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**Datasheet for the decision
of 11 August 2014**

Case Number: T 1340/11 - 3.3.03

Application Number: 97933345.7

Publication Number: 0935446

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Language of the proceedings: EN

Title of invention:
Crosslinking Of Polyethylene For Low Wear Using Radiation And
Thermal Treatments

Patent Proprietor:
Orthopaedic Hospital
University Of Southern California

Opponent:
Smith & Nephew Orthopaedics AG

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty - main request (yes)
Inventive step - main request (yes)



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Chambres de recours**

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Case Number: T 1340/11 - 3.3.03

**D E C I S I O N
of Technical Board of Appeal 3.3.03
of 11 August 2014**

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
5 April 2011 concerning maintenance of the
European Patent No. 0935446 in amended form.**

Composition of the Board:

Chairman B. ter Laan
Members: D. Marquis
C. Brandt

Summary of Facts and Submissions

- I. The appeal by the opponent lies from the decision of the opposition division posted on 5 April 2011 maintaining European patent N° 0 935 446 (based on application number 97 933 345.7) in amended form.
- II. A notice of opposition against the patent was filed in which the revocation of the patent was requested on the grounds according to Article 100(a) EPC (lack of novelty and lack of inventive step).
- III. By a decision announced orally on 18 October 2010, the opposition division maintained the patent in amended form on the basis of the main request filed during the oral proceedings. The decision was based *inter alia* on the following documents:

D4: F.-W. Shen et al., Journal of Polymer Science: Part B: Polymer Physics, Vol. 34, 1063-1077 (1996, published April 2006)

D7: Robert M. Streicher, beta-gamma 1/89, 34-43

D14b: US-A-5 414 049

In the decision it was held that the main request (claims 1 - 23 as filed during the oral proceedings of 18 October 2010) was allowable under Article 123(2) EPC and Rule 80 EPC, that it was novel over D7 and D14b and inventive over D4 because none of the cited documents suggested to combine radiation crosslinking and thermal treatment of the crosslinked polymer composition to enhance wear resistance as shown in the examples of the contested patent.

IV. On 15 June 2011, the opponent lodged an appeal against the decision of the opposition division and paid the prescribed appeal fee on the same day. The statement setting out the grounds of the appeal was filed on 16 August 2011. The appellant requested that the patent be revoked. Documents D18 to D20 were provided:

D18: Correlations between oxidation, crosslinking, and wear performance of UHMWPE, D.C. Sun et al., 43rd Annual Meeting, Orthopaedic Research Society, February 9-13, 1997, San Francisco, California, p. 783.

D19: Assessment of gel content and crosslinking density in UHMWPE, D.C. Sun et al, 23rd Annual Meeting of the SOCIETY FOR BIOMATERIALS, April 30 - May 4, 1997, New Orleans, Louisiana, U.S.A., page 431.

D20: Orthopaedic Transactions published by The Journal of Bone and Joint Surgery, Inc., "American Academy of Orthopaedic Surgeons Scientific Program." Sixty-third Annual Meeting held in Atlanta, Georgia, February 22 through 26, 1996, pages 179, 180, 112, 113.

V. In response, by letter dated 3 January 2012 the respondent (patent proprietor) requested the dismissal of the appeal or the maintenance of the patent on the basis of two sets of claims as first and second auxiliary requests.

VI. On 2 April 2014, the parties were summoned to oral proceedings to be held on 11 August 2014. On 16 Mai 2014, a communication was issued by the Board in which a preliminary opinion was given. Regarding the main request, the admissibility of claims 22 and 23 under Rule 80 EPC was questioned and the novelty of the claims over D14b in view of documents D18 to D20 was

addressed. Also, the question was posed whether D18 to D20 disclosed the same ultrahigh molecular weight polyethylene (UHMWPE) as that used in D14b. It was also mentioned that each of D4, D7 and D14b could be seen as closest prior art for the assessment of inventive step. The Board also pointed out the bad legibility of Fig.12 of D7 and that, as a result, no information could be derived from that figure (point 7.1.2).

- VII. By letter of 10 July 2014, the appellant submitted arguments concerning the admissibility of D18 to D20, as well as novelty and inventive step of the main, first and second auxiliary requests.
- VIII. By letter of 11 July 2014, the respondent provided three sets of claims as main request and first and second auxiliary requests.

The main request contained 21 claims of which claims 1, 4, 5, 17 and 21 read as follows:

"1. A preformed polymeric composition comprising a crosslinked thermally treated polymer, characterised in that the composition possesses the following characteristics: a degree of swelling of between about 1.7 and about 5.3; a molecular weight between crosslinks of between about 400 and about 8400 g/mol: and a gel content of between about 95 and about 99%, wherein crosslinking is achieved by irradiation crosslinking in the solid state."

"4. An in vivo implant comprising a polymeric composition in accordance with any one of claims 1 to 3."

"5. A method for increasing the wear resistance of a

performed polymeric composition, comprising the steps of:

- (a) irradiation crosslinking the polymeric composition in a solid state; and
- (b) subjecting the crosslinked polymeric composition to thermal treatment; to produce a polymeric composition that possesses the following characteristics: a degree of swelling of between about 1.7 and about 5.3; a molecular weight between crosslinks of between about 400 and about 8400 g/mol; and a gel content of between about 95 and about 99%."

"17. A method for determining an optimal radiation dose and thermal treatment for treating a polymer to increase its wear resistance, when made into a desired product, while maintaining its desirable physical and/or chemical properties, the method comprises the steps of:

- (a) irradiating the polymer in the solid state within a range of radiation doses likely to produce the desirable wear resistance and physical and/or chemical properties;
- (b) remelting the polymer;
- (c) correlating the radiation dose with the wear rate of the desired product made from the irradiated remelted polymer using actual or simulated wear conditions for the desired product;
- (d) correlating the radiation dose with each of the physical and/or chemical properties of the desired product made from the irradiated remelted polymer using actual or simulated wear conditions for the desired product;
- (e) comparing the correlations in steps (c) and (d) to determine the optimal radiation dose that will produce a desirable wear rate while maintaining the desirable physical and/or chemical properties, if such a

radiation dose is arrived at, using this optimal radiation dose for future treatment of the polymer;

(f) if the optimal radiation dose cannot be arrived at in step (e), then determining a dose that would produce a desirable wear rate based on the correlation of step (c) and annealing instead of remelting the polymer that has been irradiated to said dose;

(g) correlating the physical and/or chemical properties of the desired product made from the irradiated and annealed polymer using actual or simulated wear conditions for the desired product, with different annealing times and temperatures;

(h) determining an annealing temperature and time that will provide the desirable wear rate and physical and/or chemical properties, if this is possible, then using the radiation dose and annealing conditions determined at this step for future treatment of the polymer;

(i) if step (h) does not provide the desirable wear rate and physical and/or chemical properties, then applying a lower radiation dose and repeating steps (c) to (i) or (h) until the optimal radiation dose and annealing conditions are determined or the steps confirm that no optimal radiation dose and annealing conditions can be obtained for the desired wear rate and physical and/or chemical properties, wherein the desirable physical and chemical properties are: a degree of swelling of between about 1.7 and about 5.3; a molecular weight between crosslinks of between about 400 and about 8400g/mol; and a gel content of between about 95 and 99%."

"21. A process for treating a polymer in accordance with any one of claims 5 to 16, wherein the process employs a radiation dose and remelting or annealing conditions determined by the method of claim 17 or 18."

Claims 2 to 4 were directed to preferred embodiments of claim 1. Claims 6 to 16 were directed to preferred embodiments of claim 5. Claims 18 to 20 were directed to preferred embodiments of claim 17.

IX. Oral proceedings were held on 11 August 2014.

X. The appellant's arguments may be summarised as follows:

Main request

- Admissibility of D18 to D20

D18 to D20 should be admitted to the proceedings because they were very relevant to the properties of the UHMWPE polymer disclosed in the examples of D14b. Those documents were filed late because they were scientific publications which were difficult to find in the relevant document databases.

- Novelty

D14b disclosed a preformed polymeric composition that comprised a crosslinked and thermally treated polymer. Method D explicitly disclosed the irradiation of a surgical grade UHMWPE, after which the UHMWPE was subjected to a thermal treatment. D14b did not provide a value for the degree of swelling, the molecular weight between cross-links or the gel content of that crosslinked composition but those properties were disclosed in D18 to D20. Those documents referred to a composition prepared by the method disclosed in D14b so that the properties disclosed therein pertained to the same composition as that of D14b. The gel content of the composition was disclosed in D18, D19 and D20 and the degree of swelling was disclosed in D19. The

molecular weight between crosslinks, which was directly related to the gel content, could be calculated from the gel content using the theory of Flory and Rehner as shown in D4. The value obtained was the same as claimed in claim 1 of the contested patent. Claim 1 therefore lacked novelty over D14b.

D7 and D4 also took away the novelty of the claimed subject-matter of the main request. The objections based on those two documents were provided for the first time during the oral proceedings on appeal, but they should be admitted to the proceedings because of their relevance.

D7 disclosed an UHMWPE that was crosslinked by irradiation with a gel content and degree of swelling in the claimed ranges, as could be seen from Figure 12. The irradiation of that polymer could be seen as a thermal treatment because it resulted in a temperature rise. Based on Figure 12, the molecular weight between the crosslinks was calculated to fall within the claimed range.

D4 disclosed the thermal treatment of a chemically crosslinked polymer composition. Chemical crosslinking was not excluded from claim 1 of the main request so that D4 was relevant. The irradiation of this composition resulted in further crosslinking of the polymer. The resulting composition had a gel content, a degree of swelling and a molecular weight between the crosslinks falling within the ranges now being claimed. The measurement of these properties had been carried out on the preformed composition.

- Inventive step

D4 was the closest prior art. The patent in suit did not show the presence of a surprising technical effect for the claimed preformed polymers. The use of irradiation crosslinking instead of chemical crosslinking of D4 was obvious. The use of irradiation to crosslink the composition was also found in D7. The patent also provided no proof of a technical effect related to the thermal treatment. Starting from D4 the claimed subject-matter therefore lacked an inventive step.

XI. The respondent's arguments may be summarised as follows:

Main request

- Admissibility of D18 to D20

Documents D18 to D20 were published more than 15 years ago and could have been cited at the beginning of the opposition proceedings. Those documents were filed late and should not be admitted to the proceedings.

- Novelty

D14b did not anticipate claim 1 of the main request because it did not disclose a preformed polymer and it did not disclose the gel content, degree of swelling or molecular weight between the crosslinks of the composition. D18 to D20 did not relate to the same material as that used in D14b.

The novelty objections based on D7 and D4 were provided for the first time at the oral proceedings so that the respondent had not had sufficient time to prepare

arguments relating to those documents. Those objections should not be admitted to the proceedings.

D7 did not disclose thermal treatment of the polymer composition; it was even taught to avoid thermal treatment.

D4 disclosed chemical and not irradiation crosslinking. D4 also indicated that irradiation of the chemically crosslinked polymer composition resulted in de-crosslinking of the composition. Also, D4 only disclosed total hip prosthesis and no preformed polymers.

- Inventive step

D4 was the closest prior art. The irradiation in D4 was performed on the final product and not on the preformed polymer. Chemical crosslinking was presented as essential so that a person skilled in the art would not contemplate to apply irradiation crosslinking instead on the compositions of D4. The problem solved in the patent in suit was to provide a preformed polymer obtained without chemical crosslinking that displayed good wear resistance. The irradiation disclosed in D4 was carried out as a sterilization step, it was not sufficient to crosslink the polymer composition. D4 not only taught away from irradiation crosslinking but also from the thermal treatment of the composition. The claimed subject-matter was therefore inventive in view of the cited documents.

XII. The appellant requested that the decision under appeal be set aside and that European patent No. 0 935 446 be revoked.

XIII. The respondent requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or on the basis of one of the auxiliary requests 1 or 2, all requests as filed with letter dated 11 July 2014.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. Amendments

The main request corresponds to the set of claims maintained by the opposition division from which claims 22 and 23 are deleted. The appellant did not raise any objections under Articles 123(2) and (3) EPC and the Board sees no reason to take a different view.

3. Novelty

3.1 D14b discloses a method for producing a medical implant formed from an olefinic material, the material having improved oxidation resistance, comprising the steps of: sealing the implant in an oxygen impermeable package in an oxygen reduced non-reactive atmosphere; radiation sterilizing said packaged implant; and heating said packaged implant for a predetermined time at a temperature of between about 37°C and the melting point of said olefinic material to form cross-links between free radicals in neighboring polymeric chains (claim 1).

In the examples of D14b, surgical grade ultrahigh

molecular weight polyethylene (UHMWPE) samples were processed. The UHMWPE is not further characterized in D14b. In Method D according to the examples, the UHMWPE sample was sterilized by irradiation with gamma-rays in a dose of 2.5 Mrad. After the irradiation, the UHMWPE sample was heat treated at 50°C for 144 hours in an oven. In Method D of the examples of D14b the UHMWPE polymer is therefore irradiated in the solid state and thermally treated. However, neither the degree of swelling, nor the molecular weight between crosslinks nor the gel content of the resulting irradiated and thermally treated polymer composition is reported in D14b.

3.2 D18, D19 and D20 relate to UHMWPE implants. The UHMWPE compositions of those documents are said to be processed, which included irradiation and thermal treatment according to the method disclosed in D14b (D18, page 783, second paragraph, footnote 3; D19, page 431, second paragraph, footnote 2; D20, page 180, first paragraph, lines 8 to 13). Therefore, the UHMWPE described in those documents appears to have undergone the treatment described in present claim 5. For that reason D18 to D20 seem *prima facie* relevant enough to be admitted to the proceedings.

3.3 However, D18 to D20 only disclose that the method of D14b was applied; they do not disclose that their results were obtained with the same UHMWPE polymer composition as that used in D14b. As a result, it cannot be ascertained that the irradiated and heated UHMWPE samples of D18 to D20 and those of D14b display the same values of gel content and degree of swelling. Even if D14b and D18 to D20 were all surgical grade UHMWPE (D18 and D19 mention the type GUR 415), other types of surgical grade UHMWPE existed, as can be seen

from paragraph [0021] of the contested patent. No evidence was provided that those different UHMWPE polymers all displayed the same set of properties after irradiation and thermal treatment.

3.3.1 Furthermore, D18, D19 and D20 do not disclose the same combination of properties (degree of swelling, molecular weight between crosslinks and gel content) as claimed in the present main request.

3.3.2 In D18 the gel content of the treated UHMWPE is disclosed in the form of a curve in figure 3. The figure does however not allow a reading of a numerical value so that it is not possible to conclude that the gel content would be in the claimed range. Also, D18 does not disclose the degree of swelling, nor the molecular weight between crosslinks of the treated material.

3.3.3 D19 discloses the irradiation and heat treatment of GUR 415 UHMWPE rods. The degree of swelling and gel content for the UHMWPE treated according to the method of D14b are disclosed in Table 2. The value of the degree of swelling or swell ratio was 2.7 at a gel content of 100%. The molecular weight between crosslinks of the treated material is not disclosed. Therefore, it cannot be concluded that the treated polymer of D19 or the polymer of D14b is according to claim 1 of the main request

3.3.4 D20 is a collection of several scientific articles. One article is described on pages 179-180 of D20 and is entitled "Development of stabilized UHMWPE implants with improved oxidation resistance via crosslinking". On page 180, lines 6 to 8, it refers to "a new manufacturing process, described in U.S. Patent

#5,414,049" (which is D14b) to prevent radiation induced oxidation of UHMWPE. It then goes on to describe the radiation and low temperature heating of UHMWPE. The crosslink, creep and wear of the material so produced is disclosed in the table on page 180, left column, but neither the degree of swelling, nor the molecular weight between crosslinks nor the gel content of that material is provided.

The second article, on pages 112-113 of D20, is entitled "Effect of radiation-induced crosslinking on creep and wear performance of UHMWPE". There is no reference to a material produced according to D14b in that article. Curves representing the variations of the gel content of UHMWPE materials as a function of the depth into the sample are disclosed in figure 2 on page 113. A value of the gel content can however not unambiguously be derived from that figure because of its bad quality and the lack of gradation between 80 and 100% on the gel content axis. The degree of swelling and the molecular weight between crosslinks are not disclosed for the materials of the second article.

In view of the above, none of D18 to D20 provides the combination of degree of swelling, molecular weight between crosslinks and gel content as claimed in the main request. Therefore, even if it could be accepted that those documents describe the material of D14b - which it cannot, see point 3.3 above -, they do not disclose all the features of present claim 1 or of claim 5.

- 3.4 Therefore, it cannot be concluded that D14b discloses clearly and unambiguously the claimed products or the claimed methods.

3.5 D7 discloses irradiation as a means of sterilization and modification of medical grade UHMWPE materials. Some samples of the UHMWPE disclosed in D7 were further annealed at 80°C to study the postoxidation behaviour of the materials as a result of the temperature applied (page 39, right column, second paragraph). Figure 12 on page 37 is a graph representing swelling and gel content of electron beam irradiated polyethylenes as a function of the absorbed dose. Neither the figure nor the corresponding text passage on page 39 (right column, 6th full paragraph) indicate whether the material studied had been annealed so that it cannot be concluded that the material of figure 12 had been thermally treated. No evidence was provided that irradiation of the materials represented in figure 12 would result in a temperature rise within the material that could be seen as a thermal treatment. Furthermore, the poor legibility of figure 12, which had been commented on in the Board's communication in preparation of the oral proceedings, does not allow the retrieval of any value for the swelling nor gel content of the irradiated materials. Nor did the appellant provide any values for those parameters so that it cannot be concluded that the materials presented in figure 12 fall under the scope of claim 1 of the main request. As the argument regarding lack of novelty of claim 1 over D7 was filed for the first time during oral proceedings on appeal and D7 does not clearly and unambiguously disclose the subject-matter now being claimed, that argument is not admitted to the proceedings (Article 13(3) RPBA).

3.6 D4 discloses the preparation of acetabular cups for artificial hip joints by compression moulding in the presence of a peroxide. These peroxide crosslinked cups were sterilized with gamma rays at room temperature in

an air atmosphere to an average dose of 3,4 Mrad (page 1063, synopsis). In the passage bridging pages 1067-1068 an irradiated peroxide crosslinked UHMWPE composition is described. The composition was crosslinked with 1% peroxide and after irradiation had a gel content of 97,5%, a degree of swelling of 3,35 and a molecular weight between the crosslinks of 2800 g/mol, which is within the ranges of claim 1 of the main request.

According to the passage bridging pages 1067 and 1068, irradiation of peroxide crosslinked UHMWPE reduced the gel content, network chain density and crosslink density. This was also observed in figure 1 on page 1068, according to which irradiation of the peroxide crosslinked UHMWPE materials led to a reduced gel content. The passage bridging the two columns of page 1075 states that irradiation produces crosslinking in amorphous regions but also extensive scission of taut tie molecules, leading to increased crystallinity and crystal perfection, reduced gel content and increased degree of swelling of a crosslinked network. However, peroxide crosslinking reduces the effect of irradiation on the crosslinked network. Therefore, the information of D4 suggests that irradiation reduces crosslinking. In view of this, the question was raised whether the irradiation of D4 could in fact be seen as crosslinking.

That question had not been raised in the statement of grounds of appeal nor in the following written procedure on appeal; it was raised for the first time during oral proceedings before the Board in the course of the novelty discussion. Since the objection of lack of novelty of claim 1 over D4 was raised at such a late stage and the question of the crosslinking (or not)

action of irradiation on UHMWPE raised new issues that the Board nor the respondent could reasonably be expected to deal with without adjournment of the oral proceedings, the novelty objection based on D4 is not admitted to the proceedings (Article 13(3) RPBA).

3.7 In view of the above, it is concluded that the subject-matter of claims 1 and 5 of the main request complies with Article 54 EPC.

4. Inventive step

4.1 The patent in suit relates to methods for enhancing the wear resistance of polymers for use in implants, for example as components of artificial joints such as acetabular cups (paragraph [0001]).

D4 aims at producing acetabular cups for artificial hip joints with less wear.

Although in the statement of the grounds of appeal the appellant had considered D7 to represent the closest prior art, at the oral proceedings before the Board both parties agreed that D4 represented a better starting point. D4 had also been considered to be the closest prior art in the contested decision. The Board sees no reason to take a different view.

4.2 The problem mentioned in the patent in suit was to provide wear resistant crosslinked preformed polymeric compositions (paragraphs [0001] and [0015]). The question to be answered is whether an improvement has been achieved vis-à-vis the closest prior art D4 by the solution offered by the patent, i.e. by the composition according to claim 1 and the method according to claim 5, in particular irradiation crosslinking and thermal

treatment of the polymer (paragraphs [0017] and [0018]).

- 4.3 From the examples of the patent in suit it can be concluded that the claimed compositions are suitable for their purpose: making implants or as components of artificial joints. The patent in suit does however not contain any comparative example with the materials of D4 so that it cannot be concluded that the claimed composition and methods lead to an improvement over D4. Starting from D4 as the closest prior art, the problem can therefore only be seen as to provide further polymeric compositions suitable for making implants or as components of artificial joints and further methods for preparing such compositions.
- 4.4 It remains to be decided whether the solution to that problem, as defined in the claims of the patent in suit, was obvious in view of the prior art.
- 4.5 The aim of D4 is to elucidate the relevance of crystallinity of UHMWPE materials to wear behaviour of acetabular cups for artificial hip joints prepared by compression molding. This document shows that irradiation of UHMWPEs, which are known to be highly crystalline materials (page 1063, last paragraph), produces crosslinking in amorphous regions of the material as well as extensive scissions of taut tie molecules leading to further increased crystallinity (page 1075, last paragraph of column 1) commonly associated with increased fatigue wear of the material (page 1063, first paragraph of column 2). D4 discloses that the use of peroxide to crosslink the UHMWPE in the melt during compression molding leads to a decrease in the degree of crystallinity of the material (page 1075, Conclusions, first part). It further shows that, in

general, peroxide crosslinking reduces the effect of sterilization irradiation on the crosslinked network, because chemical crosslinking stabilizes chain fragments resulting from radiolytic scission and suppresses recrystallization of broken chains from amorphous regions. As a result, wear rates were much lower for chemically crosslinked cups than for irradiation crosslinked cups (page 1075, last paragraph).

The teaching of D4 is therefore to use peroxide crosslinking rather than irradiation so as to improve wear resistance of UHMWPE based materials. From D4 it can also be concluded that peroxide crosslinking can be used as a means of reducing irradiation induced crystallization in the material and so improve its wear resistance. On the basis of the information available in D4, it cannot be concluded that the sterilization irradiation of the material can be seen as a means of crosslinking and improving the wear resistance of UHMWPE materials. D4 teaches away from the use of irradiation and it alone does therefore not point to the use of irradiation in order to crosslink the material.

- 4.6 D7 does not contain any hint to substitute or complement peroxide crosslinking of UHMWPEs with an irradiation crosslinking step. According to D7 (page 39, right column, second last paragraph), radiation doses in the range of 50 to 120 kGy (which is equivalent to 5 to 12 Mrad) are used for crosslinking, which is a higher dosage than the 3.4 Mrad used in D4 for sterilization purposes (page 1071, left column, paragraph about the effect of irradiation on thermal properties of a crosslinked network).

Since the teaching of D4 is to reduce irradiation in order to suppress the resulting crystallization, the skilled person would not have combined the teaching of D7 with that of D4 so as to arrive at the subject-matter now being claimed.

- 4.7 For those reasons, the subject-matter of claim 1 of the main request is inventive. The subject-matter of claims 5, 17 and 21, based on the compositions of claim 1 is therefore also inventive. It can be concluded that the main request fulfils the requirements of Article 56 EPC.
5. Since the main request is allowable, there is no need to go into the admissibility of any of the auxiliary requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the main request as filed with the letter dated 11 July 2014 and after any necessary consequential amendment of the description.

The Registrar:

The Chairman:



S. Sánchez Chiquero

B. ter Laan

Decision electronically authenticated