited to pH, temperature and pressure.

2.6 Thus, the description of the application as filed does not give an exhaustive, and thus delimiting, definition of what is meant by the term "responsive" when used in the feature "responsive when exposed to body fluids", such that even when resorting to information derived from the description, said feature is not unambiguously defined.

2.7 Since it has not been shown that an unequivocal generally accepted meaning for said feature exists in the art, the skilled person can never be sure whether a particular hydrogel falls under the claim or not, as he does not know what type of response needs to be detected. It would clearly represent an undue burden to the skilled person to investigate whether a particular hydrogel exhibits any response whatsoever under any conditions to body fluids. The skilled person thus does not know **what** he is trying to detect, let alone **how** it should be measured.

2.8 The Board thus concludes that the feature "responsive when exposed to body fluids" in claim 1 does not identify clearly a specific class of hydrogels, such that this claim lacks clarity, contrary to the requirement of Article 84 EPC, with the consequence that the main request and the auxiliary request are not allowable.

Article 113(1) EPC

3. The oral proceedings were held in the absence of the Appellant pursuant to Rule 115(2) EPC.

3.1 In the communication accompanying the summons to oral proceedings (see point IV above), the objection under Article 84 EPC as discussed above in respect of claim 1 of both requests was already raised, albeit with respect to the term "environmentally-responsive" present in claim 1 of the requests then on file.

3.2 In response to said communication, the Appellant filed new requests in which the term "environmentally-responsive" specifically objected to in said communication was replaced by the feature "responsive when exposed to body fluids", but provided no arguments as to why said feature should now be considered to fulfil the requirements of Article 84 EPC.

3.3 Hence, the absent - albeit duly summoned - Appellant could have expected the question of clarity of the feature "responsive when exposed to body fluids" to be discussed at the oral proceedings and was aware from the proceedings to date of the actual criteria on which it would be judged (see T 341/92, OJ EPO 1995, 373, point 2.3.3 of the reasons).

3.4 Indeed, the replacement of "environmentally-responsive" with the feature "responsive when exposed to body fluids" merely results in the environment in which the hydrogel should be "responsive" being further specified, but still does not address which type of response of the hydrogel qualify as "responsive", nor the **conditions** under which said "response" should be measured (see point 2.7 above). As such, this amendment

results in the offending feature being subject to almost the same clarity objection that was raised in the communication of the Board, namely the feature has no well-recognised meaning in the art, such that the skilled person still cannot clearly distinguish hydrogels that fall under the claim from those that do not.

3.5 The present decision is thus based on facts upon which the Appellant has had an opportunity to present comments, such that the Board is satisfied that it complies with the requirements of Article 113(1) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated