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**Datasheet for the decision  
of 26 February 2013**

**Case Number:** T 0212/10 - 3.3.10

**Application Number:** 97908650.1

**Publication Number:** 881919

**IPC:** A61L 27/00

**Language of the proceedings:** EN

**Title of invention:**

Radiation and melt treated ultra high molecular weight polyethylene prosthetic devices

**Patent Proprietor:**

MASSACHUSETTS INSTITUTE OF TECHNOLOGY  
THE GENERAL HOSPITAL CORPORATION

**Opponent:**

SigmaRC GmbH

**Headword:**

Radiation and melt treated polyethylene/MIT

**Relevant legal provisions:**

EPC Art. 123(2)

**Keyword:**

"Main and auxiliary requests 1 to 6: amendment (not allowable)  
- not unambiguously derivable from the application as filed"

**Decisions cited:**

-

**Catchword:**

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Case Number: T 0212/10 - 3.3.10

**DECISION**  
of the Technical Board of Appeal 3.3.10  
of 26 February 2013

**Appellant I:** MASSACHUSETTS INSTITUTE OF TECHNOLOGY  
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**Appellant II:** SigmaRC GmbH  
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**Representative:** Held, Stephan & Lunz, Manfred  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
9 November 2009 concerning maintenance of  
European patent No. 881919 in amended form.**

**Composition of the Board:**

**Chairman:** P. Gryczka  
**Members:** J.-C. Schmid  
D. S. Rogers

## Summary of Facts and Submissions

- I. The Appellant I (proprietors of the patent) and Appellant II (opponent) lodged appeals against the interlocutory decision of the Opposition Division which found that the European patent No. 881 919 in amended form met the requirements of the EPC.
- II. Notice of opposition was filed against the granted patent by Appellant II requesting revocation of the patent-in-suit in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC), insufficient disclosure (Article 100(b) EPC), and of extending the subject-matter of the patent-in-suit beyond the content of the application as filed (Article 100(c) EPC).
- III. With respect to the issue of added subject-matter, the Opposition Division considered that the method according to claim 22 of the then pending main request and to claim 1 of the then pending auxiliary request 1b fulfilled the requirements of Article 123(2) EPC.
- IV. At the oral proceedings before the Board, held on 26 February 2013, the Appellant I defended the maintenance of the patent-in-suit in amended form based on the claims according to a main and six auxiliary requests, all requests filed on 19 March 2010.

Independent claim 22 of the main request read as follows:

"22. A method for making a cross-linked ultra high molecular weight polyethylene having 2 or 3 melting

peaks and substantially no detectable free radicals, comprising the steps of:

providing ultra high molecular weight polyethylene having polymeric chains and which is pre-heated to a temperature above room temperature but below the melting point of said ultra high molecular weight polyethylene;

irradiating said ultra high molecular weight polyethylene at a dose and dose rate so as to (i) cross-link said polymeric chains and (ii) provide irradiation-induced heat to at least partially melt the polyethylene; and

cooling said irradiated ultra high molecular weight polyethylene."

Claim 18 of auxiliary requests 1, 2 and 3 differed from claim 22 of the main request only in that "the temperature of said polyethylene after said irradiation step is at least 130°C".

Claim 18 of auxiliary request 4 differed from claim 22 of the main request only in that "the temperature of said polyethylene after said irradiation step is 130°C to 200°C".

Claim 18 of auxiliary request 5 differed from claim 18 of auxiliary request 4 only in that polyethylene is "pre-heated to a temperature between 100°C to below the melting point of said ultra high molecular weight polyethylene".

Claim 2 of auxiliary request 6 differed from claim 18 of auxiliary request 5 only in that the temperature of

said polyethylene after said irradiation step is 140°C to 200°C.

- V. Appellant II submitted *inter alia* that there was no basis in the application as filed for the amendment concerning the irradiation of the preheated ultra high molecular weight polyethylene (UHMWPE) at a dose and dose rate so as to provide irradiation-induced heat to at least partially melt the polyethylene. This amendment was present in the method-claims of the main and auxiliary requests 1 to 6, which hence did not comply with the requirements of Article 123(2) EPC.
- VI. According to Appellant I, the amendment concerning the dose and the dose rate at which the pre-heated UHMWPE is irradiated according to the claimed method was supported by page 3, lines 34 to 39 or by page 15, line 17 to 21 of the application as filed in combination with page 15, lines 27-28 disclosing that adiabatic melting is meant to include complete or partial melting or with page 16, lines 22-24 disclosing that the adiabatic heating completely melts the UHMWPE or only partially melts the UHMWPE.
- VII. The Appellant I requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or, subsidiarily, on the basis of any of the auxiliary requests 1 to 6, all requests filed on 19 March 2010.

The Appellant II requested that the decision under appeal be set aside and the patent be revoked.

VIII. At the end of the oral proceedings the decision of the Board was announced.

### Reasons for the Decision

1. The appeals are admissible.
2. *Amendments (Article 123(2) EPC)*

#### *Main request*

- 2.1 Claim 22 of the main request has been amended vis-à-vis claim 22 as granted *inter alia* in that the step of irradiating the UHMWPE is performed at a dose and dose rate so as to provide irradiation-induced heat to at least partially melt the polyethylene.
- 2.2 According to the Appellant I, the basis for this amendment was found on page 3, lines 34 to 39 and on page 15, line 17 to 21 in combination with page 15, line 26 or page 16, lines 22 to 24 of the application as filed.

However the sections of page 3, lines 34 to 39 and page 15, line 17 to 21 of the application as filed are directed to a method in which the pre-heated UHMWPE is irradiated to a high enough total dose and at a fast enough dose rate so as to generate enough heat in the polymer to **melt substantially all the crystals** in the material (see page 3, lines 34 to 37 and page 15, lines 17 to 20) and, hence, cannot provide a basis for irradiating the pre-heated UHMPWE at a dose and dose rate so as to provide induced heat to only at least

**partially melt** the polyethylene as required by the method according to claim 22 of the main request.

The section on page 15, lines 27-28 of the application as filed merely provides the definition of an adiabatic melting within the meaning of the patent-in-suit, and thus, as such, cannot provide a basis for the minimum dose and dose rate required by claim 22 of the main request for irradiating the polyethylene.

The section on page 16, lines 22 to 23 of the application as filed discloses that in certain embodiments the adiabatic heating only partially melts the UHMWPE. This section alone does not provide a proper basis for the contested amendment. Furthermore, this embodiment wherein the adiabatic heating only partially melts the UHMPWE is different from the method disclosed on page 3, lines 34 to 37 and page 15, lines 17 to 20, requiring an irradiation step generating enough heat to melt substantially all the crystals in the polymer in order to ensure elimination of substantially all detectable free radicals.

Therefore, the features relating to the method disclosed in the sections of page 3, lines 34 to 39 and of page 15, lines 17 to 21 cannot be read in combination with those of the embodiment of page 16, lines 22 to 24.

Accordingly, the Board comes to the conclusion that there is no support in the application as filed for the feature in claim 22 of the main request relating to irradiating the pre-heated UHMPWE at a dose and dose rate so as to provide irradiation-induced heat to at

least partially melt the polyethylene, as now required by the method of claim 22 of the main request.

Consequently, claim 22 does not comply with the requirements of Article 123(2) EPC.

*Auxiliary request 1 to 6*

2.3 Claim 18 of auxiliary requests 1 to 5 and claim 2 of auxiliary request 6 also comprise the step of irradiating the ultra high molecular weight polyethylene at a dose and dose rate so as to provide irradiation-induced heat in the polyethylene to at least partially melt the polyethylene. Thus, for the reasons given in point 2.2 above, these claims are also amended in such a way that subject-matter extending beyond the application as filed is added, contrary to the requirements of Article 123(2) EPC.



**Order**

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

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar

The Chairman

C. Rodríguez Rodríguez

P. Gryczka