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Datasheet for the decision of 5 March 2013

Case Number: T 1029/11 - 3.2.08

Application Number: 01934941.4

Publication Number: 1276436

IPC: A61F 2/02, A61F 2/30, A61L 2/08, A61L 27/00, A61L 31/00, B01J 19/08, C08J 3/28, C08F 110/02, A61F 2/32

Language of the proceedings: EN

Title of invention:
Oxidation-resistant and wear-resistant polyethylenes for human joint replacements and methods for making them

Patent Proprietor:
Orthopaedic Hospital

Opponent:
DMV Marketing & Vertriebs GmbH

Headword:
-

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

Keyword:
"Main request - novelty (no)"
"Auxiliary requests - remittal to the first instance"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1029/11 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 5 March 2013

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 24 February 2011 revoking European patent No. 1276436 pursuant to Article 101(3)(b) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: M. Alvazzi Delfrate
D. T. Keeling

Summary of Facts and Submissions

I. By decision posted on 24 February 2011 the opposition division revoked European patent No. 1 276 436.

II. The appellant (patent proprietor) lodged an appeal against that decision on 6 May 2011, paying the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 6 July 2011.

III. Oral proceedings before the Board of appeal took place on 5 March 2013.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the Main Request (patent as granted) or that the case be remitted to the Opposition Division for further prosecution on the basis of Auxiliary Requests 3 to 6 as filed on 6 July 2011 or Auxiliary Requests 7 to 9 as filed on 5 February 2013.

The respondent (opponent) requested that the appeal be dismissed or, in the alternative, that the case be remitted to the Opposition Division.

IV. Claim 1 of the **Main Request** reads as follows:

"A method to improve the wear resistance and oxidation resistance of an implant made of an ultrahigh molecular weight polyethylene or a high molecular weight polyethylene, said method comprising the steps of:

(1) providing an oxidation-resistant implant; and

(2) irradiating the oxidation-resistant implant at a radiation dose above 4 Mrad but below about 100 Mrad in order to crosslink the implant to improve its wear resistance, without melting or annealing said irradiated oxidation-resistant implant;
wherein the oxidation-resistant implant is machined from an oxidation-resistant polyethylene, and said oxidation-resistant polyethylene is made by mixing an anti-oxidant with the polyethylene powder and fusing the polyethylene powder to form an oxidation-resistant polyethylene."

V. The following documents play a role in the present decision:

E1: Mc Kellop et al. "Development of an Extremely Wear-Resistant Ultra High Molecular Weight Polyethylene for Total Hip Replacements" J. Orthop. Res., Vol. 17, No. 2, pages 157-167 (1999);

E9: JP -A- 11 239611 (as well as its English translation);

E15: Shibata et al. "Defect initiation at subsurface grain boundary as a precursor of delamination in ultrahigh molecular weight polyethylene", J. Biomat. Mater. Res. (Appl. Biomater.), (2003), pages 276-284; and

E16: Shibata et al. "The anti-oxidative properties of α–tocopherol in γ-irradiated UHMWPE with respect to fatigue and oxidation resistance" Biomaterials 26 (2005), pages 5755-5762.

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

Main Request

In order to arrive at the subject-matter of claim 1 from E9 three different selections were necessary. First of all, the performance of sterilisation after moulding the implant instead of during moulding had to be chosen. Secondly, performance of sterilisation by irradiation had to be selected. Finally, a value of the radiation dose within the range of present claim 1 had to be selected. E9 did not disclose those three selections in combination.

Moreover, the latter selection was not taught by E9 since the only example with an irradiation intensity according to claim 1 was a comparative one. Hence, the person skilled in the art would not seriously contemplate the choice of a radiation dose according to claim 1. This was confirmed by the fact that in the experiments described in documents E15 and E16 the author of E9 chose a lower dose of radiation.

Therefore, the subject-matter of claim 1 was novel.

Remittal of the case to the opposition division

Document E9 had been introduced at a late stage of the opposition proceedings. As a reaction, two auxiliary requests were filed during the oral proceedings before the opposition division. During those oral proceedings the appellant also expressed the wish to file further

auxiliary requests. However, the opposition division surprisingly announced its decision to revoke the patent without giving a possibility to submit those further auxiliary requests. Therefore, in the event that the Main Request were to be considered as not allowable, it was requested to remit the case to the opposition division in order to allow the auxiliary requests, which had not been decided upon by the opposition division, to be considered by two instances.

VII. The arguments of the respondent can be summarised as follows:

Main Request

E9 disclosed all the features of claim 1. In particular, it described irradiation as the preferred method of sterilisation. It was true that according to E9 sterilisation could be performed either during or after moulding. However, when the choice fell on sterilisation by irradiation it was clear that this step was performed after moulding. As to the value of the irradiation dose, E9 disclosed a range of 0.1 Mrad or higher, with a preferred range between 0.5 and 5 Mrad. There was no reason for the person skilled in the art to limit himself to the lower values of that preferred range. On the contrary, he would have seriously contemplated working in its upper portion or even above 5 Mrad when an improvement in wear resistance was desired, as disclosed in paragraph [0021] of E9 and as also known from E1. Accordingly, the subject-matter of claim 1 lacked novelty in view of E9.

Remittal of the case to the opposition division

It is true that the announcement of the decision of the opposition division during the oral proceedings took the parties by surprise, since the patent proprietor had expressed the wish to file further auxiliary requests. In the event that the Board did not allow the Main Request the case should be remitted for further prosecution to the opposition division.

Reasons for the Decision

1. The appeal is admissible

2. Main Request

E9 discloses a method to improve the wear resistance and oxidation resistance of an implant (see abstract) made of an ultrahigh molecular weight polyethylene (see claim 1 and paragraph [0029]), wherein said method comprises the step of providing an oxidation-resistant implant machined from an oxidation-resistant polyethylene (see paragraph [0019]), and said oxidation-resistant polyethylene is made by mixing an anti-oxidant (vitamin E, see claim 1) with the polyethylene powder and fusing the polyethylene powder to form an oxidation-resistant polyethylene (see paragraph [0019]).

According to paragraph [0020] the oxidation-resistant polyethylene must be sterilised. Although several sterilisation methods are mentioned, irradiation is disclosed as the preferred one, which is also used in

the examples (see paragraphs [0029] to [0030]), because it can easily sterilise completely in a short period and cause crosslinking of polyethylene.

It is true that paragraph [0020] stipulates that sterilisation can be carried out either during moulding or after moulding. However, in the examples, all involving sterilisation by irradiation, this step is carried out after moulding, i.e. irradiation is performed on the implant (see paragraph [0031]). Indeed, there is no disclosure in E9 of irradiation during moulding. Hence, this document teaches to irradiate the oxidation-resistant implant after moulding. The irradiated oxidation-resistant implant is neither molten nor annealed (see paragraph [0005]).

In respect of the radiation dose paragraph [0021] discloses that the intensity of the radiation beam is not particularly restricted, as long as it can cause sterilisation, which is normally possible by a radiation of 0.1 Mrad or higher. Hence, the range according to claim 1 of the Main Request (above 4 Mrad but below about 100 Mrad) is a selection within that broad range disclosed in E9. Paragraph [0021] further discloses that an intensity sufficient to cause a crosslinking reaction in the polyethylene to enhance the wear resistance is preferable. Preferably between 0.5 and 5 Mrad is used to provide that crosslinking. Accordingly, the person skilled in the art is taught to work in particular in the region of that preferred range which overlaps with the range in accordance with present claim 1. The fact that the example in table 2 wherein a radiation beam of 5 Mrad is used is a comparative one is not inconsistent with that teaching

since paragraph [0034] makes clear that the comparative examples are such by virtue of the lack of vitamin E addition or nitrogen gas substitution and not as a result of the value of the radiation dose. Therefore, E9 discloses that the irradiation can be performed with a radiation dose which falls in the range above 4 Mrad but below about 100 Mrad in order to crosslink the implant to improve its wear resistance.

Documents E15 and E16 fail to convince to the contrary, since there is no link in E9 to those documents, which relate to experimental studies wherein an irradiation with the radiation dose commonly used for sterilisation (2.5 Mrad) is performed.

Since, as shown above, the method of claim 1 as granted is disclosed in such a way in E9 that no selection is necessary, the subject-matter of claim 1 of the Main Request lacks novelty.

3. Remittal of the case to the opposition division

The appellant requested to remit the case to the Opposition Division in the event that the Main Request were found to be not allowable. According to Article 111(1) EPC the Board of Appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution. Accordingly, it is left to the discretion of the Board, on consideration of the circumstances of the particular case, to decide to remit the case or not.

Although no absolute right to have the issues considered at two instances exists and the need for overall procedural economy has to be taken into account, substantial amendments of the claims in appeal proceedings may call for a remittal, since the primary function of the appeal proceedings is a review of the decision of the first instance.

In the present case auxiliary requests 3 to 9 have not been the subject of the decision of the opposition division and relate to aspects, such as the degree of swelling, gel content, and the molecular weight between crosslinks that are not discussed in that decision.

Moreover, the appellant submitted that during the oral proceedings in front of the opposition division it expressed the wish to file further auxiliary requests. It is true that neither the decision under appeal nor the minutes of the oral proceedings, which merely mention an objection of the proprietor raised after the announcement of the decision (see points 14 to 16), refer to a request of the appellant in that sense. However, the appellant's submission has been confirmed by the respondent, who was also surprised by the announcement of the decision of the opposition division. Hence, although no correction of the minutes of the oral proceedings before the opposition was requested, the Board is satisfied that the appellant expressed the wish to submit further auxiliary requests.

Accordingly, it is considered that a remittal of the case for prosecution on the basis of auxiliary requests 3 to 9 is not only consistent with the review function

of the appeal proceedings but also fair, since during the opposition proceedings the appellant expected to have further auxiliary requests considered by the opposition division, and also the respondent suggested a remittal to the first instance.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division for further prosecution on the basis of Auxiliary Requests 3 to 6 as filed on 6 July 2011 or Auxiliary Requests 7 to 9 as filed on 5 February 2013.

The Registrar: The Chairman:

V. Commare T. Kriner