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Datasheet for the decision of 6 December 2007

Case Number: T 1186/05 - 3.3.09

Application Number: 96301926.0

Publication Number: 0733472

IPC: A61J 1/10

Language of the proceedings: EN

Title of invention:
Multilayer films for packaging and administering medical solutions

Patentee:
Cryovac, Inc.

Opponent:
Baxter Healthcare Corpn

Headword:
-

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 54(3), 56

Keyword:
"Main request - Novelty - no, prior art value rounded up to allow comparison"
"Auxiliary request 1 - inventive step - yes, unexpected improvement"

Decisions cited:
T 0708/05, T 0074/98

Catchword:
-

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Case Number: T 1186/05 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 6 December 2007

Appellant: (Opponent)	Baxter Healthcare Corpn One Baxter Parkway Deerfield, IL 60015 (US)
Representative:	Dee, Ian Mark Eric Potter Clarkson LLP Park View House 58 The Ropewalk Nottingham NG1 5DD (GB)
Respondent: (Patent Proprietor)	Cryovac, Inc. 100 Rogers Bridge Road Building A Duncan, S.C. 29334-0464 (US)
Representative:	Price, Nigel John King J.A. Kemp & Co. 14 South Square Gray's Inn London WC1R 5JJ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 3 August 2005 rejecting the opposition filed against European patent No. 0733472 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: P. Kitzmantel
Members: J. Jardón Álvarez
M-B. Tardo-Dino

Summary of Facts and Submissions

I. The grant of European patent No. 0 733 472 in respect of European patent application No. 96301926.0 in the name of Cryovac, Inc. which had been filed on 21 March 1996 claiming a US priority of 22 March 1995 (US 408668), was announced on 4 December 2002 (Bulletin 2002/49) on the basis of 8 claims. Independent Claims 1 and 8 read as follows:

"1. A multilayer film capable of withstanding heat sterilization at 121°C (250°F), comprising:

(a) an interior layer comprising a homogeneous ethylene/alpha-olefin copolymer having a density from 0.89 to 0.92 grams per cubic centimeter or a blend of two or more homogeneous ethylene/alpha-olefin copolymers having a density from 0.89 to 0.92 grams per cubic centimeter;

(b) a first exterior layer comprising a homopolymer of polypropylene, a copolymer of polypropylene, a blend of homopolymer of polypropylene and elastomer, a blend of copolymer of polypropylene and elastomer, high density polyethylene, or copolyester; and

(c) a second exterior layer comprising a polyamide, copolyamide, polyester, copolyester, high density polyethylene, or polycarbonate.

8. A pouch suitable for the packaging and administration of a medical solution, said pouch

comprising a film according to any one of the preceding claims."

Claims 2 to 7 were dependent claims.

II. A Notice of Opposition was filed against the patent by Baxter Healthcare Corporation on 3 September 2003. The Opponent requested the revocation of the patent in its full scope on the grounds of lack of novelty and inventive step (Article 100(a) EPC) and extension beyond the content of the application as originally filed (Article 100(c) EPC).

In the course of the opposition proceedings, *inter alia* the following documents were filed:

D1: WO - A - 95/13918;

D2: US - 4 643 926;

D4: US - 5 206 075;

D7: EP - A - 0 600 425;

D9: US - 3 645 992; and

D10:"Enter a New Generation of Polyolefins" J.H. Schut, PLASTICS TECHNOLOGY, pages 15 - 19, November 1991.

III. By its decision orally announced on 6 July 2005 and issued in writing on 3 August 2005, the Opposition Division rejected the opposition.

The Opposition Division concluded that the opposed patent did not contain subject-matter which extended beyond the content of the application as originally filed. The Opposition Division also noted that the Opponent had withdrawn the grounds of opposition under Article 100(c) EPC during the oral proceedings.

The Opposition Division held in the appealed decision that the subject-matter of the claims was novel because neither D1 nor D2 disclosed a multilayer film comprising an inner layer of a homogeneous ethylene/alpha-olefin copolymer having a density from 0.89 to 0.92 grams per cubic centimetre, or a blend of two or more such copolymers. Moreover, the multilayer films known from D7 were not capable of withstanding heat sterilisation at 121°C, since they tended to return to their original unstretched dimensions when heated.

As to inventive step, the Opposition Division, starting from D2 as the closest prior art document, saw the problem to be solved by the invention as being the provision of a multilayer, polyolefin-based film as a replacement for PVC as a material for the manufacture of medical solution pouches and having improved optical properties after the pouch has been heat-sterilized. In its opinion, the examples and comparative examples in the patent showed that the claimed multilayer films had much better optical properties following heat sterilization than films comprising heterogeneous VLDPE copolymer in the core layer. These improved optical properties after heat sterilization were not suggested by the available prior art and consequently the Opposition Division acknowledged an inventive step.

IV. On 9 September 2005 the Opponent (Appellant) lodged an appeal against the decision of the Opposition Division and on 16 September 2005 paid the appeal fee.

In the Statement of Grounds of Appeal filed on 9 December 2005, the Appellant requested that the decision under appeal be cancelled in its entirety and that the European patent No. 0 733 472 be revoked on the grounds of lack of novelty and lack of inventive step. The Appellant also filed the following fresh evidence:

D11: EP - A - 0 506 348;

D12: EP - A - 0 468 768;

D13: US - 4 803 102;

D14: EP - A - 0 228 819;

E9: Datasheet for Tafmer™ products including Tafmer™ A - 4085;

E10: Datasheet for Exact™ 4024;

E11 and E12 Datasheets for Exact™ Plastomers including Grade 4011.

V. The Patent Proprietor (Respondent) presented its counterstatement in a written submission dated 21 April 2006. The Respondent disputed all the arguments submitted by the Appellant and requested that the appeal be dismissed and the patent be maintained as

granted (main request). The Respondent further filed sets of claims for six auxiliary requests and the following document:

Declaration B: Declaration by the inventor, Walter Berndt Mueller, dated 19 April 2006.

The claims of the auxiliary request 1 are identical to the claims of the main request except that in Claim 1 the range of density of the homogeneous ethylene/alpha-olefin copolymer (or the blend of two or more copolymers) has been amended to read "0.90 to 0.92 grams per cubic centimeter".

VI. On 22 May 2007 the Board dispatched the summons to attend oral proceedings. In a communication dated 20 September 2007 with a preliminary opinion, the Board informed the parties that it had no objections to the admittance of the new evidence filed during the appeal proceedings and drew the attention of the parties to the points to be decided during the oral proceedings.

VII. The arguments presented by the Appellant in its written submissions and at the oral proceedings held on 6 December 2007 may be summarised as follows:

– The Appellant denied the novelty of Claim 1 of the main request having regard to the disclosure of D1, essentially because the multilayer films disclosed there included in their core layer homogeneous ultralow density polyethylene (such as Tafmer™ A-4085 and Exact™ 4024) having a density of 0.885 g/cm^3, equivalent to 0.89 when rounded up according to standard mathematical rules. It

submitted the films of Figures 2, 4 and 6 to 9 were novelty destroying for the subject-matter of Claim 1 of the main request.

– Concerning auxiliary request 1, the Appellant had objections only in relation to inventive step. It presented three different lines of argument:

  – Firstly, the claimed subject-matter lacked an inventive step because it had not been credibly shown that the problem underlying the patent in suit had been solved across the whole scope of the claim. In particular the Appellant pointed out that no lower limit was given for the amount of component (a) in the claims and that no data had been provided for amounts of this component below 15% by weight.

  – Secondly, the Appellant, starting from D2 as closest prior art, considered that the sole distinction between the films of this document and the claimed films was that the interior layer included a homogeneous ethylene/alpha-olefin copolymer having a density from 0.90 to 0.92 g/cm^3. The use of such homogeneous copolymers for improving optical properties of different films was already known from the cited prior art (cf. D7, see also D4, D9 and D10). It would then be obvious for the skilled person to try such homogeneous copolymers in order to improve the optical properties of the films of D2. The fact that this improvement was also maintained after heat-sterilization was an

additional/bonus effect which could not justify an inventive step.

– Finally, the Appellant argued that the claimed subject-matter also lacked an inventive step when starting from D7 as closest prior art document. The only difference between the films of D7 and the claimed films was that the seal layer of the claimed films comprised a homopolymer of polypropylene or a copolymer of polypropylene. However, seal layers of these materials were conventional in medical films (cf. D12, D13 and D14) and their use could not justify the presence of an inventive step.

VIII. The written and oral arguments of the Respondent may be summarised as follows:

– The Respondent submitted that documents D11 to D14 and E9 to E12 should not be admitted into the appeal proceedings. None of these documents was *prima facie* sufficiently relevant to justify its admittance at this stage. Insofar as they were intended as evidence of common general knowledge, they should have been filed at an earlier stage in the proceedings, namely with the notice of opposition.

– Concerning novelty, the Respondent pointed out that the claimed density range (0.89 - 0.92 g/cm^3) did not embrace copolymers having lower density values, such as Mitsui Tafmer™ A - 4085 disclosed in D1. Moreover the reference to this copolymer in D1 was made in relation to the exterior layer, not to the interior layer. The Mitsui Tafmer™ ULDPE used in the

interior layer in the examples could be any other Tafmer™ ULDPE copolymer having a density ranging from 0.865 to 0.885 g/cm^3 (cf. E9). But even if a copolymer having a density of 0.885 g/cm^3 had been used in D1 in the interior layer, this would not amount to a clear and unambiguous disclosure of a density of 0.89 g/cm^3 because reducing this value to two decimal places could be performed by rounding either up or down. Consequently the films of D1 were not embraced by the claims. The Respondent referred to decision T 74/98 of 19 October 2000, not published in OJ EPO, in order to support its affirmation that it was not appropriate to round up values in the prior art such that they would fall within a claimed range.

– Concerning inventive step, the Respondent relied on the evidence in the patent specification and in Declaration B from Mr Mueller and justified the presence of an inventive step by the improved post-sterilization optical properties of the pouches formed using the claimed films including a homogeneous ethylene alpha-olefin copolymer having a density within the claimed range. The unexpected improved optical properties of the pouches were not achieved when using heterogeneous ethylene alpha-olefin copolymers or homogeneous copolymers having a density outside the claimed range.

None of the documents cited against inventive step provided any teaching or suggestion that the optical properties of a multilayer film following heat sterilization could be improved by the use of a homogeneous copolymer having a density within the

claimed range. The claimed subject-matter thus satisfied the requirements of Article 56 EPC.

IX. The Appellant requested that the decision under appeal be set aside and that the European patent No. 0 733 472 be revoked.

The Respondent requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained on the basis of Claims 1 to 8 of any one of the auxiliary requests 1 to 6 filed with letter dated 21 April 2006. The Respondent requested further that the new documents E9, E10, E11, E12, D11, D12, D13 and D14 be not admitted into the proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. *Submissions not filed in due time*.

2.1 The Appellant with its Statement setting out the Grounds of Appeal filed the further documents D11 - D14 and E9 - E12 and the Respondent with letter dated 21 April 2006 filed declaration B with further experimental results.

2.2 In the Board's judgement the filing of these new pieces of evidence by the respective parties cannot be considered as a tactical abuse of the proceedings. The submissions were made at the due stage of the appeal proceedings with regard to Art. 10a (RPBA) (1) a) and b)

and the other party had enough time to take them into consideration.

2.3 The documents and exhibits filed by the Appellant aim mainly to support its previous arguments and to establish the skilled person's general common knowledge. The experimental report filed by the Respondent was filed in response to the objections raised by the Appellant in the Grounds of Appeal concerning the significance of the experimental examples in the patent, and to demonstrate that the problem had been solved over the whole area claimed.

2.4 Accordingly in application of Art. 10(4) RPBA the Board decides to admit these submissions into the proceedings.

MAIN REQUEST

3. *Novelty (Article 54 (3) EPC).*

3.1 Claim 1 of the patent in suit is essentially directed to a multilayer film capable of withstanding heat sterilization at 121°C comprising:

(a) an interior layer comprising a homogeneous ethylene/alpha-olefin copolymer having a density from 0.89 to 0.92 grams per cubic centimetre or a blend of two or more homogeneous ethylene/alpha-olefin copolymers having a density from 0.89 to 0.92 grams per cubic centimetre;

(b) a first exterior layer as defined in the claim; and

(c) a second exterior layer, also as defined in the claim.

3.2 The novelty of Claim 1 of the main request has been contested by the Appellant having regard to the disclosure of D1. D1 was filed on 16 November 1994 and published on 26 May 1995, after the priority date of the present patent. D1 entered the European regional phase as European application 95902620.4 and it is therefore to be considered as state of the art in accordance with Article 54(3) EPC.

3.3 D1 discloses multiple layer polymer films which may be fabricated into medical grade articles such as containers or bags for storing medical solutions (see page 5, lines 6 - 11). D1 describes films comprising a skin layer, a radio frequency susceptible layer and a core layer interposed between said layers, the core layer including an ultra low density polyethylene (see Claims 8 to 11).

The films having the reference numbers "Figure 2", "Figure 4" and "Figure 6 to Figure 9" (see pages 19 - 23) include as one of the components of the core layer 40% of "Mitsui Tafmer™ ULDPE". These films anticipate the subject-matter of Claim 1 of the main request, which is therefore not novel.

3.4 It is not disputed that the skin layer and the radio frequency susceptible layer of the films according to these Figures of D1 correspond to the exterior layers of features (b) and (c) of the claimed films. These exterior layers are therefore not a distinguishing feature over the disclosure of D1.

3.5 In order to justify the novelty of the subject-matter of Claim 1, the Respondent argued essentially that Tafmer™ A - 4085 was not explicitly mentioned in the Figures of D1 and that another Tafmer™ product could have been used, these other products having densities varying from 0.865 to 0.885 g/cm^3 (see E9 under "1. Samples"). In any case Tafmer™ A-4085 was mentioned in D1 not in relation to the core layer but in relation to the radio frequency susceptible layer, and its density value, 0.885 grams per cubic centimetre, was outside the claimed range of 0.89 to 0.92 grams per cubic centimetre.

3.6 The Board notes, however, that even if in Figures 2, 4, and 6 to 9 of D1 the low density polyethylene used in the core layer is referred to unspecifically as "Mitsui Tafmer™ ULDPE", it is evident for the skilled person from reading D1 that this "Mitsui Tafmer™ ULDPE" can only be Tafmer™ A - 4085.

3.6.1 The core layer in D1 consists of three components, the second component being an ultra low density polyethylene ("ULDPE") (see page 6, lines 24 - 32). Suitable types of ULDPE are discussed in more detail on pages 9 and 10 in relation to the radio frequency susceptible layer. They are said to include ultra low density polyethylenes commercially available and sold under the trademark Tafmer™ (Mitsui Petrochemical Co.) with the product designation A - 4085 (page 9, lines 23 - 25, the reference to "485" being a typing mistake) which is then mentioned as one of the preferred components (page 10, lines 29 - 30, now without the typing mistake).

3.6.2 The film of Figure 2 is described in detail on page 12, line 33 to page 13, line 20. The second component of the layer is said to be chosen to confer flexibility on the core layer and preferably is ULDPE or polybutene-1 (page 13, lines 8 - 13 and page 19, Figure 2 film). It is clear for the skilled person that the Mitsui Tafmer™ ULDPE mentioned in Figure 2 as an ingredient of the core layer and of the RF layer can only be the Tafmer™ A - 4085 because it is the only Tafmer™ polymer specifically disclosed in D1.

3.6.3 Tafmer™ A - 4085 has a density of 0.885 grams per cubic centimetre which, when rounded off according to standard mathematical rules, results in a value of 0.89 grams per cubic centimetre, that is to say within the range covered by Claim 1 of the patent in suit.

3.6.4 The Board cannot accept the argument of the Respondent that the value 0.885 could also be rounded down to 0.88 and thus outside the claimed range. The mathematical conventions for rounding values wherein the last digit is 5 (or more) require that the value be increased, or rounded up, resulting in a value of 0.89 in the present case.

3.6.5 For the definition of the density range the Respondent has chosen to use only two decimal places. This implies that a comparison with the prior art identifying three decimal places can only be made if the prior art values are also reduced to two decimals, that is to say rounded. The skilled person reading D1 would thus be obliged to round the disclosed value up to 0.89 for

comparison (see decision T 0708/05 of 14 February 2007, not published in OJ EPO, under point 3 of the Reasons).

It is noted also that polyolefin densities are usually indicated with the accuracy of three decimal places, with the consequence that where only two decimal places are indicated, as in present Claim 1, this implies that rounding has already occurred. It is of interest in this context that the respective densities disclosed in the original application (and maintained in the granted specification) are preceded by the qualification "about".

3.6.6 The above finding is not in contradiction with decision T 74/98 cited by the Respondent. In that case the Board considered that rounding up to the next integer (thus matching the lower limit of the claimed "inventive" range) of a component's molar percentage having two decimal places, calculated by conversion from its weight proportion, was not justified because (i) this would lead to a broadening of the claimed range and (ii) by reconversion of the rounded molar percentage to the corresponding weight proportion, would also imply a modification of the latter, ie would alter the true meaning of this specific disclosure. The factual situation of that case is quite different from the present one in that according to T 74/98 a real gap existed between the calculated molar percentage and the claimed lower limit while according to the present case rounding up is required to enable comparing two density values, each one reflecting a "true" density value having three (or more) decimal places, but expressed to a different degree of accuracy, ie one having three the other one having only two decimal places. Thus, the

rounding exercise does not bridge a real gap but puts the claimed and the prior art density values on the same level by using the mathematical rule existing for that purpose. This exercise has no impact on the density value as disclosed in the prior art document.

3.7 For these reasons the subject-matter of Claim 1 according to the main request lacks novelty having regard to the disclosure of document D1.

AUXILIARY REQUEST 1

4. *Novelty (Article 54 EPC).*

4.1 The subject-matter of Claim 1 of auxiliary request 1 has been limited to density values of 0.90 to 0.92 g/cm^3. The films of D1 discussed above using polyethylene having a density of 0.885 g/cm^3 no longer fall inside the claimed range. The subject-matter of Claim 1 is therefore clearly novel.

As the novelty of this subject-matter was also acknowledged by the Appellant no further comments are needed.

5. *Inventive step (Article 56 EPC)*.

5.1 Closest prior art.

5.1.1 The patent in suit relates to multilayer films which are suitable for the packaging and administration of medical solutions in the form of flexible pouches.

According to the introductory section of the specification, these pouches must meet a number of performance criteria, including collapsibility, optical clarity and transparency, high-temperature heat-resistance, and sufficient mechanical strength. These medical pouches must be able to endure heat sterilization without deterioration (see [0001] - [0004]). Heat sterilization of medical pouches is carried out typically in an autoclave at about 121°C for periods of 15 to 30 minutes (see [0005]). Pouches made from highly plasticized polyvinyl chloride are known but they show some drawbacks (see [0007] - [0008]) and alternatives to these PVC pouches are sought.

5.1.2 From the documents cited by the Appellant only documents D2 and D11 disclose films suitable for medical solution pouches. These documents disclose PVC-free medical pouches made from multilayer films including in their interior layer a **heterogeneous** ethylene/alpha-olefin copolymer (see D2 Claims 1 and 5, and also examples 5 and 6) and D11 (Claims 1 and 12, and also example 8).

The disclosure of these documents represents the closest prior art.

5.2 The objective problem to be solved and its solution.

5.2.1 A drawback of the pouches of D2 and/or D11 is that during heat sterilization the steam which is used to heat the pouches penetrates into the film from which the pouch has been formed. When the sterilization process is completed and the pouch is allowed to cool, some of the steam in the film condenses and remains

trapped inside the film, giving the pouch a hazy, cloudy appearance which can make it difficult to inspect the medical solution contained in the pouch.

5.2.2 The technical problem to be solved by the patent in relation to said prior art can thus be formulated as the provision of a multilayer film for the manufacture of medical solution pouches having improved optical properties after the pouch has been heat-sterilized.

5.2.3 This problem is solved by the films according to Claim 1 having an interior layer of the film comprising a **homogeneous** ethylene/alpha-olefin copolymer having a density from 0.90 to 0.92 grams per cubic centimetre or a blend of two or more homogeneous ethylene/alpha-olefin copolymers.

5.2.4 The results in the specification of the patent and the further experimental evidence supplied by the Respondent (Declaration B) demonstrate that by replacing the heterogeneous ethylene/alpha-olefin copolymers used in D2 and/or D11 by homogeneous ethylene/alpha-olefin copolymers improved optical properties after heat sterilization are achieved.

Thus, examples 1 to 3 in the patent show that pouches made from the claimed films have better optical properties (haze, clarity and gloss) than the comparative film of example 4 (which corresponds to the film of example 8 of D11) having a heterogeneous ethylene/alpha-olefin copolymer.

Declaration B filed by the Respondent during the appeal proceedings further demonstrates the superior optical

properties after heat-sterilization of the films having an interior core layer formed from a homogeneous ethylene/alpha-olefin copolymer.

A comparison of the pre- and post-sterilization optical properties of films comprising homogeneous or heterogeneous ethylene/alpha-olefin copolymers shows that, while the pre-sterilization optical properties are similar for both the inventive and the comparative films, the films of the invention exhibited improved post-sterilization optical properties. The optical properties of the comparative films, particularly haze and gloss, degraded much more than those of the claimed films so that all post-sterilization optical properties of the inventive films are superior to those of the comparative films (see Declaration B, Tables 1, 2 and 3).

5.2.5 The Appellant did not dispute such improvement but doubted that the experimental evidence provided by the Respondent was sufficient to show that said problem was credibly solved across the whole scope of the claims. In particular, it criticized the fact that there was no mention of the amount of homogenous ethylene/alpha-olefin copolymer used in the claims and that it was doubtful that the presence of very low amounts of the homogeneous ethylene/alpha-olefin copolymer would result in improved post-sterilization optical properties.

5.2.6 The Board cannot agree with this argument of the Appellant. The results in the declaration B of the Respondent show that the improvement in post-sterilization optical properties is also achieved when

lowering the proportion of the homogeneous ethylene/alpha-olefin copolymer in the core layer. The films of Tables 4, 5 and 6 using 15%, 25%, 50%, 75% and 100% of homogeneous ethylene/alpha-olefin copolymer in the core layer exhibit in all cases improved post-sterilization optical properties when compared with a film having only heterogeneous ethylene/alpha-olefin copolymer in the core layer. These results show an improvement in post-sterilization optical properties with increasing homogeneous ethylene/alpha-olefin content in the core layer.

The Appellant (who has the burden of proof) has not adduced any experimental evidence showing that an embodiment covered by the claims did not show the required improved post-sterilization optical properties. Insofar as very small amounts of homogeneous ethylene/alpha-olefin copolymers are within the claimed subject-matter, it is noted that the present invention is based on the use of homogeneous ethylene/alpha-olefin copolymers as replacement of the known heterogeneous ethylene/alpha-olefin copolymers and it is clear for the skilled person that a certain amount should be used in order to obtain the desired effect. This amount can be determined by the skilled person on the basis of the information in the specification.

5.3 Obviousness.

5.3.1 It remains to be decided whether, in view of the available prior art documents, it would have been obvious for the skilled person to solve this technical problem by the means claimed, namely by using a homogeneous ethylene/alpha-olefin copolymer.

5.3.2 There is no hint to this solution in the above mentioned prior art documents D2 or D11 as they do not mention the possible use of homogeneous ethylene/alpha-olefin copolymers.

5.3.3 There is also no suggestion of this solution in the other documents cited by the Appellant. These documents are mainly directed to the use of homogeneous ethylene/alpha-olefin copolymers in lieu of heterogeneous ethylene/alpha-olefin copolymers in a variety of films. Films incorporating said homogeneous copolymers are said to generally exhibit improved physical and optical properties as compared to films of heterogeneous copolymers (see, for instance, D7, page 4, lines 4 - 5). However, none of these documents mentions post-sterilization optical properties at all and for these reasons cannot give a hint to its use in the now claimed films.

In particular D7, on which the Appellant mainly relied, is directed to heat-shrinkable, thermoplastic films (see title). The films of D7 have been oriented by stretching at elevated temperature followed by quickly quenching to retain the films stretched dimensions (see page 5, lines 8 - 16) and are therefore not capable of withstanding heat sterilization, since they would return to their original unstretched dimensions when heated. The skilled person does not find any hint in this document suggesting the use of homogeneous ethylene/alpha-olefin copolymers in order to improve the post-heat sterilization optical properties of medical solution pouches.

5.3.4 The Appellant argued further that it would have been obvious for the skilled person to try the homogeneous ethylene/alpha-olefin copolymers in order to improve the optical properties of the films *per se* (before sterilization). The fact that by this measure the post-sterilization properties of the films were also improved would merely be a bonus effect which could not justify an inventive step.

Apart from the fact that the Board cannot see any objective reason to ignore the very problem of the claimed subject-matter already set out in the application as filed, it furthermore accepts the Respondent's argument advanced during the oral proceedings, namely that the lower melting point range of about 60 - 110°C, i.e. below the steam-sterilization temperature, of the homogeneous ethylene/alpha-olefin copolymers would certainly not encourage the skilled person to use such copolymers for the intended purpose. The assertion of the Appellant that it would anyway have been obvious to try out these new copolymers can only be made with the knowledge of the invention.

5.3.5 Insofar as the Appellant relied on D7 as closest prior art, the Board notes that this document is not an appropriate starting point for the assessment of inventive step as it does not relate to medical solution pouches and as the films therein disclosed are not suitable for resisting steam-sterilization (see above 5.3.3).

5.3.6 Hence, the Board considers that, in the light of the cited prior art, it would not have been obvious to a person skilled in the art to replace the heterogeneous

ethylene/alpha-olefin copolymer used in D2 or D11 by the homogeneous ethylene/alpha-olefin copolymers now used in order to solve the above-mentioned problem. The subject-matter of Claim 1 of the auxiliary request 1 thus involves an inventive step within the meaning of Article 56 EPC.

5.3.7 Dependent Claims 2 to 7 and Claim 8, which relates to pouches comprising the films of said claims, also satisfy the requirements of Article 56 EPC.

6. As the claims of the auxiliary request 1 of the Respondent fulfil the requirements of the EPC, there is no need for the Board to deal with the auxiliary requests 2 to 6.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the Opposition Division with the order to maintain the patent on the basis of Claims 1 to 8 of the first auxiliary request as filed with the letter dated 21 April 2006 after any necessary consequential amendment of the description.

The Registrar | The Chairman

G. Röhn | P. Kitzmantel