

**Internal distribution code:**

- (A) [ - ] Publication in OJ
- (B) [ - ] To Chairmen and Members
- (C) [ - ] To Chairmen
- (D) [ X ] No distribution

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

**Case Number:** T 1266/14 - 3.2.08

**Application Number:** 01934941.4

**Publication Number:** 1276436

**IPC:** A61F2/02, A61F2/30, A61L2/08,  
A61L27/00, A61L31/00,  
B01J19/08, C08J3/28,  
C08F110/02, A61F2/32

**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. 84, 56

**Keyword:**

Clarity  
Inventive step

**Decisions cited:**

T 1029/11

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

European Patent Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89 2399-4465

Case Number: T 1266/14 - 3.2.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.08**  
**of 15 September 2016**

**Appellant:** Orthopaedic Hospital  
(Patent Proprietor) 2400 South Flower Street  
Los Angeles, CA 90007-2693 (US)

**Representative:** Grünecker Patent- und Rechtsanwälte  
PartG mbB  
Leopoldstraße 4  
80802 München (DE)

**Respondent:** DMV Marketing & Vertriebs GmbH  
(Opponent) Friedrich-Bergius-Str. 33  
85662 Hohenbrunn (DE)

**Representative:** Popp, Eugen  
Meissner Bolte Patentanwälte  
Rechtsanwälte Partnerschaft mbB  
Widenmayerstraße 47  
80538 München (DE)

**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 25 March 2014  
revoking European patent No. 1276436 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairwoman** P. Acton  
**Members:** M. Alvazzi Delfrate  
D. T. Keeling

## **Summary of Facts and Submissions**

- I. By a first decision posted on 24 February 2011 the Opposition Division revoked European patent No. 1 276 436. In appeal (decision T 1029/11 of 5 March 2013) this first decision was set aside and the case was 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.
- II. By a second decision posted on 25 March 2014 the Opposition Division revoked the patent again. The Opposition Division found that Auxiliary Requests 3 to 7 and 9 did not comply with Articles 83 and 84 EPC and that the subject-matter of claim 1 of Auxiliary Request 8 did not involve an inventive step in view of
- E9: JP -A- 11 239611 (as well as English translation);  
and  
E17: WO -A- 98/01085.
- III. The present appeal is directed against said second decision and has been lodged by the appellant (patent proprietor) in the prescribed form and within the prescribed time limit.
- IV. Oral proceedings before the Board were held on 15 September 2016.

The appellant requested that the decision under appeal be set aside and the patent maintained on the basis of any of Auxiliary Requests 3 to 9, as originally filed in the proceedings before the Opposition Division and re-filed with the grounds of appeal.

The respondent (opponent) requested that the appeal be dismissed.

V. Claim 1 of **Auxiliary Request 3** reads as follows (features added in respect of the claims as granted underlined):

"1. 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, and wherein the polyethylene has a gel content of between 95% and 99% after irradiation."

**Auxiliary Request 4** differs from Auxiliary Request 3 by the addition in claim 1 of the feature according to which the polyethylene has

"a degree of swelling of between 1.7 to 3.6 after irradiation".

**Auxiliary Request 5** differs from Auxiliary Request 3 by the addition in claim 1 of the feature according to which the polyethylene has

"a molecular weight between crosslinks of between 400 to 3500 g/mol, after irradiation".

**Auxiliary Request 6** differs from Auxiliary Request 3 by the addition in claim 1 of the feature according to which the polyethylene has

"a degree of swelling of between 1.7 to 3.6 and a molecular weight between crosslinks of between 400 to 3500 g/mol, after irradiation".

**Auxiliary Request 7** differs from Auxiliary Request 6 in that in claim 1 the radiation dose is

"above 5 Mrad to 25 Mrad".

**Auxiliary Requests 8 and 9** differ from respectively the granted claims and Auxiliary Request 6 in that in claim 1 the radiation dose is

"above 10 Mrad to 25 Mrad".

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

*Clarity*

It was true that in claim 1 of Auxiliary Request 3 to 7 and 9 the irradiation step was partly defined in terms of the result to be achieved, namely by the gel content of the polyethylene after irradiation. However, this result defined the radiation dose to be used during the

irradiation step in a way that was precise and did not unduly restrict the scope of the claim, as would have been the case if the ranges of the radiation dose disclosed in the patent had been used. Therefore, this definition was allowable and did not cause claim 1 of Auxiliary Request 3 to 7 and 9 to infringe Article 84 EPC.

*Inventive step*

When considering Auxiliary Request 8, the problem solved starting from the closest prior art E9 was the provision of a method resulting in improved wear resistance. This problem was solved in accordance with claim 1 by the use of a radiation dose in the range of 10 to 25 Mrad.

Table 1 of E9 showed for embodiments 1 and 2, which both comprised an antioxidant, that irradiation resulted in cracking and flaking, i.e. in wear. This behaviour was different from what could be observed for comparative examples 1 and 2, to which no antioxidant was added, and where irradiation reduced the wear. In view of this disclosure the person skilled in the art would not consider the teaching of documents dealing with materials without antioxidants, such as E17, to solve the problem above when starting from E9, which dealt with polyethylene with antioxidants. Moreover, the prior art disclosed the use of annealing or re-melting, which were excluded by present claim 1.

Therefore, the method of claim 1 of Auxiliary Request 8 was not rendered obvious by the prior art.

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

*Clarity*

Claim 1 of Auxiliary Request 3 to 7 and 9 defined the irradiation step by the gel content of the polyethylene and hence as a result to be achieved. This definition rendered the claim unclear, because a more precise definition in terms of the actual method step, by means of the radiation dose, was possible without unduly restricting the scope of the claim. Therefore, claim 1 of Auxiliary Request 3 to 7 and 9 did not comply with Article 84 EPC.

*Inventive step*

The closest prior art for claim 1 of Auxiliary Request 8 was represented by E9, which disclosed a method according to claim 1 as granted. The problem to be solved starting from E9 was to improve the wear resistance of the implant. In order to solve this problem the person skilled in the art would have considered E17, which dealt with the reduction of wear. Nor would table 1 of E9 have dissuaded him from doing so, because this table did not provide any clear disclosure that irradiation would affect the wear of samples with added antioxidant in a way different from that of samples without antioxidant, such as those treated in E17. Since the teaching of E17 in respect of the effect of the radiation dose on wear resistance was virtually identical to that of the patent, E17 rendered it obvious to solve the problem above by choosing a radiation dose in accordance with claim 1. Therefore, the subject-matter of claim 1 of Auxiliary Request 8 did not involve an inventive step.



## **Reasons for the Decision**

### 1. Clarity

- 1.1 In claim 1 of Auxiliary Request 3 the irradiation step is partly defined in terms of the result to be achieved, namely by the gel content of the polyethylene after irradiation. This feature was added to the claim from the description after grant. Hence, its compliance with Article 84 EPC must be examined.

Claims which attempt to define the invention by a result to be achieved may be allowed if the invention either can only be defined in such terms or cannot otherwise be defined more precisely without unduly restricting the scope of the claims.

A definition in terms of the radiation dose would be more precise than a definition in terms of the gel content of the irradiated product, since it corresponds to the actual method step and is not dependent on the particular measuring method.

The appellant argued that limiting the claim on the basis of the values of the radiation dose disclosed in the patent (and in the application as originally filed) would result in a narrower, and thus unduly restricted, claimed scope. However, this is a matter linked to the particular values chosen by the applicant, under its own responsibility when drafting the application, for the ranges of the gel content and the radiation dose. Said particular values are immaterial for the general question to be considered here, namely whether a definition in terms of radiation dose instead of gel content would unduly restrict the scope of the claim.

Indeed there is no evidence in the file that such a definition in terms of radiation dose would be an undue restriction of the claimed scope. On the contrary, paragraph [0062] of the patent in suit clearly states that the definition by gel content is an alternative to the use of the radiation dose as a criterion.

Since the chosen definition in terms of gel content of the resulting product leads to a less precise definition of the claimed method which is not justified by the need to avoid an undue restriction of the claimed scope, the claim lacks clarity. Accordingly, claim 1 of Auxiliary Request 3 does not comply with Article 84 EPC.

- 1.2 The same objection applies to claim 1 of Auxiliary Requests 4 to 7 and 9.
  
- 2. Inventive step
  - 2.1 It is undisputed that the closest prior art for claim 1 of Auxiliary Request 8 is represented by E9. As established in decision T 1029/11 (Point 2 of the Reasons), E9 discloses a method to improve wear resistance and oxidation resistance of an implant made of a high or ultra-high molecular weight polyethylene according to claim 1 as granted. This method comprises in particular the step of irradiating the implant, made of oxidation-resistant polyethylene obtained by the addition of an anti-oxidant (Vitamin E), to cross-link the implant to improve its wear resistance, without melting or annealing said irradiated oxidation-resistant implant.
  
  - 2.2 The problem to be solved starting from E9 is to improve the wear-resistance of the implant.

This problem is solved in accordance with claim 1 by the selection of an irradiation dose of above 10 Mrad to 25 Mrad. According to paragraph [0060] of the patent in suit "the radiation dose is more preferably from about 5 to about 25 Mrad, and most preferably from about 5 to about 10 Mrad". This most preferable range is based on achieving a reasonable balance between improved wear resistance and minimal degradation of other important physical properties. However, according to paragraph [0061] "if a user is primarily concerned with reducing wear, and other physical properties are of secondary concern, then a higher dose than the above stipulated most preferable range (e.g., 5 to 10 Mrad) may be appropriate". Thus an improvement of the wear resistance in respect of the preferred method of E9, which discloses an irradiation of 0.1 Mrad or higher and preferably between 0.5 and 5 Mrad (paragraph [0021]), is credibly achieved.

2.3 The appellant submitted, referring to table 1 of E9, that the person skilled in the art would not have consulted documents dealing with polyethylenes without antioxidants, such as E17, to solve the problem above.

Table 1 of E9 shows the results of measurements of different properties performed on samples to which antioxidants have (embodiments 1, 2 and 3) or have not (comparative examples 1 and 2) been added and which have not (embodiments 1, 3 and comparative example 1) or have (embodiment 2 and comparative example 2) been subject to irradiation. The Board concurs with the appellant that the area of cracking and the occurrence or not of flaking indicated in table 1 are related to the wear (see also paragraph [0033]). Thus, the table shows that for the samples not comprising an

antioxidant (the comparative examples) irradiation results in a reduction of cracking, i.e. of wear. However, for the samples comprising an antioxidant (the embodiments) a clear indication of the area of cracking and of the occurrence of flaking is provided only for embodiment 2 (which was subjected to irradiation). By contrast, for embodiments 1 and 3 the table indicates for both the area of cracking and flaking the symbol "--". This symbol does not necessarily mean that no cracking or no flaking occur but can also indicate that no measure is given for these parameters. This is particularly the case, since in embodiment 2 the fact that no flaking occurs is described by the wording "no occurrence". Hence, there is no clear disclosure of results showing that, as understood by the appellant, embodiment 2 subject to an irradiation of 2.5 Mrad would show a worse wear resistance than embodiment 1, which comprises the same amount of antioxidant and has not been irradiated.

Indeed such a disclosure would be at odds with the rest of the disclosure of E9 according to which, at least for radiation up to 5 Mrad, the use of irradiation results in an improvement of the wear resistance (paragraph [0021]). Hence, in the Board's view, table 1 of E9 does not disclose that, when an antioxidant is added, the use of gamma irradiation results in lower wear resistance, a behaviour that would be different from what the same table shows for samples without an antioxidant addition.

Thus, when trying to solve the above problem starting from the method of E9, which uses an antioxidant, the person skilled in the art would have no reason to discard the teaching provided by documents that deal with materials without antioxidants.

2.4 One such document is E17, whose disclosure in respect of the effect of irradiation on the wear resistance is almost literally identical with that of the patent in suit. Page 13 discloses that the irradiation dose is "preferably from about 1 to about 100 Mrad, and more preferably, from about 5 to about 25 Mrad, and most preferably from about 5 to about 10 Mrad". This most preferable range is based on achieving what the inventors of E17 have determined to be a reasonable balance between improved wear resistance and minimal degradation of other important physical properties. However, "if a user is primarily concerned with reducing wear, and other physical properties are of secondary concern, then a higher dose than the above stipulated most preferable range (e.g., 5 to 10 Mrad) may be appropriate". Therefore, E17 teaches, like the patent in suit, that an improved wear resistance can be achieved by selecting a radiation dose in the presently claimed range.

It is true that E17 teaches also to perform annealing or re-melting (see for instance the abstract), a step excluded by present claim 1. However, the purpose of this treatment is to reduce oxidation (page 20, lines 31-35). In the method of E9, thanks to the use of vitamin E, which is more effective in preventing oxidation than the use of annealing or re-melting (paragraphs [0005] to [0007]), there is no need to perform these additional steps. Hence, the person skilled in the art would dispense with them.

Accordingly, the combination of E9 and E17 renders it obvious to perform irradiation with a dose in the claimed range without the necessity of performing annealing or re-melting. Therefore, the subject-matter

of claim 1 of Auxiliary Request 8 lacks an inventive step.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated