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Datasheet for the decision of 22 July 2014

Case Number: T 2290/11 - 3.2.08

Application Number: 00978735.9

Publication Number: 1233725

IPC: A61F2/06

Language of the proceedings: EN

Title of invention:
ENDOLUMINAL DEVICE EXHIBITING IMPROVED ENDOTHELIALIZATION AND METHOD OF MANUFACTURE THEREOF

Patent Proprietor:
Advanced Bio Prosthetic Surfaces, Ltd.

Opponents:
Boston Scientific Limited
Acandis GmbH & Co. KG

Headword:

Relevant legal provisions:
EPC Art. 100(b)

Keyword:
Grounds for opposition - insufficiency of disclosure (yes)

Decisions cited:

Catchword:

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Case Number: T 2290/11 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 22 July 2014

Appellant: (Patent Proprietor)	Advanced Bio Prosthetic Surfaces, Ltd. 4778 Research Drive San Antonio, TX 78240 (US)
Representative:	Michalski Hüttermann & Partner Patentanwälte mbB Speditionstraße 21 40221 Düsseldorf (DE)
Respondent: (Opponent 1)	Boston Scientific Limited One Scimed Place Mailstop A 150 Maple Grove, MN 55311-1566 (US)
Representative:	Peterreins, Frank Fish & Richardson P.C. Highlight Business Towers Mies-van-der-Rohe-Strasse 8 80807 München (DE)
Respondent: (Opponent 2)	Acandis GmbH & Co. KG Kolpingstrasse 5 76327 Pfinztal (DE)
Representative:	Kilchert, Jochen Meissner, Bolte & Partner GbR Widenmayerstrasse 47 80538 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 19 August 2011 revoking European patent No. 1233725 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	T. Kriner
Members:	C. Herberhold
	D. T. Keeling

Summary of Facts and Submissions

I. By its decision posted on 19 August 2011 the Opposition Division revoked European Patent EP-B-1 233 725 on the grounds of Article 100(c) and (b) EPC.

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

III. Oral proceedings before the Board of Appeal were held on 22 July 2014.

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

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (Main Request) or, in the alternative, that the patent be maintained on the basis of the Auxiliary Request filed on 8 February 2010 (referred to as the "Auxiliary Request" in the following), or on the basis of Auxiliary Request A filed at the oral proceedings before the Opposition Division, or on the basis of Auxiliary Request B filed with the grounds of appeal.

The respondents (opponents 1 and 2) requested that the appeal be dismissed.

IV. The independent product claim of the Main Request reads as follows (only the product claims have played a role for the present decision):

Main Request, Claim 1:
"A medical device implantable within a body lumen fabricated as a tubular member having luminal and

abluminal surfaces thereof and being capable of radially expanding from a first diameter to a second diameter, **characterised in that** at least the luminal surface has controlled heterogeneities thereupon."

Claim 1 of the Auxiliary Request differs from claim 1 of the Main Request in that the expression "medical device implantable within a body lumen" has been restricted to "implantable endoluminal stent".

Claim 1 of Auxiliary Request A is identical to claim 1 of the Auxiliary Request.

Claim 1 of Auxiliary Requests B differs from claim 1 of the Auxiliary Request and of the Auxiliary Request A in that the "tubular member" has been restricted to a "metal tubular member" and by the additional feature that the controlled heterogeneities "are grain size and wherein the controlled heterogeneities define cell-adhesion domains having interdomain boundaries less than the surface area of the human endothelial cell".

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

Sufficiency of disclosure

Main request, Auxiliary Request, Auxiliary Request A

The invention defined an implantable medical device with a luminal surface having controlled heterogeneities thereupon. In view of the disclosure it was clear to the skilled person that a perfectly homogenous surface could not be attained, and that the invention was thus to exert a certain control on the unavoidable heterogeneity of the luminal surface in

order to obtain an improved endothelialisation of the device. In this respect Figure 1 showed a diagrammatic representation of accordingly controlled heterogeneities, whereas Figure 2 depicted a micrograph of uncontrolled heterogeneities. By comparing the two Figures, the person skilled in the art would understand what the term "controlled heterogeneities" implied, and how controlled heterogeneities were to be distinguished from uncontrolled heterogeneities. The patent also gave a clear teaching with several examples how such controlled heterogeneities could be made using metal deposition methodology. While it was true that a certain amount of experimentation was required to obtain the desired controlled heterogeneities, such experimentation was in fact intrinsic in deposition methodology, which routinely required fine tuning of the different parameters. As also recognised in the case law, a certain amount of trial and error and even failure was permissible when it came to sufficiency of disclosure, in particular if – as in the present case – the structural outcome as well as the desired endothelialisation favouring effect were readily verifiable by experiments.

Consequently, the invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Auxiliary Request B

Controlled heterogeneities being grain size could be appreciated in Figure 1 of the patent. Furthermore the surface area of a human endothelial cell was known. The person skilled in the art was thus well capable of determining whether the grain size showed "controlled heterogeneities" and of comparing the cell adhesion

domains and their corresponding interdomain boundaries with the surface area of the endothelial cell. Consequently, it was possible to identify the technical measures necessary to solve the problem underlying the invention, the invention thus being sufficiently disclosed.

VI. The essential arguments of the respondents can be summarised as follows:

Sufficiency of disclosure

Main request, Auxiliary Request, Auxiliary Request A

There were two major hindrances which made it impossible for the person skilled in the art to carry out the invention:

Firstly, the term "controlled heterogeneities" neither had a well-defined meaning in the art nor was it defined in the specification. On the one hand the luminal surface was said to show substantially homogeneous surface properties, on the other hand it was defined to have heterogeneity in grain size, grain phase, grain material composition, stent material composition, and surface topography. The technical meaning of the term "controlled heterogeneities" was thus contradictory and the person skilled in the art did not know what surface structure might qualify as having "controlled heterogeneities" thereupon and which might not. In this respect also the two Figures of the patent could not provide any help: Figure 1 showed grains of various sizes and orientations like in any metallic bulk material. There was no indication what might qualify these grain heterogeneities as "controlled heterogeneities". Indeed, a micrograph of

the material shown in Figure 1 would exhibit grains cut in different heights and orientations, thus showing heterogeneities comparable to those in Figure 2. Even considering the Figures, it remained mysterious how "controlled heterogeneities" could be differentiated from "uncontrolled heterogeneities". The alleged invention thus amounted to nothing more than the creation of the new term "controlled heterogeneities", without providing sufficiently clear information what the term actually meant.

Secondly, what was disclosed as "examples" in the specification could not be considered a way clearly indicated enabling the person skilled in the art to carry out the invention. The parameter ranges given for substrate temperature, bias voltage, hyperthermal energy and deposition pressure were extremely broad, essentially covering all values at all possible in the field of metal deposition methodology. Furthermore, important details as e.g. the substrate material, the particular metal composition used, the film thickness and the post processing of the device were not specified at all. In particular in view of the fact that the use of metal deposition methodology for stent manufacture was already known, the person skilled in the art could not derive from the specification the technical measures necessary to produce the inventive surface having favourable endothelialisation properties because of the "controlled heterogeneities" thereupon. Without knowing what surface structure would qualify as "controlled heterogeneities", the person skilled in the art would need to experimentally determine for each combination of the many possible deposition methodology parameters the resulting endothelialisation properties in order to know whether the effect of the invention could be so reached or not. This amounted to an

extensive research program covering essentially the whole field of metal deposition methodology and clearly had to be seen as an undue burden for carrying out the invention.

The invention was therefore so ill-defined that the person skilled in the art was not able to determine from the disclosure which technical measures were necessary to put it into practice and to solve the problem underlying the invention. Thus, the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by the person skilled in the art.

Auxiliary Request B

The amendments in the independent product claim of Auxiliary Request B could not overcome the insufficiently clear and complete disclosure of the patent. It remained undefined, what qualified as "controlled heterogeneities" even with the heterogeneities being grain size, there being several possibilities of defining the grain size. It was also unclear what qualified as cell-adhesion domains and as the respective interdomain boundaries defined by controlled heterogeneities being grain size. The term "domain" usually referred to sub-parts of proteins, an interpretation which obviously made no sense in the present context. It was thus unclear what the term cell-adhesion domain could mean in the context of controlled heterogeneities being grain size. Did it refer to a particular part of the grain or to a particular grain (super-) structure? As discussed for the higher ranking requests, the invention was thus not sufficiently clearly and completely disclosed.

Reasons for the Decision

1. The appeal is admissible.

2. Sufficiency of disclosure

2.1 Main request, Auxiliary Request, Auxiliary Request A

Article 100 (b) EPC stipulates that an opposition may be filed on the ground that "the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art".

In the present case - to carry out the invention – the person skilled in the art following the teaching both of claim 1 and of the patent specification, has to provide an endoluminal device with a luminal surface having "controlled heterogeneities" thereupon. The term has no established meaning in the relevant art and it is not defined in the patent in suit. Thus, carrying out the invention requires an interpretation of the term "controlled heterogeneities" in order to then produce a device having such "controlled heterogeneities".

The specification gives different characterizations for said luminal surface of the device according to the invention:

In several passages, the blood contact surface is disclosed to be "substantially homogenous" in material constitution (paragraph [0012], line 30), having "substantially homogeneous surface properties, specifically surface energy and electrostatic

charge" (paragraph [0015], line 10-14) or having substantially homogeneous metal constitution (paragraph [0016], lines 25, 26). According to paragraph [0011], lines 5-8, the manufacture of stents and other intravascular devices (according to the current invention) is controlled to attain a regular, homogeneous atomic and molecular pattern of distribution along their surface.

On the other hand, other passages define the very same luminal surface as having "controlled heterogeneities", the heterogeneities which are controlled including grain size, grain phase, grain material composition, stent-material composition and surface topography (see e.g. [0012], lines 31-38). Moreover, it is disclosed that the controlled heterogeneities are controlled by fabricating the bulk material of the stent to have defined grain sizes which yield areas or sites along the surface of the stent having optimal protein binding capability.

There is thus an inconsistency in the disclosure regarding the terms "homogenous" and "heterogeneities". Although the device is substantially homogenous, having a homogenous atomic and molecular pattern of distribution along the surface, certain heterogeneities are not only permissible, but even required as essential characteristics of the invention in order to form areas having optimal protein binding and thus endothelialisation capability.

It is however not apparent from the specification which heterogeneities qualify as "controlled" and how the extent and type of such heterogeneities correlate with the solution of the problem to be solved, i.e. with favouring endothelialisation of the luminal surface.

Moreover, the description does not indicate any method of determining whether a given surface structure qualifies as having "controlled heterogeneities" or not. The diagrammatic representation in Figure 1 shows various grains which considerably vary in size and orientation. A regular pattern or structure is not apparent. When cut and etched like the micrograph depicted in Figure 2, the different grains will show differently sized cutting surfaces, i.e. a heterogeneity, depending on the orientation and localization of the cut with respect to the particular grain. It is not derivable from these two Figures, which are moreover two different types of representations (diagrammatic representation vs micrograph), what makes the heterogeneities in Figure 1 "controlled" and the ones in Figure 2 "uncontrolled" and how the two may be distinguished.

In other words, from the information available in the patent, the person skilled in the art cannot know whether a particular surface structure can be considered as having "controlled heterogeneities" thereupon, and whether he/she is working within the scope of the claims and consequently embodying the invention and solving the problem to improve endothelialisation, or not.

It is true that the description proposes metal deposition methodology as a method of manufacturing the inventive devices. However, the parameter ranges proposed are indeed very broad. Without a clear criterion to distinguish between a surface having "controlled heterogeneities" and one having "uncontrolled heterogeneities", structural examination of the resulting device is not sufficient to ascertain

whether a stent according to the invention, solving the problem of favouring endothelialisation, has actually been produced. As conceded by the appellant, whether a device having favourable endothelialisation properties has been obtained has to be determined experimentally in subsequent endothelialisation trials. Given the broad ranges indicated in the examples, this task amounts to a full research program and implies a considerable burden for the person skilled in the art. Therefore, the disclosure as a whole does not make it possible to identify without undue burden the technical measures necessary to produce a surface having "controlled heterogeneities" and thus solving the problem underlying the patent. Thus, the invention cannot be considered disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Consequently, the opposition ground according to Article 100 (b) EPC prejudices the maintenance of the patent as granted. The argumentation applies equally to the Auxiliary Request as well as to Auxiliary Request A.

2.2 Auxiliary Request B

Auxiliary Request B further specifies that the controlled heterogeneities are grain size and that the grain size heterogeneities define cell adhesion domains having interdomain boundaries less than the surface area of a human endothelial cell.

However, the further parametric definition comparing interdomain boundaries of cell adhesion domains defined by grain size heterogeneities with the surface area of a human endothelial cell is manifestly unclear: there

is no information how the "cell adhesion domains" and the respective "interdomain boundaries" are defined by the grain size heterogeneities. Figure 1 does not identify any such cell adhesion domains or show any recognizable repeating pattern. The skilled person is thus at a loss how to identify the "adhesion domains" and their respective "interdomain boundaries" on a given device surface, even if the device luminal surface had the grain structure shown in Figure 1. Consequently, he/she is also at a loss how to evaluate whether interdomain boundaries less than the surface area of a human endothelial cell are present. The unclarity of the parametric definition in the claim also amounts to an unclear disclosure of the invention (as it is defined in Auxiliary Request B) in the full specification, because there is no further passage linking endothelial cell binding domains to grain size heterogeneities. The analysis in section 2.1 above thus remains unchanged, the definition remaining so ill-defined and unclear that the skilled person is not able to identify without undue burden the technical measures necessary to solve the problem underlying the patent.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Wolinski T.Kriner

Decision electronically authenticated