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Datasheet for the decision of 28 April 2017

Case Number: T 0673/15 - 3.3.10

Application Number: 05853314.2

Publication Number: 1819374

IPC: A61L27/40, A61L29/14, A61K49/00

Language of the proceedings: EN

Title of invention:
CONTRAST AGENT COATED MEDICAL DEVICE

Patent Proprietor:
Cook Medical Technologies LLC

Opponent:
MaRVis Medical GmbH / Düring Klaus

Headword:

Relevant legal provisions:
EPC Art. 100(b), 111(1)

Keyword:
Grounds for opposition - insufficiency of disclosure (no)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:
T 0409/91, T 0435/91, G 0003/14

Catchword:

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Case Number: T 0673/15 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 28 April 2017

Appellant: (Patent Proprietor)	Cook Medical Technologies LLC 750 North Daniels Way Bloomington, IN 47404 (US)
Representative:	Ellis, Katherine Elizabeth Sleigh Williams Powell Staple Court 11 Staple Inn Buildings London, WC1V 7QH (GB)
Respondent: (Opponent)	MaRVis Medical GmbH / Düring Klaus Auf dem Rotental 47 50226 Frechen (DE)
Representative:	Schüssler, Andrea Kanzlei Huber & Schüssler Truderinger Strasse 246 81825 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 15 January 2015 revoking European patent No. 1819374 pursuant to Articles 101(2) and 101(3)(b) EPC.**

Composition of the Board:

Chairman	P. Gryczka
Members:	R. Pérez Carlón
	F. Blumer

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division to revoke European patent No. 1 819 374.

II. Notice of opposition had been filed on the grounds of insufficiency of disclosure (Article 100(b) EPC) and lack of novelty and inventive step (Article 100(a) EPC).

III. The opposition division concluded that the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. There were three reasons for this. Firstly, the patent in suit did not contain a single detailed example; secondly, determining which coating materials could be non-porous represented an undue burden and, lastly, those embodiments including Gd as contrasting agent would not work.

IV. Independent claims 1 and 8 of the main request, which is the patent as granted, read as follows:

"1. An implantable medical device comprising

a base material forming a structure for implantation into a patient;
a contrasting agent intermingled in the base material; and
a non-porous coating layer posited on the surface of the base material.

8. A method of making a medical device as claimed in any preceding claim, comprising:

mixing a base material and a contrast agent together to make a magnetically visible mixture; forming a generally tubular member from the magnetically visible mixture; and positing a non-porous layer on top of the tubular member."

V. The arguments of the appellant relevant for the present decision were the following:

The subject-matter of the claimed invention was technically very simple, as claim 1 merely required a base material, a contrasting agent intermingled therein, and a non-porous coating layer on its surface. The specification provided guidance towards materials suitable for each of these three components, a preferred embodiment related to the combination of silicone as base material with tocopherol, diluted Gd, or $NiSO_4$ as contrasting agent, and a preferred non-porous coating made of parylene derivative.

The feature "non-porous" merely indicated that any layer impervious enough to prevent contact between the contrasting agent and biological material was suitable for the claimed invention; non-porous coating layers were well known in the art.

Lastly, it argued that the issues resulting from the use of Gd or tocopherol could be solved by using aqueous compositions, which were commercially available.

The appellant thus concluded that the claimed invention was sufficiently disclosed for it to be carried out by a person skilled in the art.

VI. The arguments of the respondent (opponent) relevant for the present decision were the following:

The claimed invention was not sufficiently disclosed if only for the reasons given by the opposition division in the contested decision.

During the oral proceedings before the board, the respondent argued that not only Gd but also tocopherol required contact with water, which would not be possible due to the presence of the non-porous layer required by claim 1. Therefore, some of the agents disclosed in the patent in suit could not be considered "contrasting agents", as that feature implicitly required those agents to be active upon use. For this reason, the claimed invention was not sufficiently disclosed.

It further argued that the non-porous layer required by claim 1 did not have any technical effect if the contrasting agent was non-volatile. Also for this reason, the skilled person did not have information about how to obtain such a device.

Lastly, the respondent argued that there was no effect of a non-porous layer over an extruded device containing a base material having iron oxide particles. Also for this reason, the disclosure of the patent in suit was insufficient.

VII. Oral proceedings before the board of appeal took place on 28 April 2017.

VIII. The final requests of the parties were the following:

- the appellant requested that the decision under appeal be set aside and the patent maintained as granted (main request) or, subsidiarily, in the form of one of the first to third auxiliary requests, all auxiliary requests having been filed with the statement setting out the grounds of appeal dated 22 May 2015.

- the respondents requested that the appeal be dismissed.

IX. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Sufficiency of disclosure

2. According to the case law of the Boards of Appeal, the requirements of sufficiency of disclosure are met only if the claimed invention can be performed by a person skilled in the art over the whole area claimed without undue burden, using common general knowledge and having regard to the information in the patent in suit (T 409/91, OJ 1994, 653, Reasons 3.5; T 435/91, OJ 1995, 188, Reasons 2.2.1). A reasonable amount of trial and error is permissible, provided that a skilled person finds adequate information leading necessarily and directly towards success through the evaluation of initial failures (Case Law of the Boards of Appeal, 8th ed. 2016, II.C.5.6.1).

3. Claim 1 of the patent as granted relates to an implantable medical device comprising a base material,

a contrasting agent intermingled in the base material, and a non-porous coating layer posited on the surface of the base material.

4. The opposition division concluded that the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, for three reasons. Firstly, the patent in suit did not contain a single detailed example; secondly, determining which coating materials could be non-porous represented an undue burden and, lastly, those embodiments including Gd as contrasting agent would not work.

5. Absence of detailed examples

5.1 The opposition division argued that the patent in suit did not contain a single detailed example of the claimed medical device, and there was no hint towards a preferred combination of base material, contrasting agent and non-porous layer. Due to that lack of guidance, selecting suitable combinations represented an undue burden.

However, claim 1 relates to a structure which merely contains two layers. One of them, the base layer, contains a contrasting agent, and the second layer is a non-porous coating.

The patent in suit acknowledges that the base material envisaged by claim 1 is conventional [0023], and provides in paragraph [0024] a list of suitable materials, being silicone preferred [0025].

Contrasting agents are also known in the art, and encompass any paramagnetic compound visible in MRI,

such as Gd, solutions or suspensions of tocopherol, solutions or suspensions of tocopherol derivatives (generally referred to as vitamin E), metal ions, salts or chelates, such as $NiSO_4$, being vitamin E particularly suitable [0018]. It is not disputed that these substances could be intermingled with a base material.

Non-porous coating layers suitable for the claimed invention [0034] are curable coatings, preferably made of parylene derivatives [0037].

The patent in suit thus describes materials suitable for the claimed medical device. It is not disputed that these materials are common in the technical field of medical devices. There is no apparent difficulty in intermingling a contrasting agent in a material suitable for a medical device or in applying a non-porous coating to it.

For these reasons, the claimed invention can be carried out by a person skilled in the art, even in the absence of a detailed example.

6. Feature "non-porous"

6.1 The opposition division considered that the patent in suit failed to define the degree of porosity which could be considered as "non-porous" within the meaning of the claimed invention. Also for this reason, the claimed invention could not be carried out.

However, the patent in suit discloses parylene coatings as a non-porous layer suitable for the claimed invention. Whether or not a different coating layer would be non-porous, as required by claim 1, is a

clarity issue already present in claim 1 as granted, outside the scope of opposition proceedings (G 3/14, OJ EPO 2015, A102, order).

7. Embodiments lacking a technical effect

7.1 The opposition division concluded with respect to Gd contrast agents, which required a proton source, that the presence of a non-porous layer over the base layer containing the contrasting agent would prevent Gd from coming into contact with any proton source, so that it would not act as a contrast agent, and thus the implantable medical device would not work.

The respondent further argued that water could not be included in the base material, as it was removed from the medical device during extrusion, which was the most common technique employed for manufacturing the claimed devices. The same problems would arise with respect to tocopherol as contrasting agent.

Claim 1 required the presence of a "contrasting agent". This feature, defined in terms of its function, required the agent intermingled in the base material to be effective as a contrasting agent in the claimed device. The patent in suit did not disclose how to manufacture devices containing compounds which it considered to be "contrasting agents", such as Gd and tocopherol. In addition, claim 1 was not restricted to medical devices containing volatile contrasting agents. If the contrasting agent was non-volatile, the non-porous layer required by claim 1 did not have any technical effect.

7.2 Paragraph [0018] of the patent in suit discloses that contrast agents in the sense of the claimed invention

are Gd, solutions or suspensions of tocopherol, solutions or suspensions of tocopherol derivatives (generally referred as vitamin E) and metal ions, salts or chelates, such as $NiSO_4$. It is not disputed that these materials are commonly used contrasting agents. No passage in the description discloses that the contrasting agents required by claim 1 are limited in any way over and above being known as capable of enhancing contrast.

It is thus concluded that claim 1 merely requires the base material of the claimed implantable medical device to contain such an agent, and there is no apparent reason why the skilled person could not produce implantable devices containing them.

Whether or not every implantable medical device according to claim 1 would provide a technical effect, for example in terms of contrast, is an issue under Article 56 EPC and not under sufficiency, as none of those properties is required by claim 1 (see Case Law of the Boards of Appeal, 8th edition 2016, II.C.2, last two paragraphs).

7.3 It is thus considered that the ground of opposition under Article 100(b) EPC does not preclude the maintenance of the patent as granted.

8. Remittal

The decision under appeal did not deal with all the grounds for opposition, but only with sufficiency of disclosure.

The respondent asked the board to decide on all the grounds of opposition in view of the duration of the

proceedings and the additional expense involved.

However, it is not normally the function of an appeal board to consider and decide upon questions for the first time during appeal proceedings. Under the present circumstances, the board considers it appropriate to remit the case to the opposition division for further prosecution on the basis of the claims according to the main request (Article 111(1) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The file is remitted to the opposition division for further examination on the basis of the main request (claims as granted).

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated