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(54) Title: PACKAGING MEANS FOR INCORPORATING A BLISTER PACK

(57) Abstract: A foldable, unitary, packaging means for use in conjunction with one or more blister pack(s) containing medicament comprising: (i) a first surface area presenting the medicament/blister pack(s); and (ii) a second surface area presenting text containing information/instructions relating to the medicament; wherein the ratio of the first surface area to the second surface area is greater than 1:2. The invention also extends to processes for preparing the said packaging means and uses thereof.



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Packaging Means for Incorporating a Blister Pack

5 The invention provides a packaging means for use in packaging solid dose pharmaceutical formulations, methods and processes for the preparation of said packaging means and uses thereof.

10 Goods need to be transported from the place of manufacture eventually to end-users, preferably without sustaining damage in the process. Thus packaging means are widely used in the form of boxes in various sizes. This is also true of pharmaceuticals, which may be manufactured in one country and sold in a different country.

15 Generally boxes containing solid dose formulations of medicament contain several internal units in which the medicament is sealed, for example, in blister packs. A separate instruction/information leaflet will also be included to provide the end-user with instructions/information on the correct use of the medicament. The boxes are often bulky and the blister packs may be removed by the end-user to facilitate transit of medicament, for example, in a handbag or wallet.

20 Accordingly, the medicament is no longer located in its original packaging, which would provide greater protection than the blister pack alone, and also is no longer in the proximity of the instruction leaflet. Alternatively the instructions may simply be lost.

25 These traditional methods of packaging involve several components and during the packaging of the medicament each component used requires an individual identifying code. Vigorous safeguards are necessary to ensure the correct components are used to ensure the final products received by the end-users are acceptable in every respect. The more components used the more complicated the safeguards need to be to protect the process, as the potential for error is greater.

30 Pharmaceuticals must be prepared in accordance with Good Manufacturing Practice (GMP) and this practice extends to the packaging of the end product. This is because a pharmaceutical product may be prepared to the required standards but if an error occurred where the product went into packaging for a different pharmaceutical, a patient may take a dose of their prescribed medication, for example, where the patient has an
35 attack of asthma or angina, and if the medicament is wrong as a result of incorrect

packaging, the dose will not relieve the symptoms. This could have serious repercussions and even be life threatening. So it is extremely important that medicaments are packaged correctly in every aspect.

- 5 It may also be true that the more components used the more raw materials used and hence the greater the cost associated with the product.

10 The present invention ameliorates or eliminates the above mentioned disadvantages whilst simultaneously providing good protection for a blister pack contained within the packaging means.

15 EP 0940 353 describes a form of self-contained reclosable packaging especially suitable for containing different medicament types. WO98/00351 describes a foldable blister pack wherein the blister parts are offset relative to each other and are contained in a supporting unit. US4974729 discloses a calendar type dispenser, WO01/66438 discloses a packaging system for storing and dispensing individual doses of medication and GB2228922 discloses a packaging with certain doses of medicaments grouped together. The aim of such packaging is to aid patient compliance with particular dosing regimes. GB2266880 describes a blister package comprising two card portions which are sealable on the other by contact adhesive. EP0430013 provides a container with an external flap capable of detachable bonding to walls of the container. US3756384 describes a resealable paperboard carton wherein the batch number printed on the blister pack is visible when said blister pack is contained within the carton. WO94/21530 describes blister packaging provided from thermoplastic material.

25 Thus the present invention provides a foldable, unitary, packaging means for use in conjunction with one or more blister pack(s) containing medicament comprising:

- 30 (i) a first surface area presenting the medicament/blister pack(s); and
- (ii) a second surface area presenting text containing information/instructions relating to the medicament;

35 wherein the ratio of the first surface area to the second surface area is greater than 1:2.

Preferably the ratio will be 1:5 or greater, in particular 1:7 or greater.

The present invention provides a packaging means wherein said means is unitary and substantially complete. Thus the packaging means does not require any additional component other than the blister pack to be added to it to form the final product. This may mean that, for example, where the packaging means is prepared from paper card, or similar flexible material, the starting material may be "one sheet" which is scored strategically so that when folded the packaging means is formed. However it is also contemplated that the individually component surfaces may have previously been fixed relative to each other to provide a unitary packaging means.

The fact the packaging means is unitary is important because only one product code is necessary to identify the said packaging means. This means the potential for errors is much smaller as it is not necessary to ensure that the correct combination of components, including the instruction leaflet, is used. Thus there is a safety aspect and possibly a cost benefit associated with the unitary nature of the packaging means.

The said folding mechanism allows the packaging means to be essentially unitary whilst still performing all the necessary functions.

The first and second surface areas of the packaging means are defined in panel(s) which are hingedly located to facilitate a folding type mechanism. This allows the packaging means to fold into a compact unit that is convenient for transit and also has a large total surface area that is made available when the packaging means is open.

This large total surface area can accommodate the instructions/information relating to the medicament.

A panel comprises two substantially parallel surface areas which are defined by, for example, edges and/or fold lines.

Fully assembled refers to the packaging means after the blister pack has been inserted i.e. as the packaging would be used by a patient to obtain a dose of medicament.

An exemplary folding means is illustrated in the diagrams and described as follows.

Fig 1 which illustrates: 4 panels wherein (a) is the first surface and (b), (c) and (d) represent the second surface; an edge (1) and a fold line (2).

One folding mechanism as shown in figs 1, 1a, 1b and 1c comprises:

- 5 (i) keeping panel (b) stationary and moving panel (a), which contains the blister pack, such that it comes to rest above and substantially parallel to panel (b);
- (ii) moving panel (c) such that it comes to rest above and substantially parallel to panel (a) and (b) wherein panel (a), is effectively sandwiched between panel (b) and panel (c) as shown in fig 1b; and
- 10 (iii) moving panel (d) until it comes to rest such that the packaging means is closed as shown in fig 1c.

Optionally one or more panels will move through more than one plane during the folding mechanism, for example in fig.1 bb panel (c), which has previously moved through one
15 plane to come to a resting position as shown in fig 1b, moves through a second perpendicular plane until it comes to rest as shown in fig 1c.

Thus the invention includes a packaging means as described above wherein at least one panel travels through at least two planes which are perpendicular to each other
20 during the folding to close the said means.

An alternative folding mechanism is shown in figs 2, 2a, 2b and 2c comprising:
steps (i) to (ii) above and the further step of folding panel (e) until it comes to rest above and substantially parallel to panel (d). The final step is then folding the combined
25 panels (d) and (e) as in step (iii) above to close the said means as shown in fig 2c.

Analogous methods of folding could be applied to a packaging means illustrated in fig 3.

Fig 4 shows a packaging means comprising 8 panels and a method of folding
30 comprising:

- (a) folding panel Z containing the blister pack until it comes to rest substantially parallel to panel Y as shown in fig. 4a; and
- (b) folding panel V until it comes to rest substantially parallel to panel W as shown in fig 4b; and

(c) folding panel U until it comes to rest substantially parallel to panel (t) as shown in fig 4c; and

(d) folding panel Y/Z, as formed in step (a) above, until it comes to rest substantially parallel to panel X such that panel Z is sandwiched between panel X and panel Y as shown in fig. 4d; and

(e) folding panel V/W, as formed in step (b) above, until it comes to rest substantially parallel to panels X/Z/Y, as formed in step (d) above, as shown in fig 4e; and

(f) folding panel U/T, as formed in part (c) above, until it comes to rest substantially parallel to panel S, such that panel U is sandwiched between panels S and T as shown in fig 4f; and

(g) folding panel S/U/T, as formed in step (f) above, such that it comes to rest such that the packaging means is substantially closed as shown in fig 4g; and

(h) optionally a flap R can be folded such that the packaging means is retained in the closed position as shown in fig 4h.

An alternative example of a method of folding the packaging means as shown in fig. 4bb, fig 4cc, fig 4ee and fig 4dd comprises:

(a) folding panel Z containing the blister pack until it comes to rest substantially parallel to panel Y as shown in fig. 4a; and

(b) folding panel Y/Z, as formed in step (a) above, until it comes to rest substantially parallel to panel X such that panel Z is sandwiched between panel X and panel Y as shown in fig. 4bb; and

(c) folding panel V until it comes to rest substantially parallel to panel W as shown in fig 4cc; and

(d) folding panel V/W, as formed in step (b) above, until it comes to rest substantially parallel to panels X/Z/Y, as formed in step (b) above, as shown in fig 4dd; and

(e) folding panel U until it comes to rest substantially parallel to panel T as shown in fig 4ee; and

(f) folding panel U/T, as formed in part (e) above, until it comes to rest substantially parallel to panel S, such that panel U is sandwiched between panels S and T as shown in fig 4f; and

(g) folding panel S/U/T, as formed in step (f) above, wherein it comes to rest such that the packaging means is substantially closed as shown in fig 4g; and

(h) optionally a flap R can be folded such that the packaging means is retained in the closed position as shown in fig 4h.

The number of possible methods of folding the packaging means increases with the number panels which said means is composed of. Thus the methods described above are simply examples.

5 Variations of these folding mechanisms are within the scope of this invention, for example, where the number of panels is varied and/or wherein the medicament is located in a panel other than a or Z and/or where the order of folding the panels is different.

10 The folding mechanism of the packaging means protects the blister pack efficiently due to at least one layer of material covering each side of the said blister pack and usually a multiplicity of layers covering the foil side of the blister pack, which is the side most susceptible to damage.

15 The said folding mechanism used also has the advantage that a deliberate act of unfolding is required to open the packaging means. Thus if the said packaging means is dropped the content is less likely to spill out due to the natural bias in the system to remain closed, unlike a box wherein the fastening flap may be forced open when dropped. Thus another aspect of the invention is a packaging means which once
20 closed has an inherent bias to remain closed.

The packaging means can be used with existing blister packs, which means the expense and delay of redesigning the blister packs, to be inserted, may be avoided. Advantageously the packaging means is extremely flexible in that it can easily be varied
25 and designed to facilitate use with various shaped blister packs. This means development times for the packaging means are rapid.

In addition the design of the said packaging means allows the blister pack(s) to be inserted without the need for processing which may induce changes in the blister
30 pack(s), for example by printing on the blister pack.

The surface area presenting the medicament/blister pack is the surface(s) wherein the blister pack is visible and/or wherein the medicament will exit the packaging prior to ingestion.

On the surface of the packaging means that covers the foil exit panel of the blister pack, perforations in the material may preferably be used to facilitate access to the pharmaceutical formulation which is located behind it.

- 5 Preferably the blister pack will be inserted into the packaging means as part of the manufacturing process. Hence the product will be provided complete for patients and end users. Although the component materials from which the packaging means is made will preferably be recyclable it is not envisaged that, for example, a new blister pack will be inserted into the said packaging means after the patient has used all the
10 medicament held in the original blister pack.

Preferably the packaging means is disposable.

- 15 Preferably the packaging means will contain one type of medicament or one type of therapy. One therapy type may require one or more medicaments to be present in the same packaging.

- 20 An aspect of the invention is a packaging means with a surface area presenting substantially complete instructions. Thus the packaging means must provide a surface area capable of accommodating all the necessary patient instructions and/or information, optionally for a variety of classes of patients, which obviates the requirement for a supplementary instruction/information leaflet to be supplied with the said packaging means.

- 25 The packaging means usually has a total surface area (the sum of the first and second surface areas) which, when fully open (ie unfolded), is significantly larger than the external surface visible when the packaging means is closed (i.e. folded up). This is achieved by the folding mechanism employed therein. Preferably the total surface area will be more than 2 times larger than the external visible surface area when the said
30 packaging means is closed. More preferably the total surface area will be 4 to 10 times larger, in particular 5 to 8 times larger.

- 35 This has the advantage that the instructions remain with the medicament throughout its life unless the packaging is destroyed and the internal blisters pack removed deliberately. In addition the instructions can be presented in braille which has not been

possible previously as the materials on which the instructions have usually been printed have generally been too thin for braille to be inscribed thereon.

5 It may be suitable to provide the information as a mixture of braille and printed material as the product would then be useful to a major proportion of the relevant population without the need to adapt the packaging for use with sub-categories of end-users, which may be cost effective. The presentation of information in braille is also a legal requirement in some countries.

10 A further aspect of this invention is a packaging means made of material which is conducive to the presentation of information, for example, by printing directly or indirectly onto the surface of the packaging means (an example of the latter would be sticking pre-printed labels onto the surface of the material) or inscribing braille onto the surface of the packaging means.

15 Preferably the presentation of information on the surface of the packaging means will be by *direct and/or indirect printed means and/or braille*. More preferably by *direct printed means and/or braille*, especially printed means or braille.

20 A further feature of the invention is that it allows the packaging to be printed on the production line which may provide further cost and safety advantages.

25 Additional fastening means can be incorporated into the design of the said packaging means. Preferably the said fastening means is reusable, for example, a resealable adhesive strip or a slot and corresponding tab mechanism.

30 Once the packaging means is closed it has the advantage of being slimline due to the efficient use of space and all the elements being in close proximity possibly leading to a certain amount of resistance to moderate crushing. This in conjunction with the lightweight of the complete unit makes the packaging means very suitable for transit by the end-user, for example, in a purse or wallet, and also to the end-user as the slimline design and preferably regular shape, when closed, allows efficient packing of the said packaging means for bulk transportation. The latter may result in cost savings if more units can be transported with less weight per unit in less space, which may be
35 advantageous.

These features mean the end-user will also be encouraged to keep the medicament in its original packaging.

5 A further aspect of this invention is the use of said means in the packaging of pharmaceutical formulations, preferably solid dose pharmaceutical formulations.

10 The said packaging means may be made from a variety of materials, for example, paper card or plastic, having the necessary features of flexibility and resilience. However paper card is the preferred material for use in preparing the packaging means as it is lightweight, extremely suitable for the presentation of information and may also be environmentally friendly if recycled materials are used.

A suitable process for preparing a packaging means comprises:

- 15 (i) cutting the raw material into the required shape;
(ii) scoring lines to define panels; and
(iii) folding to form panels.

In a preferred aspect a process for preparing a packaging means comprises:

- 20 (i) cutting the raw material into the required shape;
(ii) printing the instructions/information onto the surface of the raw material
(iii) scoring lines to define panels;
(iv) inserting a blister pack; and
(v) folding to form panels.

25 The order the steps of the process are performed in may vary and/or two or more steps may be performed concomitantly depending the specific manufacturing used.

The outline shape will be designed to satisfy the specific needs of the individual product to be packaged. Examples of outlines shapes are given in figs 1, 2 and 3.

30

Scoring is a procedure wherein a cut which only extends part way through the material in question is made. This facilitates folding which occurs along the lines defined by the scoring.

The packaging means may be treated, for example, with a coating after processing to provide wear resistance.

5 Additional safety and anti-counterfeiting measures may optionally be incorporated into the packaging means. This may, for example, be by overwrapping the packaging means when the processing is complete. Overwrapping may be foil or plastic. Preferably the overwrap will be transparent, more preferably a sealed plastic film. Such an overwrap may provide extra protection to the packaging means during transit and an anti-counterfeiting/anti-tamper deterrent, i.e. if the overwrap is damaged it may be an indication the product has been tampered with.

10

Throughout the specification and the claims which follow, unless the context requires otherwise, the word 'comprise', and variations such as 'comprises' and 'comprising', will be understood to imply the inclusion of a stated integer or step or group of integers but not to the exclusion of any other integer or step or group of integers or steps.

15

Claims

1. A foldable, unitary packaging means for use in conjunction with one or more blister pack comprising:

5

(i) a first surface area presenting the medicament/blister pack; and

(ii) a second surface area presenting information/instructions relating to the medicament;

10

wherein the ratio of the first surface area to the second surface area, is greater than 1:2.

2. Packaging means according to claim 2, wherein the said ratio is 1:5 or greater.

15

3. Packaging means according to claim 2, wherein the said ratio is 1:7.

4. Packaging means according to anyone of claims 1 to 3 wherein at least one panel travels through at least two planes which are perpendicular to each other during the folding to close the said means.

20

5. Packaging means according to any one of claims 1 to 4, wherein said means has a surface area when fully open which is significantly larger than the external surface visible when the packaging means is closed.

25

6. Packaging means according to claim 5, wherein the surface area when fully open is between 5 and 8 times larger than the external surface.

7. Packaging means according to any one of claims 1 to 6, wherein the means comprises defined panels hingedly located to facilitates a folding type mechanism necessary to close the said package means.

30

8. Packaging means according to any one of claims 1 to 7, wherein said presentation means is printed directly or indirectly means or a mixture thereof on the surface of the packaging.

35

9. Packaging means according to any one of claims 1 to 8, wherein said presentation means comprises printed and braille means.
- 5 10. Packaging means according to claim 9, wherein said presentation means is printed directly on the surface of the packaging means.
11. Packaging means according to claims 1 to 7, wherein the information/instructions are in braille.
- 10 12. Packaging means according to any one of claims 1 to 11, which once closed has an inherent bias to remain closed.
13. Packaging means according to any one of claims 1 to 12, which contains a fastening mechanism.
- 15 14. Packaging means according to claim 13, wherein fastening means is reusable.
15. Packaging means according to claim 14, wherein fastening mechanism is a resealable adhesive strip.
- 20 16. Packaging means according to claim 14 wherein fastening mechanism is a slot and corresponding tab.
- 25 17. Packaging means according to any one of claims 1 to 16, which when closed is resistant to crushing.
18. Packaging means according to any one of claims 1 to 17, which when closed is slimline.
- 30 19. Packaging means according to any one of claims 1 to 18, which when closed is a regular shape conducive to bulk packing.
20. Packaging means according to any one of claims 1 to 19, which has only one code allocated to it when used in conjunction with automated packaging systems.
- 35

21. Packaging means according to any one of claims 1 to 20, suitable for containing pharmaceutical solid dose formulations.

5 22. Packaging means according to any one of claims 1 to 21, which contains perforations to facilitate access to the pharmaceutical solid dose formulations contained therein.

10 23. Packaging means according to any one of claims 1 to 22, wherein the material from which the means is prepared is paper card.

24. Packaging means according to claim 23, wherein the paper card is treated with a coating to improve wear resistance.

15 25. Packaging means according to any one of claims 1 to 24, wherein the packaging means is covered by a suitable overwrap.

26. Packaging means according to claim 25, wherein the overwrap is transparent.

20 27. Packaging means according to claim 26, wherein the overwrap is a sealed plastic film.

28. A process for the preparation of packaging means as defined according to any one of claims 1 to 27 comprising:

- 25 (i) cutting the raw material into the required shape;
(ii) scoring lines to define panels; and
(iii) folding to form panels.

29. A process of filling pharmaceutical solid dose formulations into a packaging means as defined according to any one of claims 1 to 28.

30 30. Use of a blister package in a packaging means according to any one of claims 1 to 29.

35 31. A method of folding a packaging means as claimed in any one of claims 1 to 30 comprising:

- (a) folding panel Z containing the blister pack until it comes to rest substantially parallel to panel Y as shown in fig. 7a; and
- (b) folding panel V until it comes to rest substantially parallel to panel (w) as shown in
5 fig 7b; and
- (c) folding panel U until it comes to rest substantially parallel to panel (t) as shown in fig 7c; and
- (d) folding panel Y/Z, as formed in step (a) above, until it comes to rest substantially
10 parallel to panel X such that panel Z is sandwiched between panel X and panel Y as shown in fig. 7d; and
- (e) folding panel V/W, as formed in step (b) above, until it comes to rest substantially parallel to panels X/Z/Y, as formed in step (d) above as shown in fig 7e; and
- (f) folding panel U/T as formed in part (c) above, until it comes to rest substantially
15 parallel to panel S, such that panel U is sandwiched between panels S and T as shown in fig 7f; and
- (g) folding panel S/U/T, a formed in step (f) above, such that it comes to rest such that the packaging means is substantially closed as shown in fig 7g; and
- (h) optionally a flap R can be folded such that the packaging means is retained in the
20 closed position as shown in fig 7h.

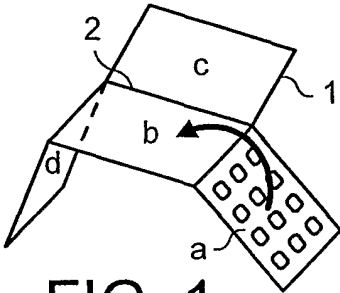


FIG. 1

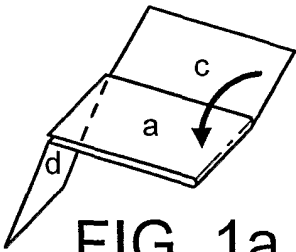


FIG. 1a

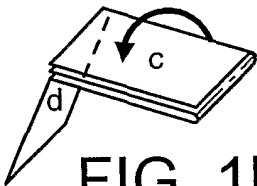


FIG. 1bb

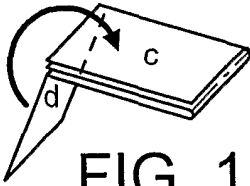


FIG. 1b

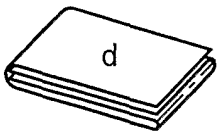
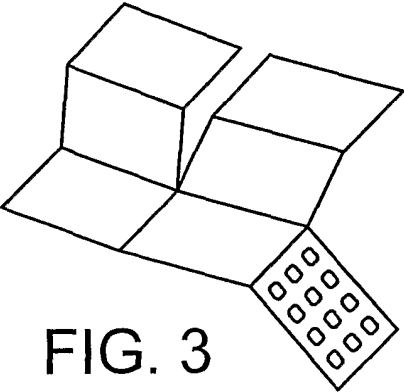
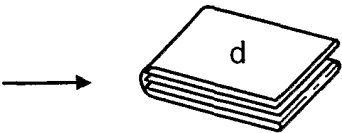
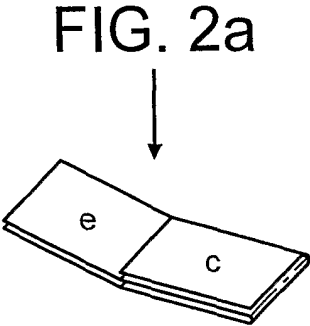
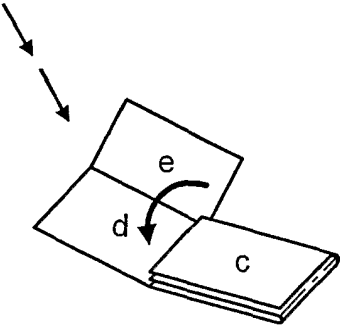
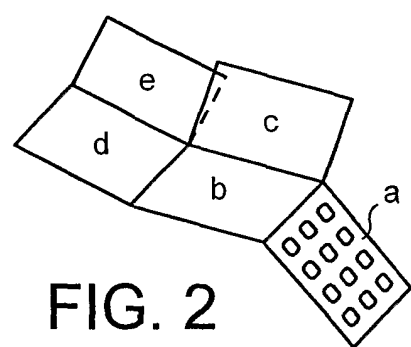


FIG. 1c



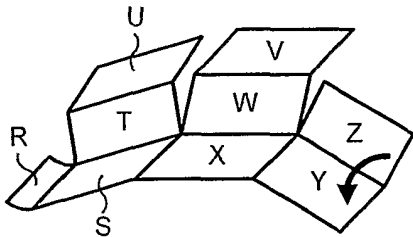


FIG. 4

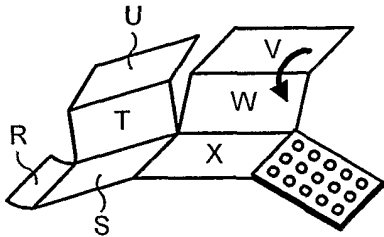


FIG. 4a

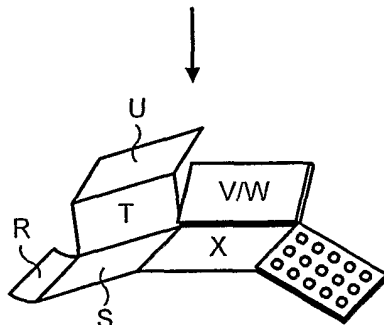


FIG. 4b

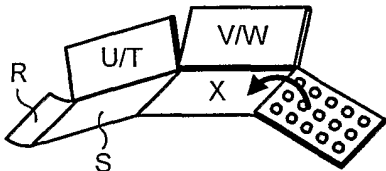


FIG. 4c

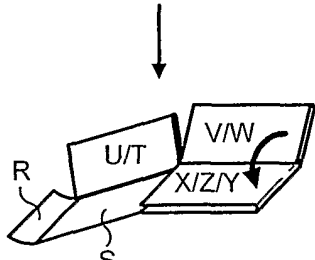


FIG. 4d

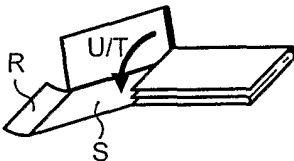


FIG. 4e

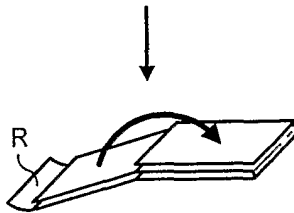


FIG. 4f

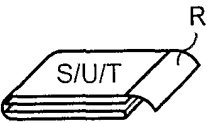


FIG. 4g



FIG. 4h

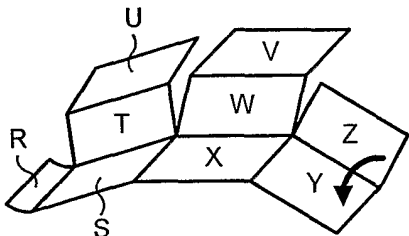


FIG. 4

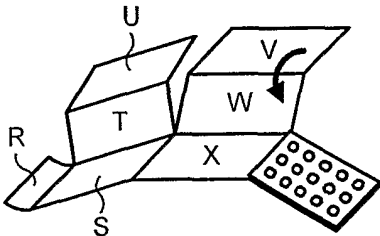


FIG. 4a

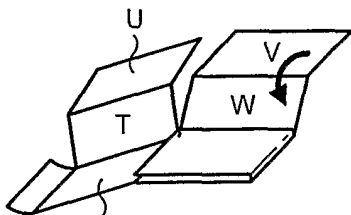


FIG. 4bb

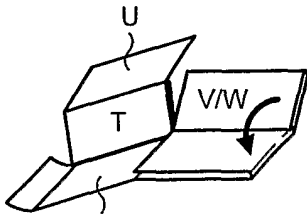


FIG. 4cc

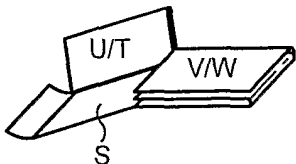


FIG. 4ee

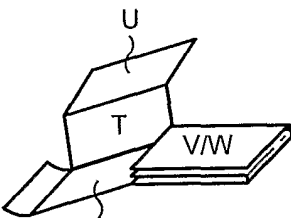


FIG. 4dd