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D E C I S I O N
of 25 February 1999

Case Number: T 0944/96 - 3.2.1

Application Number: 93922566.0

Publication Number: 0662918

IPC: B65D 75/32

Language of the proceedings: EN

Title of invention:
Stepped-edge blister pack and use of steps

Applicant:
R.P. Scherer Corporation

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no)"

Decisions cited:
T 0021/81

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0944/96 - 3.2.1

D E C I S I O N
of the Technical Board of Appeal 3.2.1
of 25 February 1999

Appellant: R.P. Scherer Corporation
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 14 June 1996 refusing European patent application No. 93 922 566.0 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: F. A. Gumbel
Members: S. Crane
J. van Moer

Summary of Facts and Submissions

I. European patent application No. 93 922 566.0 was refused by a decision of the Examining Division dated 14 June 1996.

II. The reason given for the decision was that the subject-matter of the independent claims of the main and auxiliary requests then on file lacked inventive step (Article 56 EPC) with respect to the state of the art represented by the following pre-published documents:

(D1) US-A-4 305 502

(D2) US-A-3 941 248.

III. An appeal against this decision was filed on 16 August 1996 and the fee for appeal paid at the same time. The statement of grounds of appeal was filed on 15 October 1996.

IV. In a preliminary communication dated 12 December 1997 the Board, *inter alia*, pointed to the potential relevance of (D3) DE-U-1 927 967, a document referred to in the introductory description of document D2.

V. On 21 April 1998 the appellants (applicants for the patent) made further submissions and filed sets of claims according to new main, first and second auxiliary requests for the grant of a patent.

Independent claims 1 and 7 of the main request read as follows:

"1. A multi-unit blister pack comprising a base sheet (12) of substantially rectangular shape with aligned blister pockets (16) arranged on either side of the long axis thereof; and a lidding sheet (l4) substantially corresponding in shape to the base sheet (12) and peelably adhered thereto to close the blister pockets (16), the lidding sheet (14) having a first tear line (26) extending along the long axis of the base sheet and second tear lines (26) extending perpendicular thereto between adjacent blister pockets (16), each blister pocket (l6) containing a unit dosage form (20) that has been subjected to a sublimation process,
CHARACTERISED IN THAT
the base sheet (12) is formed with stepped portions (18) along opposite long sides forming corrugated external edges thereof, with the lidding sheet (14) overlaying the stepped portions (18) to form tabs (24) facilitating removal of the lidding sheet (14) from the base sheet (12) over a given pocket (16)."

"7. A method of manufacturing blister pack comprising a substantially rectangular base sheet (12) having a plurality of blister pockets (16) and a substantially planar portion surrounding each blister pocket defining top openings thereof, in which a substantially planar lidding sheet (14) is peelably secured to the substantially planar portions of the base sheet (12) to cover the top openings of the pockets (16), each blister pocket (16) containing a unit dosage form (20) that has been subjected to a sublimation process,
CHARACTERISED IN THAT
the base sheet (12) is formed with stepped portions (18) along opposite long sides forming corrugated

external edges thereof, with the lidding sheet (14) overlaying the stepped portions (18) to reinforce the base sheet (12) and prevent undulation of the base sheet (12) and the lidding sheet (14) during the manufacturing process."

Independent claims 1 and 7 of the first auxiliary request correspond to those of the main request with the additional feature added to the respective preamble that the unit dosage form has been subjected to an "in situ" sublimation process.

The single independent claim 1 of the second auxiliary request reads as follows:

"A method of manufacturing a blister pack comprising the steps of forming a substantially rectangular base sheet (12) having a plurality of blister pockets (16) arranged on either side of a longitudinal axis of the blister pack having a substantially planar portion surrounding each blister pocket defining top openings thereof, depositing a unit dosage (20) in each blister pocket (16) and subjecting this to a sublimation process, and peelably securing a substantially planar lidding sheet (14) to the substantially planar portions of the base sheet (12) to cover the top openings of the pockets (16) by a heat sealing process

CHARACTERISED IN THAT

the base sheet (12) is formed with stepped portions (18) along opposite long sides forming corrugated external edges thereof, with the lidding sheet (14) overlaying, but not secured to, the stepped portions (18) to reinforce the base sheet (12) and

prevent undulation of the base sheet (12) and the lidding sheet (14) during the manufacturing process."

VI. Oral proceedings before the Board were held on 25 February 1999.

At the oral proceedings the appellants proposed according to a third and a fourth auxiliary request that the term "to reinforce the base sheet and" be inserted after the term "to form tabs (24)" in the characterising clause of claim 1 according to the main and first auxiliary request respectively.

VII. The arguments put forward by the appellants in support of their requests were essentially as follows:

The claimed invention was concerned with the solution of two technical problems associated with a multi-unit blister pack as described in document D1. The first problem was the improvement of accessibility to the individual dosage forms, especially for patients with limited dexterity. The second problem was the reduction of undulations in the base sheet and lidding sheet which tended to occur during manufacture, particularly in the case where the dosage forms had been subjected to *in situ* sublimation which necessarily entailed the exposure of the base sheet to extremes of temperature.

The appellants had solved both of these problems by means of a single measure, namely the formation of stepped portions along the side edges of the base sheet. On the one hand these stepped portions gave rise to unadhered tabs in the lidding sheet which could readily be gripped by the user, the stepped portion

providing access for the user's finger. On the other hand the resulting corrugated side edges reinforced the base sheet.

There was nothing in the state of the art which would have led the skilled person to adopt stepped edge portions in the base sheet to solve either one or the other of the problems addressed by the invention and certainly not both of them in combination. In particular, although document D2 indeed disclosed recesses in the base sheet which provided finger access to tabs formed in the lidding sheet, these recesses were deliberately arranged within the body of the base sheet, away from its edges, and only became accessible once the base sheet had been divided into individual sections. The whole purpose of the arrangement disclosed in document D2 was to make access to the dosage forms more difficult, not to improve it. Furthermore, there was no suggestion in the document that the recesses in the base sheet had anything to do with preventing undulation of it during the manufacturing process. As for document D3, the tabs in the lidding sheet disclosed there were arranged at one end of the blister pack and did not provide access to individual dosage forms. The associated recesses in the base sheet were of very limited extent and provided no significant reinforcement of it.

Reasons for the Decision

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

therefore admissible.

2. *Main request*

The preamble of claim 1 of the main request is based on the disclosure of document D1. This document, which was referred to extensively in the application as originally filed, is particularly concerned with the *in situ* formation of rapidly disintegratable unit dosage forms of a pharmaceutical in the pockets of the base sheet of a blister pack. Preferably formation of the unit dosage forms is by means of a sublimation process ("freeze-drying"). As more particularly described the base sheet of the blister pack is of substantially rectangular shape with two rows of blister pockets arranged on either side of its long axis. The lidding sheet corresponds in shape to the base sheet and is peelably adhered thereto, preferably by heat sealing. The lidding sheet has a first tear line extending along the long axis of the base sheet and second tear lines extending perpendicular thereto between adjacent blister pockets. The tear lines thereby define individual areas of the lidding sheet specific to each blister pocket so that removal of any one such area gives access to the corresponding unit dosage form. In order to facilitate access the lidding sheet is not adhered to the base sheet along narrow strips at the side edges of the blister pack thereby creating edge peel tabs.

It is indicated in the penultimate paragraph of page 2 of the original application that an attempt to further improve access for patients with limited dexterity by means of enlarging the edge peel tab has resulted in

blister packs with severe edge undulation due to uneven shrinkage after heat sealing. The invention set out in claim 1 therefore proposes to improve access by forming stepped portions along the opposite long side edges of the base sheet, which thereby take on a corrugated profile. The areas of the lidding sheet overlying the stepped portions are not adhered to the base sheet and thus form tabs which can be easily gripped by insertion of a finger into the gap between the stepped portion of the base sheet and the lidding sheet.

Document D2 is particularly concerned with childproof packaging of the blister pack type. At column 1, lines 19 to 32, of this document there is a discussion of the proposal of document D3 to provide grasping recesses in the base sheet of a blister pack in order to provide easy access to the lidding sheet. The point is made that the desired easy opening of the pack has the disadvantage of unauthorised removal, especially by children. Thus document D2 sets out to provide a blister pack which is protected to a high degree against unauthorised opening, particularly by children, yet which retains the advantage of easy grasping and removal of the lidding sheet. In principle, this aim is met by concealing the grasping recesses in such a way that the lidding sheet cannot be grasped without additional action. In particular, with respect to the embodiment of Figures 5 to 7, document D2 discloses a blister pack with two rows of blister pockets arranged in corresponding longitudinal strips of the base sheet. Each of the strips of the base sheet is detachable connected along a tear line to a respective side edge of an intermediate web extending along the long axis of the base sheet. Each strip is divided by further

transverse tear lines extending between respective pairs of blister pockets. The edge of each strip adjacent the intermediate web is provided with a series of stepped portions, one for each blister pocket, which form recesses to which the lidding sheet is not adhered. Once a part of the strip has been separated along the tear lines from the remainder of the base sheet the recess becomes accessible and the lidding sheet can be easily gripped and removed.

In the opinion of the Board it will be obvious to the person skilled in the art seeking to improve the accessibility of the dosage forms of a blister pack of the type shown in document D1, but who is not concerned with providing a childproof pack, that the simple arrangement of the stepped portions proposed in document D2 not inside the area of the base sheet but merely along its side edges will serve the required purpose. Accordingly the subject-matter of claim 1 cannot be seen to involve an inventive step (Article 56 EPC).

Although independent claim 7 of the main request is notionally directed to a method of manufacturing a blister pack, the bulk of its features are concerned with the structural features of that pack, which is defined in somewhat broader terms than the blister pack of claim 1 (no indication of the spatial arrangement of the pockets in the base sheet or of the tear lines in the lidding sheet). For the appellants the significant difference between the subject-matter of claim 7 and that of claim 1 lies not so much in the fact that the former is directed to a method of manufacture but in the stated purpose of the provision of the stepped

portions in the side edges of the base sheet, namely to reinforce the base sheet and prevent undulation of the base sheet and the lidding sheet during the manufacturing process. In this context the Board notes that the only specific references in the original application to the creation of unwanted undulations are in the penultimate paragraph of page 2, as mentioned above, and in the paragraph bridging pages 8 and 9. In both cases the creation of the undulations is tied to a consideration of what happens when the edge tabs disclosed in document D1 are extended to improve accessibility. Nevertheless, the original application did include, in the paragraph bridging pages 5 and 6, a statement in general terms that it was a further object of the invention to reduce undulation at the unsealed edge of the blister pack by strengthening the edge with one or more steps or recesses. In this regard the appellants have argued that production of the unit dosage forms by *in situ* sublimation, in which it is necessary to submit the base sheet to low temperatures for an extended period of time, exacerbates the problem of undulations being formed along its side edges. This argument seems feasible on the technical facts involved and the Board is prepared to accept its correctness for the basis of further consideration. As a consequence the Board understands the statement of purpose contained in claim 7 as meaning that the stepped portions in the side edges of the base sheet have to provide sufficient reinforcement to prevent undulations arising in the course of the whole manufacturing process, especially one involving an *in situ* sublimation process for producing the unit dosage forms.

Despite the shift in emphasis in claim 7 compared with claim 1 as to the reason why the stepped portions are provided in the side edges of the base sheet it remains an unalterable fact that the Board has already decided that the provision of stepped portions of the general form disclosed in document D2 along the side edges of the blister pack according to document D1 was an obvious measure. The relative size and shape of the stepped portions shown in Figures 5 to 7 of document D2 correspond closely to those shown in the drawings of the present application. The Board cannot therefore but conclude that the inevitable consequence of the obvious provision of those stepped portions in the side edges of the blister pack as disclosed in document D1 will be a reinforcement of the base sheet sufficient to prevent undulation thereof during the manufacturing process. The result of these considerations is that the subject-matter of claim 7 also follows in an obvious manner from the state of the art and the fact that document D2 does not mention reinforcement of the base sheet as a collateral advantage of the provision of the recesses in the base sheet for facilitating access cannot change this conclusion (see for example T 21/81, OJ EPO 1983, 15).

Thus the subject-matter of claim 7 of the main request also lacks inventive step.

3. *First auxiliary request*

The independent claims 1 and 7 of the first auxiliary request differ from those of the main request solely in that they require the sublimation process to which the unit dosage forms have been subjected to have been

performed *in situ*. This feature is already disclosed in document D1 and therefore appears in the preamble of the claims. Insofar as the feature can play a role when evaluating the inventive step of subject-matter of the claims it has already been taken into account with respect to the claims of the main request, see the above discussion as to the possible causes of undulation in the side edges of the base sheet.

Thus, the independent claims of the first auxiliary request are also unallowable for lack of inventive step.

4. *Second auxiliary request*

In substance the subject-matter of claim 1 of the second auxiliary request differs from that of claim 7 of the first auxiliary request only in the following respects: In the preamble it is stated that there are blister pockets arranged on either side of a longitudinal axis of the blister pack (corresponding in essence to what is stated in claim 1 of the main request in this respect) and that a heat sealing process is used to peelable secure the lidding sheet to the base sheet. In the characterising clause of the claim it is specified that the lidding sheet is not secured to the stepped portions of the base sheet.

It is evident from a consideration of the reasons given above for denying an inventive step in the subject-matter of the independent claims of the main and first auxiliary requests that the features added to the preamble of claim 1 of the second auxiliary request, known *per se* from document D1, cannot lead to a

different conclusion. As for the feature added to the characterising clause of the claim this appears to be implicit in the requirement of claim 1 of the main request that "tabs" are formed in the lidding sheet. In any case it is clear in document D2 that the lidding sheet overlays but is not secured to the recesses in the base sheet in order to form the required gripping tabs. This feature can also therefore make no inventive contribution to the method claimed.

Accordingly, the subject-matter of claim 1 of the second auxiliary request also lacks an inventive step.

4. *Third and fourth auxiliary requests*

Claim 1 according to third auxiliary request has been derived from claim 1 of the main request by the addition of the indication that the formation of the stepped portions in the side edges of the base sheet is also "to reinforce the base sheet" as well as to facilitate removal of the lidding sheet. Claim 1 according to the fourth auxiliary request has been derived from claim 1 according to the first auxiliary request in the same manner.

It is apparent from what has been said in point 2 above that the Board is of the opinion that reinforcement of the base sheet would be the inevitable result of the obvious step of providing stepped portions along the sides edges of the blister pack disclosed in document D1, on which the preamble of claim 1 of both the third and fourth auxiliary requests is based. The specific statement in the claims of this collateral advantage of that obvious step cannot lead to any other

conclusion as to the lack of inventive step of the blister pack defined in the claims in terms of its structural features. Thus the third and fourth auxiliary requests must also be rejected.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani F. Gumbel