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Datasheet for the decision of 8 October 2010

Case Number: T 0609/07 - 3.3.09

Application Number: 96300113.6

Publication Number: 0722973

IPC: C08J 3/24

Language of the proceedings: EN

Title of invention:
Chemically crosslinked ultrahigh molecular weight polyethylene for artificial human joints

Patentee:
THE UNIVERSITY OF SOUTHERN CALIFORNIA, et al

Opponent:
Zimmer Inc.

Headword:
-

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 123(2), 100(c), 83, 54, 56

Keyword:
"Amendments - added subject-matter (yes, main request)"
"Disclosure - sufficiency (no, first auxiliary request)"
"Novelty, inventive step (yes, second auxiliary request)"

Decisions cited:
T 0109/91, T 0409/91, T 0435/91

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0609/07 **-** 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 8 October 2010

Appellants: (Patent Proprietors)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office announced orally on 16 January 2007 and issued in writing on 2 February 2007 revoking European patent No. 0722973 pursuant to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: W. Sieber
Members: M. O. Müller
K. Garnett

Summary of Facts and Submissions

I. This is an appeal by the proprietor of European patent No. 0 722 973 against the decision of the opposition division to revoke the patent.

II. The granted patent contained 60 claims, Claims 1 and 3 reading as follows:

"1. An implant for use within a body, said implant being made of irradiated crosslinked ultrahigh molecular weight polyethylene having a polymeric structure of between 28% and 51% crystallinity as measured by DSC, so as to increase the wear resistance of said implant within the body."

"3. An implant for use within a body, said implant being made of irradiated crosslinked ultrahigh molecular weight polyethylene having a polymeric structure of less than 45% crystallinity as measured by DSC, so as to increase the wear resistance of said implant within the body."

III. The opponent had requested revocation of the patent in its entirety on the grounds that the claimed subject-matter did not involve an inventive step, that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and that the subject-matter of the patent in suit extended beyond the content of the application as filed (Articles 100(a), (b) and (c) EPC).

The documents cited during the opposition procedure included

D1: "Overview and Fundamentals of UHMWPE, Facts on UHMWPE", Part One of a Series on Ultra-High Molecular Weight Polyethylene, Howmedia Inc. 1994, pages 1 to 8;

D2: "Material Properties, Product Quality Control, and Their Relation To UHMWPE Performance", Part Two of a Series on Ultra-High Molecular Weight Polyethylene, Howmedia Inc. 1994, pages 1 to 20;

D3: "A Comparative Analysis of The Properties of Standard and "Enhanced" Ultra-High Molecular Weight Polyethylene", Part Three of a Series on Ultra-High Molecular Weight Polyethylene, Howmedia Inc. 1994, pages 1 to 12;

D4: J. de Boer et al., "Crosslinking of ultra-high molecular weight polyethylene in the melt by means of 2,5-dimethyl-2,5-bis(tert-butyldioxy)-3-hexyne: 2.* Crystallization behaviour and mechanical properties", Polymer, volume 23, 1982, pages 1944 to 1952;

D7: W. R. Jones et al., "EFFECT OF γ IRRADIATION ON THE FRICTION AND WEAR OF ULTRAHIGH MOLECULAR WEIGHT POLYETHYLENE", Wear, volume 70, 1981, pages 77 to 92; and

D10: I. Kamel et al., "A Model for Radiation-Induced Changes in Ultrahigh-Molecular-Weight

Polyethylene", J. Polym. Sci.: Polymer Physics Edition, volume 23, 1985, pages 2407 to 2409.

IV. In its decision which was announced orally on 16 January 2007 and issued in writing on 2 February 2007, the opposition division revoked the patent, because none of the requests on file met the requirements of the EPC. In particular, various claims of the main and first to sixth auxiliary requests contravened Article 100(c)/Article 123(2) EPC, the subject-matter of Claim 1 of the seventh and eighth auxiliary requests lacked novelty over D7 (a ground of opposition which had been introduced by the opposition division in accordance with Article 114(1) EPC), and the subject-matter of Claim 1 of the ninth auxiliary request was not inventive over D7.

V. On 5 April 2007, the appellants (proprietors) filed a notice of appeal against the above decision and paid the prescribed fee on the same day. A statement setting out the grounds of appeal was filed on 12 June 2007 together with a main and fifteen auxiliary requests. By letter of 6 August 2010, these requests were replaced by a main and ten auxiliary requests.

VI. With letter of 25 October 2007, the respondent (opponent) filed a reply to the appeal.

VII. On 8 October 2010, oral proceedings were held before the board. The appellants maintained their main request, filed new first and second auxiliary requests and withdrew all previous auxiliary requests.

(a) Claim 1 of the main request is identical to Claim 1 as granted (see point II above).

(b) The first auxiliary request contains 10 claims which no longer refer to a crystallinity range between 28% and 51%. The independent claims of this request read as follows:

"1. An implant for use within a body, said implant being made of a crosslinked ultrahigh molecular weight polyethylene having a polymeric structure of less than 45% crystallinity after irradiation sterilization as measured by DSC, so as to increase the wear resistance of said implant within the body."

"8. A method of producing an implant with improved wear resistance, comprising the steps of: crosslinking a polyethylene to produce a crosslinked ultrahigh molecular weight polyethylene having a polymeric structure characterized by less than 45% crystallinity after irradiation sterilization as measured by DSC, and annealing the crosslinked ultrahigh molecular weight polyethylene to preshrink and stabilize its size before making it into an implant."

(c) The second auxiliary request contains 9 claims, of which Claim 1 reads as follows (amendments with regard to Claim 1 of the first auxiliary request are underlined):

"1. An implant for use within a body, said implant being made of a crosslinked ultrahigh molecular

weight polyethylene having a polymeric structure of less than 45% crystallinity after sterilization by irradiation as measured by DSC wherein the crosslink is achieved according to the method selected from the group consisting of: chemically crosslinking a polyethylene, irradiation crosslinking a polyethylene in a molten state, and photocrosslinking a polyethylene in a molten state, so as to increase the wear resistance of said implant within the body."

Corresponding amendments are present in independent process Claim 7 of the second auxiliary request.

VIII. The appellants' arguments as raised during the written and oral proceedings, in as far as they are relevant to the present decision, can be summarized as follows:

Main request

The implant of Claim 1 referred to an irradiated crosslinked ultrahigh molecular weight polyethylene (UHMWPE) material. A crystallinity of between 28% and 51% for such a material was disclosed on page 9 of the application as filed. This disclosure had to be read as it stood and was not linked to any process where irradiation occurred subsequent to crosslinking.

The further sterilisation referred to in Claim 2 was based on page 11 of the application as filed, where a further irradiation step to sterilise the polymer was disclosed. Moreover, the term "further" as employed in Claim 2 did not define an additional process step, but

was obviously a further feature of the implant, defining that it was sterile as a result of having been irradiated.

The process of Claim 21 would be interpreted by the skilled person such that it referred to a method of producing an implant with improved wear resistance, rather than a method of improving the wear resistance of an already existing implant. Such a process was clearly disclosed in the application as filed.

First auxiliary request

The subject-matter of Claims 1 and 8 was clearly based on the application as filed, which did not contain any mandatory limitation on the crosslinking methods. In fact, the specific methods disclosed in the application as filed were presented as preferred embodiments only. The feature that the crystallinity was as measured by DSC was supported by the application as filed, because DSC was the method used in the examples to determine the crystallinity.

Concerning the issue of sufficiency of disclosure, the opposed patent disclosed at least one way of performing the invention. It is established case law of the boards of appeal that in such a case the invention is sufficiently disclosed. Irrespective of this, the burden of proof to show that the process variant of Claim 8, where crosslinking and sterilisation by irradiation were carried out in one and the same step, namely in the solid state, could not be carried out by the skilled person rested on the respondent. Quite apart from that, it would have been trivial to select a

UHMWPE starting material that had a sufficiently low degree of crystallinity such that even after an increase in crystallinity caused by irradiation sterilisation, the obtained values would still be lower than the upper limit of the crystallinity range cited in Claim 8. A polyethylene starting material with sufficiently low crystallinity would for example have been available in the form of the UHMWPE with a crystallinity of 38% as disclosed in Table 1 of D10. The skilled person could thus identify the appropriate starting material without undue experimentation. With the help of his common general knowledge, the skilled person therefore could have carried out the process variant where crosslinking and irradiation sterilisation were carried out in one step.

Concerning inventive step, D7 constituted the closest prior art. In Table 2 of the opposed patent, an irradiation-sterilised, initially uncrosslinked material with a crystallinity of 55.8% was compared with an irradiation sterilised material with a crystallinity of 42% that had previously been crosslinked by 1 wt% peroxide. From this comparison, it followed that due to the crosslinking with peroxide and the resulting low crystallinity, the wear resistance was drastically improved. The objective technical problem was therefore the provision of implants having improved wear resistance. The skilled person starting from D7 would not have arrived at the claimed subject-matter as D7 taught the increase of the crystallinity to values outside of the range required by Claims 1 and 8, in order to improve wear resistance. This teaching of D7 was furthermore in contradiction to that of D1 - D3, and D10, which indicated that lowering the

crystallinity led to higher wear resistance. The skilled person therefore would not have combined D7 with any of D1 - D3 or D10. Finally, D4 and D10 did not relate to implants and furthermore did not disclose anything about wear behaviour of UHMWPE when used in implants. Therefore, D4 or D10 would not have been taken into account by the skilled person wishing to improve implants.

Second auxiliary request

In view of the fact that the respondent did not raise any objections under Articles 54, 83 and 123(2) EPC at the oral proceedings held before the board, and simply maintained the previously made inventive step objections, the appellant did not comment on these issues.

IX. The respondent's arguments, as raised during the written and oral proceedings, in as far as they are relevant to the present decision, can be summarized as follows:

Main request

The wording "irradiated crosslinked ultrahigh molecular polyethylene" in Claim 1 covered UHMWPE that had been crosslinked by irradiation. The disclosure of a polymer having between 28% and 51% crystallinity on page 9 of the application as filed was in relation to a UHMWPE which had been crosslinked to have a polymeric structure of less than 45% and then subsequently irradiated to sterilise the polymer. Irradiation and crosslinking thus were separate steps in the original

disclosure of a polymer having 28% to 51% crystallinity. Claim 1 therefore extended over the content of the application as filed.

Claim 2 defined an implant of Claim 1, wherein the implant was further sterilised by irradiation. Claim 1 already defined an implant that had been crosslinked and then sterilised by irradiation. The application as filed did not disclose any further sterilisation step, ie a second sterilisation step performed after the first sterilisation step. Therefore Claim 2 was impermissible added subject matter.

Claim 21 related to a method of improving the wear resistance of an implant. To improve the wear resistance of an implant the method had to be carried out on a pre-existing implant, in this case an implant that was made from irradiated crosslinked UHMWPE. The application as filed disclosed a method of making implants but did not disclose any method for improving the wear resistance of an implant. Claim 21 therefore constituted impermissible added subject-matter.

First auxiliary request

According to the application as filed, irradiation crosslinking in the solid state was excluded, contrary to Claims 1 and 8, which covered any type of crosslinking. Furthermore, Claims 1 and 8 required the crystallinity to be as measured by DSC. However, the application as filed disclosed on pages 11 and 12 four alternative characterisation methods, namely DSC, X-ray scattering, FTIR and density measurements. The combination of a specific crystallinity range with one

specific characterisation method therefore constituted a double selection not disclosed in the application as filed (Article 100(c) EPC).

As to the requirement of sufficiency of disclosure, the opposed patent only disclosed how to achieve the defined crystallinity range in one way, namely by crosslinking in the melt to provide a material with less than 45% crystallinity and then irradiating in the solid state to sterilise. Claim 8 however additionally covered a process variant where crosslinking and sterilisation by irradiation were carried out in one and the same step, namely in the solid state. Crosslinking in the solid state by irradiation sterilisation led however to an increase in crystallinity. This was confirmed by the first experiment of Example 1 of the opposed patent were crystallinity increased from 49.2% to 55.8% as a consequence of irradiation sterilisation. In the absence of any guidance in the opposed patent, the skilled person would not know how he could crosslink in the solid state by irradiation and thereby reduce the crystallinity to less than 45% as required in the claims of the first auxiliary request.

As to inventive step, D7 could be considered to represent the closest prior art. In view of D7, the skilled person was confronted with the problem of improving wear resistance. It was already known from D1 to D3 as well as from D10 that wear resistance could be increased by lowering crystallinity. The skilled person attempting to produce implants with improved wear resistance would therefore have selected the material with the lowest crystallinity in Table I of D10 or

Table 1 of D4 and would have subjected this material to irradiation sterilisation as disclosed in D7. He would thereby automatically have arrived at the subject-matter of the variant of the first auxiliary request where crosslinking and sterilisation by irradiation were carried out in one and the same step.

Second auxiliary request

The respondent did not raise any objections under Articles 54, 83 and 123(2) EPC against the subject-matter of the second auxiliary request. With regard to inventive step, the respondent relied on its previous submissions.

X. The appellants (proprietors) requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed with letter dated 6 August 2010, alternatively the first or second auxiliary requests filed during the oral proceedings.

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

Reasons for the Decision

1. The appeal is admissible.

Main Request

2. *Amendments - Article 100(c) EPC*

2.1 Claim 1 of the main request defines an implant being made of an irradiated crosslinked ultrahigh molecular weight polyethylene (UHMWPE) having a polymeric structure of between 28% and 51% crystallinity. The wording "irradiated crosslinked ultrahigh molecular polyethylene" in Claim 1 includes two alternatives, namely

(i) UHMWPE that has been crosslinked by irradiation, representing a one step process, and

(ii) UHMWPE that has been crosslinked and then irradiated, representing a two step process.

A crystallinity range as defined in Claim 1, ie between 28% to 51% is disclosed in the application as filed on page 9, lines 7 - 14 where it is stated:

"Preferably, the **irradiated crosslinked** polymer possesses about 10% to 50%; more preferably, about 10% to 40%; and most preferably, about 10% to 30% less degree of crystallinity compared to the **uncrosslinked but irradiated** polymer. For example, the preferable degree of crystallinity of irradiated, crosslinked UHMW polyethylene is between about 28% to 51%; more preferably …" (emphasize added by the board).

This passage contains a comparison of an uncrosslinked but irradiated polymer with the corresponding irradiated crosslinked polymer. This can only mean that

the passage refers to a situation where crosslinking and irradiation are two separate steps, corresponding to alternative (ii) mentioned above. This interpretation is confirmed by the text following the passage, where reference is made to UHMWPE which was first crosslinked by peroxide and subsequently irradiated by γ-irradiation (page 9, lines 15 - 27 of the application as filed).

In view of the above it is evident that the relevant passage in the application as filed discloses a crystallinity range of between 28% and 51% only in relation to alternative (ii) but not in relation to alternative (i). Furthermore, such a crystallinity range is nowhere else disclosed in the application as filed, let alone in relation to alternative (i). Since, however, Claim 1 covers the defined crystallinity range in relation to both alternatives (i) and (ii), Claim 1 adds subject matter in contravention of Article 100(c) EPC.

2.2 An additional deficiency, this time with regard to alternative (ii) of Claim 1, is created by Claim 2 of the main request which requires that the implant of Claim 1 is subjected to a further irradiation step. For alternative (ii), this implies that the implant has been subjected to a crosslinking step, a subsequent irradiation step and thereafter to a second irradiation step to achieve sterilisation.

The appellants in their letter of 6 August 2010 cited page 8, lines 24 - 25 and page 11, lines 8 - 14 of the application as filed as a basis. The first text passage refers to "an UHMW polyethylene acetabular cup of a

total hip prosthesis which has been chemically crosslinked by a peroxide, and then sterilized by irradiation". The second text passage is a general reference relating to the fact that the crosslinked polymer may be further irradiated to sterilize the polymer. None of these text passages however discloses the sequence of a crosslinking step, a first irradiation step and second irradiation step to achieve sterilisation, as required by Claim 2 when referring back to alternative (ii) of Claim 1. Such a sequence of steps is in fact nowhere disclosed in the application as filed.

The appellants additionally argued in their letter of 6 August 2010 that the term "further" as employed in Claim 2 did not define an additional process step, but was obviously a further feature of the implant, defining that it was sterile as a result of having been irradiated. However, the claim is clearly drafted as a product-by-process claim which requires a further step "wherein the implant is further sterilized by irradiation". The appellants' argument therefore must fail.

In summary, also the subject-matter of Claim 2 of the main request is not disclosed in the application as filed (Article 100(c) EPC).

2.3 Claim 21 defines:

"A method for improving the wear resistance of an implant for use within a body, said implant being made from irradiated crosslinked ultrahigh molecular weight polyethylene, said method comprising the step of

crosslinking a polyethylene to provide a polymeric structure of between 28% to 51 % crystallinity as measured by DSC."

2.3.1 Thus, in general terms, this claim is directed to a method for **improving the wear resistance of an implant**. To improve the wear resistance of an implant the method must be carried out on a pre-existing implant, in this case an implant that is made from irradiated crosslinked UHMWPE. The application as filed, however, discloses a method of making implants but does not disclose any method for improving the wear resistance of a pre-existing implant. Consequently, Claim 21 of the main request does not meet the requirements of Article 100(c) EPC.

2.3.2 The appellants argued that Claim 21 would be interpreted by the skilled person such that it refers to a method of producing an implant with improved wear resistance. However, firstly, this interpretation goes against the literal wording of Claim 21 ("method for improving the wear resistance of an implant"). Secondly, the method of producing an implant with improved wear resistance (ie how, allegedly, Claim 21 should be interpreted by the skilled reader) is in fact already claimed in Claim 15. The skilled reader would therefore not expect to find a claim subsequent to Claim 15 claiming the same method again. Thus, the appellants' line of argument is not convincing.

2.4 In summary, Article 100(c) EPC with respect to Claims 1, 2 and 21 alone prejudices the maintenance of the opposed patent in the form of the main request. Consequently, there is no need to go into further

details as to whether or not dependent Claims 6 and 9 violate Article 100(c) EPC.

First Auxiliary Request

3. *Amendments - Articles 100(c) EPC and 123(2) EPC*

3.1 Claim 1 reads as follows:

"An implant for use within a body, said implant being made of a crosslinked ultrahigh molecular weight polyethylene having a polymeric structure of less than 45% crystallinity after irradiation sterilization as measured by DSC, so as to increase the wear resistance of said implant within the body."

3.1.1 Page 17, lines 32 - 35 of the application as filed discloses "in vivo implants that are made with the above polymer or according to the method presented herein" and that are "more wear resistant than their untreated counterpart". This disclosure creates a basis for the feature in Claim 1 of "An implant for use within a body" as well as for the wear resistance required by Claim 1.

The term "the above polymer" on page 17, lines 32 - 35 can only refer to the polymer disclosed in the preceding text passage (page 17, lines 16 - 18 and 25 - 27), namely a UHMWPE with "45% of crystallinity or less, in particular after irradiation in the solid state". The feature of an "ultrahigh molecular weight polyethylene having a polymeric structure of less than 45% crystallinity" in Claim 1 thus is based on the application as filed.

Page 5, lines 33 - 36 discloses that an "effective method for reducing the crystallinity of the polymer is by crosslinking". This disclosure is of general nature and does not contain any restriction with regard to the type of crosslinking. Moreover, crosslinking represents the only method of reducing crystallinity disclosed in the application as filed. The requirement in the above-discussed passage on page 17 that the UHMWPE has a crystallinity of 45% or less, ie a reduced crystallinity (see page 8, lines 28 - 31), therefore implies that said polyethylene is crosslinked with the type of crosslinking not being limited. This feature of Claim 1 hence is based on the application as filed as well.

Furthermore, the only irradiation in the solid state disclosed in the application as filed is irradiation sterilisation. Reference is made to page 6, lines 4 - 5, page 8, lines 4 - 5 and lines 24 - 25, page 9, lines 4 - 5, page 11, lines 10 - 11, page 15, line 31 and the examples of the application as filed. Consequently, the wording "45% of crystallinity or less, in particular after irradiation in the solid state" in the above-cited text passage on page 17, when read in the context of the remaining disclosure of the application as filed, can only refer to a crystallinity after irradiation sterilisation. This feature of Claim 1 therefore equally finds a basis in the application as filed.

Finally, the feature that crystallinity is as measured by DSC is based on page 11, lines 15 - 17 of the application as filed. The respondent noted in this

context that the application as filed disclosed various alternative measurement methods to determine crystallinity, namely X-ray scattering (page 11, line 20), FTIR (page 11, line 30) and density measurement (page 12, line 5). In the respondent's view the selection of the specific crystallinity range cited in Claim 1 in combination with the selection of a specific characterisation method (DSC) constituted a double selection that was not originally disclosed. However, apart from one single exception (page 9, lines 11 - 13), the broadest crystallinity range disclosed numerous times in the application as filed is the one required by Claim 1. Reference is made to page 8, lines 28 - 30, page 9, lines 30 - 31, page 15, lines 32 - 33, page 16, lines 8 - 10, page 18, lines 16 - 17 as well as Claims 4, 7 and 23 of the application as filed. Hence, there is a clear pointer in the application as filed towards this crystallinity range. The same applies to the DSC method. More particularly, apart from the above-discussed list of methods given on pages 11 and 12, the application as filed contains only one explicit disclosure of how to determine crystallinity and this is by way of DSC (Example 3 on page 28, lines 4 - 5). The application as filed thus provides clear pointers towards the crystallinity range and DSC characterisation as required by Claim 1. Consequently, the alleged double selection of crystallinity and characterisation method is clearly and unambiguously derivable from the application as filed.

3.1.2 From the above, it follows that the subject-matter of Claim 1 is based on the application as filed (Article 100(c)/123(2) EPC).

3.2 Apart from an additional annealing step, Claim 8 contains the same features as Claim 1. Hence, for the reasons given above, these features are based on the application as filed. The additional annealing step is based on the text passage already cited above in relation to Claim 1, namely page 17, lines 16 - 18. An additional basis is present in the form of page 16, lines 15 - 22 of the application as filed. Thus, Claim 8 meets the requirements of Article 100(c)/123(2) EPC.

3.3 The respondent did not raise any objections under Article 100(c)/123(2) EPC against the remaining claims and the board is satisfied that these claims are based on the application as filed and thus that the requirements of Article 100(c)/123(2) EPC are met.

3.4 The first auxiliary request meets therefore the requirements of Article 100(c)/123(2) EPC.

4. *Sufficiency of disclosure*

4.1 Interpretation of Claim 8

The process of Claim 8 comprises the step of "crosslinking a polyethylene to produce a crosslinked ultrahigh molecular weight polyethylene having a polymeric structure characterized by less than 45% crystallinity after irradiation sterilization".

One way of achieving the desired crystallinity of less than 45% after irradiation sterilisation is to crosslink the polymer in a **first step** and to irradiate the crosslinked polymer in its solid state at a

sterilisation dose in a **second step** (Claim 4 as filed). The crosslinking of the polymer in the first step is not carried out by irradiating the polymer in the solid state but by a method selected from (a) irradiation crosslinking of the polymer in the molten state, (b) photocrosslinking and (c) crosslinking with a free radical generating chemical (Claim 5 as filed). The first step reduces the crystallinity of the starting UHMWPE enough so that after sterilisation by irradiation (which inherently increases the crystallinity) the crystallinity is below 45%. This embodiment is clearly described in the application as filed, something that was not disputed by the parties.

However, the process of Claim 8 is not restricted to this embodiment, but includes the possibility that crosslinking and sterilisation by irradiation are carried out in one and the same step, namely in the solid state. In fact, both the appellant proprietors and the respondent insisted that the process of Claim 8 also includes this embodiment. This implies that Claim 8 covers process variants in which a UHMWPE is sterilised by irradiation in such a way that a crosslinked polymeric structure with less than 45% crystallinity is obtained.

4.2 Applicability of and criteria established by T 435/91 (OJ EPO 1995, 188) and T 409/91 (OJ EPO 1994, 653)

Claim 8 is directed to a process which is defined by a result to be achieved, namely the provision of a crystallinity of less than 45%. Though decisions T 435/91 and T 409/91 deal with cases in which the result to be achieved is part of a product claim, the

board takes the view that these decisions equally apply to process claims. This is confirmed by the statement made in the third paragraph of point 2.2.1 of the reasons of T 435/91 where it was held that "the criteria for determining the sufficiency of the disclosure are the same for all inventions, irrespective of the way in which they are defined".

As follows from these decisions (fifth and sixth paragraph of point 2.2.1 of the reasons of T 435/91 and second paragraph of point 3.5 of the reasons of T 409/91), in order for an invention claimed by means of a result to be achieved to be sufficiently disclosed, the available information must enable the skilled person to achieve the envisaged result over the whole ambit of the claim without undue difficulty. As is explicitly set out in the penultimate paragraph of point 3.4 of the reasons of T 409/91, the presence of one way of carrying out the invention therefore does not automatically imply that the invention is sufficiently disclosed.

4.3 Examination of sufficiency of disclosure over the whole ambit of claim 8

4.3.1 Based on the principles established in T 435/91 and T 409/91, it has to be analysed whether or not the specification discloses a technical concept fit for generalisation which makes available to the skilled person the host of variants encompassed by the functional definition given in Claim 8, in particular those in which the desired crystallinity is achieved via crosslinking by means of irradiation sterilisation.

4.3.2 The opposed patent contains only one embodiment which could be considered to represent an embodiment of a process where crosslinking and sterilisation are carried out simultaneously by irradiation. This is the first experiment of Example 1 (see paragraph [0065] of the opposed patent: "Irradiation produces crosslinking ..."). In this example, a UHMWPE specimen with a crystallinity of 49.2% (first row in Table 1) is irradiated with γ-rays at a sterilisation dose of 3.4 Mrad (paragraph [0057] of the patent specification). However, the crystallinity obtained by this process variant is not within the range cited in Claim 8, but significantly above the upper limit of this range (55.8% versus less than 45%). Consequently, it is evidenced by the opposed patent itself that purely applying irradiation sterilisation to crosslink a UHMWPE as covered by Claim 8 does not suffice to obtain the desired result of Claim 8.

4.3.3 Knowing that process variants in which crosslinking is effected solely by irradiation sterilisation do not give the crystallinity as required by Claim 8, the skilled person might try to modify these process variants such that a crystallinity as cited in Claim 8 is obtained. However, as was not disputed by the appellant, the opposed patent itself does not contain any teaching at all in this respect.

4.3.4 It remains to be examined whether the skilled person on the basis of his common general knowledge would have been able to modify the above-discussed process variants such as to obtain the desired crystallinity. The appellants in this respect argued that it would have been trivial to select a UHMWPE starting material

that had a sufficiently low degree of crystallinity such that, even after an increase in crystallinity caused by irradiation sterilisation, the obtained values would still be below the upper limit of the crystallinity range cited in Claim 8. The appellants in particular referred to the UHMWPE with a crystallinity of 38% as disclosed in Table I of D10 as an example of such a starting material.

However, this polyethylene represents an **annealed** sample (Table I of D10). No information on the annealing conditions is present in D10. Furthermore, as is apparent from a comparison of the values of the polyethylenes "**as received**" with the values of the annealed samples in Table I of D10, the crystallinities obtained after annealing do not correlate with the crystallinities of the polyethylenes "as received". For example, the "as received" sample with the lowest crystallinity value (54%) in Table I does not have the lowest crystallinity value after annealing. Starting from the appellants' assumption, the skilled person would therefore have to take several measures in order to arrive at a process variant in which crosslinking by means of irradiation sterilisation leads to a crystallinity as required by Claim 8. In particular, the skilled person:

- would have to realise that what needs to be done is to look for starting materials with sufficiently low crystallinity, though no guidance is present in this respect in the opposed patent;

- would have to realise on the basis of D10 that in order to obtain such a starting material, the material would have to be annealed;

- in the absence of any information available in D10 about the annealing conditions and in view of the fact that crystallinity obtained after annealing does not correlate with the initial crystallinity, would have to run a variety of annealing experiments with a variety of starting materials to find out how to obtain an annealed starting material with sufficiently low crystallinity; and

- despite the general teaching of the opposed patent to reduce crystallinity, would have to apply irradiation sterilisation, which inherently increases the crystallinity of the starting material.

In conclusion, it would only have been in deviation from and even in contradiction to the teaching of the opposed patent, and after a multiplicity of thought steps in combination with a variety of experiments, that the skilled person could have arrived at process variants in which crosslinking by irradiation sterilisation leads to a crystallinity as required by Claim 8. Therefore, what the appellants consider "trivial" in fact amounts to nothing less than setting up a new research program which deviates or even contradicts the teaching of the opposed patent. The method referred to by the appellants would therefore not have been at the disposal of the skilled person when simply reading the opposed patent and using his common general knowledge.

4.4 In other words, on the basis of the opposed patent and common general knowledge, the skilled person applying process variants where UHMWPE is crosslinked by means of irradiation sterilisation would not be able to obtain a crystallinity as required by Claim 8. Consequently, Claim 8 covers process variants that are insufficiently disclosed. The invention defined by this claim therefore does not meet the requirements of Article 83 EPC.

4.5 This finding is in agreement with the general legal principle that the protection covered by a patent should correspond to the technical contribution to the art made by the disclosure of the invention described therein (T 435/91, fourth paragraph of point 2.2.1 of the reasons and T 409/91, points 3.4 and 3.5 of the reasons). This principle excludes the patent monopoly from being extended to subject-matter, such as the above-discussed process variants covered by Claim 8, which, after reading the patent specification, would not be at the disposal of the skilled person.

4.6 The appellants argued during oral proceedings that the burden of proof that Claim 8 covers embodiments that do not lead to the crystallinity required by this claim was on the respondent. As the respondent had not submitted any experimental data in this respect, the respondent's burden of proof had not been discharged.

The board cannot agree with this view. Additional experimental evidence does not constitute a necessary precondition for the discharge of the burden of proof. On the contrary, any such discharge of the burden of

proof can be considered to have taken place as soon as evidence is available that renders a party's position more probable than not (see T 109/91 of 15 January 1992; point 2.10 of the reasons, not published in OJ EPO).

As has been set out above and as was discussed at length during the oral proceedings, this evidence exists in the present case in the form of the first experiment of Example 1 of the opposed patent.

Furthermore, this evidence was even not disputed by the appellants. More particularly, the appellants did not question that using a starting material with a crystallinity above 45%, such as 49.2% in Example 1 of the opposed patent, and applying irradiation sterilisation will not lead to a crystallinity as required by Claim 8.

Thus, the appellants' argument cannot succeed.

4.7 In summary, the first auxiliary request is not allowable in view of Article 83 EPC.

Second Auxiliary Request

5. *Amendments - Articles 100(c) EPC and 123(2) EPC*

Claims 1 and 7 are identical to Claims 1 and 8 of the first auxiliary request except that

(a) "irradiation sterilization" has been amended to "sterilization by irradiation" and

(b) the content of Claim 2 of the first auxiliary request has been incorporated into Claims 1 and 7.

Claims 2 - 6, 8 and 9 correspond to Claims 3 - 7, 9 and 10 of the first auxiliary request with the claim numbers and dependencies being adapted accordingly.

The respondent did not raise any objections under Article 123(2) EPC. The board is satisfied that the requirements of this article are met. In particular, amendment (a) is based eg on page 15, lines 31 - 34 and, in the same way as Claim 2 of the first auxiliary request, amendment (b) is based on page 7, lines 21 - 25 of the application as filed.

6. *Sufficiency of disclosure*

No objections against the sufficiency of disclosure of the invention covered by the claims of the second auxiliary request were raised by the respondent. The claimed subject-matter requires now a first step of crosslinking followed by sterilisation by irradiation. The crosslinking methods are specified in independent Claims 1 and 7 of the second auxiliary request such that crosslinking purely by way of irradiation sterilisation is no longer covered by the claims. The objection raised against this variant of the first auxiliary request thus no longer applies. The second auxiliary request therefore meets the requirements of Article 83 EPC.

7. *Novelty*

The respondent did not raise any novelty objections against the second auxiliary request.

D7, the most relevant document, studies the effect of γ-irradiation on the friction and wear properties of a single commercial grade UHMWPE. It discloses two rider specimens of UHMWPE that had been γ-irradiated at a dose of 2.5 and 5.0 Mrad without any prior crosslinking and exhibited after irradiation a crystallinity of 49% and 50% as measured by DSC (paragraph bridging pages 78 and 79 and Table 3 on page 86). The subject-matter of the independent claims differs from D7 in that the specimens were not crosslinked prior to irradiation sterilisation and also in the degree of crystallinity after irradiation sterilisation.

None of the further cited documents discloses an irradiation sterilised UHMWPE with a crystallinity within the range of any of the independent claims of the second auxiliary request in the form of an implant.

The subject-matter of the second auxiliary request is thus novel.

8. *Inventive step*

8.1 Closest prior art

The opposed patent aims at the preparation of implants with increased wear resistance (page 1, lines 5 - 8).

Generally, the closest prior art document is the prior art document disclosing subject-matter for the same purpose or aiming at the same objective as the claimed invention.

This condition is met by D7 which is concerned with the effect of sterilisation on the wear resistance of implants (first and last paragraph of the chapter "1. Introduction" on pages 77 and 78). As acknowledged by both parties, D7 therefore can be considered to represent the closest prior art.

8.2 The objective technical problem

The problem cited in the opposed patent is the provision of a polyethylene or polyethylene implant with improved wear resistance (page 2, line 5, page 3, lines 38 - 39, and page 4, lines 17 - 18 of the opposed patent).

In the sixth experiment of Example 1 of the opposed patent a UHMWPE having a crystallinity of 49.2% is chemically crosslinked with 1 wt% peroxide in a first step whereby the crystallinity is reduced to 39.8%. The following irradiation sterilisation step increases the crystallinity to 42.0%. This experiment illustrates the principle underlying the subject-matter of the second auxiliary request: In a first step the crystallinity of the starting UHMWPE is reduced by a specific crosslinking method in order to compensate for the increase in crystallinity that occurs in the second step, namely the sterilisation by irradiation. In other words, in the first step the crystallinity is reduced enough so that even after the inherent increase in

crystallinity in the second step, the "end" crystallinity is still below 45%. In Example 2 the UHMWPE of the above experiment ("modified polyethylene") is compared with an irradiation sterilised UHMWPE that was not subjected to any crosslinking prior to sterilisation by irradiation ("control polyethylene"). It is evident from Table 2 that the polyethylene according the second auxiliary request exhibits a mean wear rate of 4.12 compared to a mean wear rate of 19.19 for the control, which actually represents the teaching of D7. This significant reduction in the wear rate implies a significant improvement of wear resistance. It is thus credible that over the closest prior art document D7, the implants as defined in the second auxiliary request have an improved wear resistance. The problem cited in the opposed patent, ie the provision of implants with increased wear resistance, therefore constitutes the objective technical problem.

8.3 Obviousness

D7 does not disclose any separate crosslinking prior to irradiation sterilisation as required by the claims of the second auxiliary request. Moreover, no indication is contained in D7 that wear resistance could be improved by applying such a separate crosslinking step thereby reducing the "end" crystallinity of the sterilised implant to values below 45%. On the contrary, if anything, the opposite teaching is present in D7. In particular, it is evident from Table 2 in conjunction with Table 3 of D7 that, rather than a reduction, an increase in crystallinity from 46% to 49% or 50% is associated with a slight increase in wear

resistance (average wear rate decreases from 1.6 to 1.3). Although D7 reveals that the change in wear properties of the polymer is not significant, it thus appears that D7 would even have taught the skilled person away from reducing the crystallinity to less than 45%.

D1 - D3 are reports relating to "Facts on UHMWPE", providing the state of knowledge relating to UHMWPE as of 1994. It is conspicuous to the board that these documents relate only to uncrosslinked UHMWPE. Thus, any suggestion about the relationship (or lack thereof) between crystallinity and wear resistance relates only to uncrosslinked UHMWPE and says nothing about the behaviour of crosslinked UHMWPE or the effects of crosslinking on wear. There is in particular no hint in these documents that the crystallinity of a UHMWPE should be reduced in a first step by a specific crosslinking method in order to compensate for the inherent increase in crystallinity in a following irradiation sterilisation step, let alone that the "final" crystallinity of such a UHMWPE should be less than 45% in order to produce an implant with improved wear resistance.

D10 is a scientific paper relating to a model for radiation induced changes in UHMWPE. It discloses that UHMWPE, when irradiated for sterilization, shows an increase in crystallinity. This increase in crystallinity is usually accompanied by a loss in abrasion and wear resistance and by increased surface friction (see the abstract). But again, there is no hint in D10 that the crystallinity of a UHMWPE should be reduced in a first step by a specific crosslinking

method in order to compensate for the increase in crystallinity in the irradiation sterilisation step, let alone that the "final" crystallinity of such a UHMWPE should be less than 45% for the production of improved implants.

Finally, D4 discloses the chemical modification of UHMWPE materials by crosslinking but does not relate to medical implants. There would therefore be no incentive whatsoever for a person skilled in the art trying to improve the wear resistance of medical implants to combine this document with the closest prior art D7.

Consequently, neither D7 alone nor in combination with any of the additionally cited documents D1 - D3, D4 or D10 prejudices inventive step.

9. For the above reasons, the second auxiliary request meets the requirements of the EPC.

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 with the order to maintain the patent on the basis of Claims 1 to 9 according to the second auxiliary request filed during the oral proceedings and after any necessary consequential adaptation of the description.

The Registrar: The Chairman:

C. Eickhoff W. Sieber