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**Datasheet for the decision
of 15 March 2016**

Case Number: T 0061/14 - 3.3.10

Application Number: 07710404.0

Publication Number: 1986706

IPC: A61L24/00, A61L24/06

Language of the proceedings: EN

Title of invention:

POROUS INTRAVASCULAR EMBOLIZATION PARTICLES AND METHODS OF
MAKING THEM

Patent Proprietor:

BIOSPHERE MEDICAL, INC.

Opponent:

BIOCOMPATIBLES UK LIMITED

Headword:

Relevant legal provisions:

EPC Art. 100 (b)

Keyword:

Sufficiency of disclosure - (no) all requests

Decisions cited:

Catchword:



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Chambres de recours

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Case Number: T 0061/14 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 15 March 2016

Appellant: BIOSPHERE MEDICAL, INC.
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Respondent: BIOCOMPATIBLES UK LIMITED
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 8 November 2013
revoking European patent No. 1986706 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. 1 986 706.
- II. Notice of opposition had been filed by the respondent (opponent) *inter alia* on the ground of insufficiency of disclosure (Article 100(b) EPC).
- III. The documents filed during the opposition proceedings included the following:
 - D22: Lin *et al.* Biomaterials 24 (2003) 481-489
 - D23: Tuan *et al.* Computer-Aided Design 37 (2005) 1151-1161
- IV. The documents filed during these appeal proceedings included the following:
 - D28: Rouquerol *et al.* Pure & Appl. Chem., Vol. 66, No. 8, pp. 1739-1758, 1994
 - D29: Klobes *et al.* Natl. Inst. Stand. Technol. Spec. Publ. 960-17, 2006
 - D30: Gupta *et al.* Composite Structures 71 (2005) 423-428
 - D31: Moore *et al.* Journal of Biomedical Materials Research Part A. Vol. 71A, 258-267 (2004)
- V. 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, as the patent did not contain the necessary information on how to determine the percentage of pores of a particle which were interconnected, and there was no evidence that methods for doing so were common

general knowledge. The skilled person thus had to develop a whole new method for measuring the percentage of interconnected pores in order to carry out the invention, and that amounted to an undue burden.

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

"A dehydrated substantially spherical embolization particle for use in a method of embolization, wherein the particle comprises a crosslinked polymer, wherein the interior of said particle comprises interconnected pores that extend to the surface of the particle, wherein at least 20% of the pores are interconnected, wherein the surface pores have an average diameter of greater than 1 μm (micron), and wherein the particle has a diameter ranging from 45 to 1400 μm (microns); and wherein the method of embolization comprises the steps of rehydrating the dehydrated particle, and positioning the rehydrated particle in a target region of a blood vessel."

Claim 1 of the first, second, third and fifth auxiliary requests is directed to an embolisation particle and contains, as claim 1 of the main request, the feature *"wherein at least 20% of the pores are interconnected"*.

Lastly, claim 1 of the fourth auxiliary request, which is directed to a method of producing a particle, also requires the particle obtained by that method to have at least 20% of its pores interconnected.

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

The invention was disclosed in a manner sufficiently

clear and complete for it to be carried out by a person skilled in the art. The patent in suit provided examples of embolisation particles having at least 20% of the pores interconnected, as it was apparent from the figures that the particles of the examples had a level of interconnectivity close to 100%. The skilled person knew that the amount of interconnected pores could be varied by changing the concentration of the porogen and the crosslinking speed, so that the invention could be carried out throughout the whole subject-matter claimed with a reasonable amount of trial and error, and the result could be evaluated either by visual inspection or using the methodology disclosed in D22, D23, D30 and D31.

VIII. The arguments of the respondent relevant for the present decision were the following:

The patent in suit disclosed how to obtain embolisation particles whose pores were almost fully interconnected but not how to obtain particles with a lower relative amount of interconnected pores, so that its disclosure was not sufficient to carry out the whole subject-matter claimed. The patent in suit did not sufficiently disclose how to determine the percentage of pores of an embolisation particle which were interconnected. The appellant relied on prior art which disclosed percentages of interconnected pore volume, not of interconnected pores. Thus, the patent in suit neither provided the required information nor could this information be retrieved by a reasonable amount of trial and error. For all these reasons, the patent specification did not disclose the claimed invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

- IX. Oral proceedings before the board of appeal took place on 15 March 2016.
- X. The final requests of the parties were the following:
- The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, subsidiarily, that the patent be maintained on the basis of any of the first to fifth auxiliary requests, all auxiliary requests as filed with the statement setting out the grounds of appeal dated 18 March 2014.
 - The respondent requested that the appeal be dismissed.
- XI. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Sufficiency of disclosure

2. Claim 1 is directed to an embolisation particle and requires at least 20% of its pores to be interconnected.
3. It is not in dispute that interconnectivity is a property of some porous materials, and that the term "interconnected" is frequently used in the art (see for example D29, page 73, last line).

It has not been disputed that the percentage of interconnected pores required by claim 1 refers to all the pores of the claimed particle, not only to those which extend to the surface.

With respect to the definition of "interconnected pores", paragraph [0041] of the patent in suit discloses:

"Substantially interconnected pores (also referred to as "open") as used in the present application means pores that are in fluid communication with each other within a solid material."

4. The claimed invention relies on a structural property of the claimed embolisation particle, namely that at least 20% of its pores are interconnected. The appellant considered this feature to be essential for the invention, and that not every embolisation particle has the percentage of interconnected pores required by claim 1.

An invention should be disclosed in a manner sufficiently clear and complete for it to be carried out, throughout the whole scope claimed, by a person skilled in the art, on the basis of the disclosure in the patent specification and the general technical knowledge in the art.

If, as in the present case, an essential feature of the invention is expressed by a parametric definition the question is whether the parameter is so defined that the person of the art, on the basis of the disclosure of the patent as a whole and using his common general knowledge, could identify, without undue burden, the technical measures leading to the claimed subject-

matter (Case Law of the Boards of Appeal, 7th ed. 2013, II.C.4).

In this context, it needs to be examined whether the patent in suit and the common general knowledge provide sufficient information allowing the skilled person

- to obtain particles having the required percentage of interconnected pores, for example by disclosing at least one way to carry out the invention, and
- to obtain substantially all embodiments within the ambit of claim 1, either
 - by providing sufficient instructions in the patent in suit, or
 - by relying on the common general knowledge of a person skilled in the art, or
 - by a reasonable amount of trial and error leading a skilled person to the claimed subject-matter after the evaluation of some possible initial failures.

5. *At least one way to prepare the claimed embolisation particles*

5.1 Examples 1 to 4 of the contested patent provide instructions on how to obtain embolisation particles. The percentage of interconnected pores of the particles obtained in these examples has however not been measured.

5.2 The appellant argued that although the percentage of interconnected pores of the particles of examples 1 to

4 had not been determined, it was apparent from the figures of the patent in suit that it was close to 100% and thus in accordance with claim 1. Paragraph [0037], which disclosed that figures 4A to 4E showed scanning electron micrographs of embolisation particles "made according to the protocols described herein", and paragraph [0040] disclosed that figure 4E showed the interior surface of a cut particle in which "interior pores are clearly interconnected". The state of the art also disclosed polymer scaffolds having a connectivity greater than 99% (D22, page 484, last full paragraph) and from 99.7 to 100% (D23, table I), which proved that such particles could be obtained.

5.3 It can thus be considered that the particles obtained according to examples 1-4 of the patent in suit have a percentage of interconnected pores close to 100%.

5.4 However, sufficiency of disclosure presupposes that the skilled person is able to carry out substantially every embodiment falling within the ambit of the claims (Case Law of the Boards of Appeal, 7th ed. 2013, II.C.4.4).

Claim 1 of the patent as granted is directed to a embolisation particle having pores "at least 20%" of which are interconnected, i.e. from 20% to 100%. Sufficiency of disclosure requires that the skilled person is able to prepare not only particles having 100% of their pores interconnected but also other embodiments falling under the claim, for example particles having 50% of their pores interconnected.

5.5 The appellant relied on paragraph [0051] of the patent specification as teaching a skilled reader how to control or modify the percentage of interconnected pores of an embolisation particle.

However, this paragraph describes the influence of the period of time of separation of porogen and polyvinylalcohol prior to crosslinking only on the pore size, not on the percentage of interconnected pores.

5.6 The appellant has not provided any evidence showing that, at the filing date, it was generally known to a person skilled in the art how to modify the percentage of interconnected pores of an embolisation particles, and nor is any such evidence immediately apparent.

5.7 According to the case law, a reasonable amount of trial and error is permissible when it comes to sufficiency of disclosure, 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, 7th ed. 2013, II.C.5.6.1).

The appellant argued that interconnection was due to the coalescence of porogen globules as the polymer became more firm by crosslinking. For that reason, a skilled person would

- reduce the number of pores by reducing the amount of porogen, as fewer pores would be statistically less likely to interconnect, and
- reduce the amount of time over which the polymer was allowed to crosslink, by varying the concentration of the crosslinking agent and reactant.

By mere trial and error, a skilled person could obtain every embolisation particle according to claim 1.

However, such a trial-and-error strategy could only allow a skilled person to obtain every embodiment of the claimed invention without undue burden if he were guided necessarily and directly towards success by the evaluation of possible initial failures. In the present case, the skilled person required a suitable method for evaluating whether any change in the reaction conditions would lead to a lower percentage of interconnection.

It thus remains to be examined whether the percentage of interconnected pores can be determined.

It has not been challenged that the patent in suit does not disclose how to measure the percentage of pores which are interconnected.

As mentioned above, "interconnectivity" is a frequently mentioned property of porous solids. However, it often provides a merely qualitative definition and, if quantified, it is measured in terms of the relative amount of pore volume accessible from the outside (also called open pore volume) and not in terms of the relative amount of pores which are interconnected, which is the feature required by claim 1.

- 5.8 In a first line of argument, the appellant relied on the figures of the patent specification. Figure 4E related to a cut of an embolisation particle according to the claimed invention, whose interior pores were "clearly interconnected" (paragraph [0040]). This figure showed that the percentage of pores which were interconnected could be determined by mere visual

inspection of a cut of a particle.

Figure 4E merely provides a qualitative analysis of the porous structure, from which the appellant concludes that all the pores are interconnected.

However, this strategy does not allow to estimate, let alone measure, either the total number of pores of the embolisation particle, or how many of them are interconnected, which are the values required for calculating the percentage of interconnected pores required by claim 1. The skilled person could conclude that a particle's pores are completely interconnected (i.e. a percentage close to 100%) but would not be able to reach any conclusion for any percentage of interconnected pores lower than that. For that reason, the patent in suit does not provide the required information for determining the percentage of interconnected pores.

5.9 In a second line of argument, the appellant relied during the written procedure on the disclosure of documents D23, D23, D30 and D31 as showing that the determination of pore interconnectivity could be carried out by well-known techniques.

However, document D22 refers to relative interconnected volume and not to the relative number of interconnected pores (see last full paragraph on page 484). The same goes for document D23 (see page 1153, second paragraph under 2.6). D30 refers to the characterisation of a porous material but does not quantify its interconnectivity, let alone in terms of the percentage of interconnected pores. D31 develops an allegedly new parameter, namely the "accessible void value", as a measurement of the interconnectivity of a substrate,

and proves that quantifying said magnitude is anything but trivial. None of these documents refers, as required by claim 1, to the percentage of pores which are interconnected. Thus, the prior art did not provide information on how to measure the percentage of interconnected pores.

5.10 Therefore, even if a skilled person attempted to modify the experimental details provided in the patent with the aim of preparing particles having a different relative amount of interconnected pores, for example by modifying the nature or the amount of porogen, or the crosslinking time, due to the lack of information on whether the particles obtained fulfilled the requirements of claim 1 that person could not be guided to the claimed embodiments through evaluation of some possible initial failures.

6. The appellant argued that the respondent had not provided any evidence showing that the claimed particles could not be obtained. The disclosure of a patent could only be put into question by raising reasonable doubts, substantiated by verifiable facts, and no such facts had been provided.

However, in the present case, the respondent raised serious doubts in the form of comprehensible and plausible arguments regarding the lack of information in the patent in suit on key issues.

7. The board concludes for these reasons that the patent specification does not disclose the claimed invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and that, for that reason, the ground under Article 100(b) EPC

precludes the maintenance of the patent as granted.

8. The appellant acknowledged that the situation regarding insufficiency was the same with respect to the embolisation particles or the methods for producing such particles which represent the subject-matter of every auxiliary request.

As the board found that the embolisation particles of claim 1 of the main request were not disclosed in a manner sufficiently clear and complete, this conclusion also applies to the subject-matter of claim 1 of all the auxiliary requests, with the consequence that none of these requests is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated