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D E C I S I O N
of 23 May 2000

Case Number: T 1094/98 - 3.2.1

Application Number: 89110379.8

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IPC: B65D 81/32, B23B 27/32

Language of the proceedings: EN

Title of invention:
Filled container

Patentee:
MATERIAL ENGINEERING TECHNOLOGY LABORATORY, INC.

Opponent:
FRESENIUS AG

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-



Case Number: T 1094/98 - 3.2.1

D E C I S I O N
of the Technical Board of Appeal 3.2.1
of 23 May 2000

Appellant: FRESENIUS AG
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Representative: Ackermann, Joachin, Dr.
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Respondent: MATERIAL ENGINEERING TECHNOLOGY LABORATORY INC.
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Representative: Greenwood, John David
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Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office posted 8 October
1998 concerning maintenance of European patent
No. 0 345 774 in amended form.

Composition of the Board:

Chairman: F. Pröls
Members: S. Crane
J. van Moer

Summary of Facts and Submissions

- I. European patent No. 0 345 774 was granted on 14 September 1994 on the basis of European patent application No. 89 110 379.8.
- II. The granted patent was opposed by the present appellants on the ground that its subject-matter lacked inventive step (Article 100(a) EPC). They requested that the patent be revoked in its entirety. Of the state of the art relied upon in the opposition proceedings only the following pre-published documents have played any significant role on appeal:
- (D1) FR-A-2 423 413
- (D2) EP-A-0 196 727
- III. With its interlocutory decision posted on 8 October 1998 the Opposition Division held that the patent could be maintained in amended form on the basis of a set of documents according to a first auxiliary request submitted at the oral proceedings on 17 September 1998.

Claim 1 of this set of documents reads as follows:

"A filled container including a container made of resin and defining a plurality of compartments isolated from one another by at least one seal as a means of isolation and contents filled separately in the respective compartments, whereby upon use of the filled container the contents can be mixed together without exposure to the surrounding atmosphere by breaking the isolation means from the outside and communicating the compartments to one another,

characterized in that

said seal having easy-to-peel openability, and in that the resin taking part in direct bonding of at least one portion of a peripheral seal hermetically sealing a sheet or sheets of a main body of the container is the same as a resin taking part in direct bonding of the isolation means, and the resin taking part in the direct bondings is a resin mixture composed of at least two polyolefin resins wherein a first resin of the resin mixture is a linear low-density polyethylene resin having a lower melting starting temperature in an amount of from 80 wt.% to 20 wt.%, and a second resin of said resin mixture is a polypropylene resin having a melting starting temperature at least 8°C higher in an amount of from 20 wt.% to 80 wt.% and wherein the isolation means retains said easy-to-peel openability after the container and contents have been autoclave sterilized together."

- IV. A notice of appeal against this decision was filed on 25 November 1998 and the fee for appeal paid at the same time. The appellants requested that the decision under appeal be set aside and the patent revoked.

The statement of grounds of appeal was filed on 4 February 1999. In the statement of grounds reference was made to a further prior art document, viz.

(D12) DE-A-3 426 465.

- V. With a letter received on 25 April 2000 the respondents (proprietors of the patent) submitted further amended claims 1 to 4 according to an auxiliary request.

Claim 1 of this request corresponded to claim 1 as

accepted by the Opposition Division with the addition to the characterising clause of the features that "each of the sheet or sheets of the main body of the container is a multi-layer sheet whose innermost layer is formed of the resin mixture" and "in the multi-layer sheet at least one of said at least two polyolefin resins of the resin mixture is substantially the same as at least one resin forming an adjacent layer".

- VI. Oral proceedings before the Board were held on 23 May 2000.

The respondent requested that the patent be maintained in amended form on the basis of the documents accepted by the Opposition Division (main request) or in the alternative with claims 1 to 4 as submitted on 25 April 2000.

The appellants maintained their request for revocation of the patent in its entirety.

- VII. The arguments put forward by the appellants in support of their request can be summarised as follows:

Document D12 disclosed a compartmentalised container with a breechable seal between the compartments as defined in the preamble of claim 1 of the main request. Further, in accordance with the first feature of the characterising clause of the claim, that breechable seal had "easy-to-peel openability". The means for achieving such a seal were exemplified in document D2 as being the application of a wax or low molecular weight polyethylene to lower the bonding force between the corresponding heat sealed layers of the container. It was however obvious for the person skilled in the

art to investigate other ways of obtaining the required type of seal. In this context document D2 clearly taught that it was possible, by appropriate selection of the heat sealing temperature, to make both peelable and permanent, non-peelable, seals between layers of a resin blend of linear low-density polyethylene (LLDPE) and polypropylene. All that the claimed invention did was to make use of this teaching in an obvious way. There was no reason that the person skilled in the art would reject the proposal of document D2 as being unsuitable for use with a container that was to be autoclave sterilized with its contents, since the autoclaving temperature could be chosen to be below the temperature at which the peelable seal was formed so that no significant detrimental effect on the latter would be expected.

The additional features added to claim 1 of the auxiliary request were also known from document D2 and made no inventive contribution to the subject-matter of the claim.

VIII. In reply the respondents argued substantially as follows:

The particular field with which the invention was concerned was sterilized containers filled with solutions for intravenous injection, where the requirements related to the presence of the foreign bodies were extremely stringent. It was therefore of paramount importance that the breachable seal between the compartments of the container be of such a nature that any formation of particles from the layers of the container as they were parted from each other be kept to an absolute minimum.

There was nothing in document D2 which could suggest to the person skilled in the art that a peelable seal made according to its teachings could meet this stringent requirements, particularly after the filled and sealed container had been autoclaved sterilized. In this respect it had to be noted that the peelable seal of document D2 was made by heat sealing at a temperature and for a time which were both well below that taught by the contested patent. The risk that the seal would lose its peelability when the container was sterilized at conventional autoclaving temperatures was therefore much greater.

In this context there was a significant difference between what was taught in document D2 and the basic principle underlying the claimed invention as explained in the patent specification. This lay in the fact that the invention proposed as resin mixture which when processed into sheets produced surfaces divided into minute areas of different heat-sealability. At the lower heat-sealing temperature used to form the peelable seal only contacting areas of LLDPE in two adjacent sheets were bonded to each other but nevertheless the seal was complete in the sense that further application of heat at the same temperature would not lead to further bonding. Document D2 on the other hand taught that there should be full dispersal of one resin within the other with the result that a peelable seal formed between two layers of the resin mixture by the application of heat for a short time would not be complete and would be subject to further bonding during autoclave sterilization.

As demonstrated by the experimental results submitted with the letter received on 25 April 2000 the proposal

according to claim 1 of the auxiliary request for the particular structure to be used for multi-layer sheets contributed significantly to the strength of the peripheral seal and enhanced the overall performance of the container.

Reasons for the Decision

1. The appeal complies with the formal requirements of Articles 106 to 108 and Rules 1(1) and 64 EPC. It is therefore admissible.

2. As explained in the introductory description of the present patent specification, there are many products comprising two or more components which can only be mixed together just before use. One example, with which the patent is particularly concerned, is a medicinal composition which is subject to deterioration when stored as a mixture, especially thermal deterioration when the mixture is sterilized in an autoclave. In addition, the mixing of the components of the composition at the point of use involves the potential danger of contamination.

For this reason it had already been proposed to store the components of the mixture in separate compartments of a single container, with isolation means disposed between the compartments which can be breached from outside the container to allow mixing of the components with the container itself still closed. One known arrangement of this type discussed in the patent specification involves a plug located in a partition between the compartments and breakable from outside the container. The manufacture of such a container, in

particular the hermetic sealing of the plug therein, is however said to be difficult and involve the risk of contamination.

In contrast thereto the claimed invention proposes a container of simple form comprising a folded sheet or two superimposed sheets of polymeric resin which are hermetically sealed around their periphery and divided into two (or more) compartments by one (or more) seals having "easy-to-peel openability" (ie peelable seals as they are more commonly termed). Both the peripheral hermetic seals and the peelable seal are made by direct bonding of the layers, ie with the interposition of agents designed to influence the bond strength. In order to enable this the sheets are made of a mixture of 80 wt% to 20 wt% of LLDPE and 20 wt% to 80 wt% of polypropylene, whereby the melting start temperature of the latter is at least 8°C higher than that of the former. With this resin mixture it is possible to form both a readily peelable seal and a strong, burst-resistance, peripheral seal merely by appropriate choice of the temperature at which the heat-sealing operation is performed.

The mechanism involved is explained at page 4, lines 26 to 53, of the patent specification. As discussed there the mixing of the resins and forming the resultant mixture into sheets produces sheets with surfaces divided into minute areas having different heat-sealability. At the lower heat-sealing temperature only those contacting areas of the resin having the lower melting start temperature (ie as now claimed LLDPE) bond with each other to form a low strength peelable seal. At the higher heat-sealing temperature the whole of the surfaces are bonded together to form a high

strength seal. The patent specification includes numerous examples which demonstrate that both seals retain their required characteristics after autoclave sterilization.

Document D12 also relates to a container comprising superimposed polymeric sheets having a high strength, burst-proof, peripheral seal and a low-strength seal dividing the container into two compartments. The low-strength seal should however have sufficient strength to prevent inadvertent opening of the seal during transport and unwanted mixing of the components stored in the respective compartments. The preferred method for obtaining the low-strength seal is through the coating of the surfaces to be sealed with a wax, low molecular weight polyethylene or some other substance. The coating material should be chosen so that it does not react with the components stored in the container; if the container is for food products then the coating material would have to meet the appropriate legislative requirements (page 5, paragraphs 1 and 2). One particular field of use mentioned is compositions for taking dental impressions. On page 7, paragraph 3, it is stated that one advantage of the container described is that it can be sterilized, for example by heat.

In the opinion of the Board it would not go beyond the bounds of the normal practice of the person skilled in the art to consider ways of producing a container as disclosed in document D12 without the need for using a coating material and thus to avoid the difficulties associated with the choice of an appropriate one. In this context he is taught by document D2 that it is possible to make both low-strength peelable seals and normal high-strength seals (see column 2, lines 10 to

18) between sheets comprising a mixture of 65 wt% to 95 % LLDPE and 35 wt% to 5 wt% polypropylene merely by appropriate choice of the heat-sealing temperature. The application of that teaching to the making of a compartmentalised container having high- and low-strength seals as disclosed in document D12 is an obvious measure and not something which can be seen as involving an inventive step.

Indeed, the respondents did not seek to dispute this as such. Instead, they placed much more emphasis on the question of whether it would have been obvious for the person skilled in the art to adopt the teachings of document D2 for a compartmentalised container which was to be autoclave sterilized with its contents. They pointed to the fact that document D2 made no mention of the possibility of autoclave sterilizing containers having peelable seals of the type disclosed therein and argued that the conventional temperature involved in autoclave sterilization were higher than the preferred range disclosed in the document for forming the peelable seal; the person skilled in the art would thus expect autoclave sterilization to make the peelable seal non-peelable.

However, having regard to the fact that on the one hand document D2 proposes a temperature range for making the peelable seal which extends up to 125°C, and on the other conventional temperatures for performing autoclave sterilization are 121°C or 122° (the patent specification itself does not mention in its examples the temperature used), the Board cannot accept that the person skilled in the art would have been so deterred by worries about the effect of the sterilization procedure on the nature of the peelable seal that he

would not at least have made routine experiments to see if these worries were justified.

As can be seen from the experimental results submitted by the appellants with their statement of grounds of appeal this is clearly not the case. These show that with a sheet material composed of 75 wt% LLDPE and 25 % polypropylene and a heat-sealing temperature of 124°C for the peelable seal, autoclaving for 15 minutes at 121°C led to no measurable change in the peelability. The correctness of these results has not been challenged by the respondents. Indeed they confirmed in their own experimental report filed on 25 April 2000 that the containers of document D2 and the present invention "had easy-to-peel openability before and after autoclave sterilization ", cf. page 7, lines 4 and 5.

The respondents also sought to rely on a difference between the nature of the sheet material disclosed in document D2 and that used in the claimed invention. They argued that as this document taught that the melt viscosities of the LLDPE and polypropylene should be close to each other in order to allow the polypropylene to disperse in the LLDPE melt then the structure described in the patent specification with divided minute areas of the two polymer resins would not be achieved. Notwithstanding the fact that no comparable feature appears in claim 1 under consideration the Board cannot in any case accept that the result of blending the two polymer resins disclosed in document D2 would not be a structure as described in the patent specification since a full assimilation of the polypropylene into the LLDPE to the extent that at the microscopic level separate areas thereof in the mixture

would no longer be distinguishable does not seem feasible. For comparison it can also be noted that in Example 3 of the patent specification the melt indices of the chosen LLDPE and polypropylene resins are also very similar, namely 0.8 and 0.7 respectively.

Lastly, the respondents pointed out that document D2 did not disclose the melting point of the LLDPE and polypropylene resins used so that the requirement of claim 1 that there be an 8°C temperature difference therebetween was not taught by the state of the art. In this context it should be noted that the requirement that there be an 8°C melting starting temperature difference derives from the originally filed claims which were not restricted to a particular mixture of polymer resins and having regard to the fact that the melting temperatures of commercially available LLDPE and polypropylene resins are separated by the order of 30° to 40°C this requirement cannot be seen as imposing a further genuine limitation on the scope of the claim. Certainly there can be no doubt that the melting starting temperature of the specific polypropylene resin disclosed in document D2 is at least 8°C higher than that of the LLDPE resin disclosed there.

The Board therefore comes to the conclusion that the subject-matter of claim 1 of the main request lacks inventive step (Article 56 EPC).

3. In claim 1 according to the auxiliary request it has been specified that the sheet material making up the container is multi-layer with a layer adjacent the actual sealing layer of the mixture of LLDPE and polypropylene being composed of one of these two resins. In their experimental report filed on 25 April

2000 the respondents contrasted the strength of the high-strength seal obtained with such a multi-layer sheet and that obtained with a sheet where the layer adjacent the LLDPE/polypropylene seating layer was high density polyethylene as in Example 1 of document D2. In Example 5 of document D2 there is however taught a multi-layer sheet composed of adjacent layers of polypropylene and LLDPE/polypropylene as required by claim 1 under consideration. It is therefore apparent that this restriction cannot add anything of inventive significance to the subject-matter of the claim. The auxiliary request must accordingly also be rejected.

Order

For these reasons it is decided that:

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

The Registrar:

The Chairman:

S. Fabiani

F. Pröls