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(54) Title: PARACHUTE OSTOMY POUCH

(57) Abstract: An ostomy appliance is sufficiently small to provide the user with a desired level of discretion, and can also provide an expanded collection capacity to accommodate sudden outflows of stomal discharge.

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PARACHUTE OSTOMY POUCH

BACKGROUND

[0001] The present disclosure relates to ostomy appliances, and more particularly to an ostomy pouch for collecting body waste through a stomal opening for later disposal.

[0002] Ostomy pouches for the collection of body waste are well known. Ostomy pouches typically include flat, opposing side walls secured together along their edges to define a collection cavity. One of the side walls is provided with an opening to receive a stoma, and means such as a connecting flange is provided for securing the pouch to an adhesive barrier placed to surround the stoma so that body waste discharged through the stoma is received within the cavity. At its lower end, the ostomy pouch may have a discharge opening which may be closed during collection of the body waste material but may be opened for draining the body waste material from the pouch after a period of use. Alternatively, the ostomy pouch may be designed for a single use, in which case, it will not be provided with a discharge opening since the entire pouch will be discarded after it has substantially filled with stomal discharge.

[0003] Ostomy pouches are available in various sizes for different collecting capacity needs for different users or for different situations of an individual user. For example, the user will want to use a large ostomy bag over night, but may desire to use a smaller ostomy bag or cap for discretion during public activities or when exercising. However, as stomal discharge cannot be regulated at will, the small ostomy bag or cap may not provide sufficient collection capacity to contain a sudden outflow of stomal discharge.

[0004] Accordingly, there is a need for an improved ostomy pouch that is small enough to provide the discretion desired by the user, yet can also provide a sufficient collection capacity to contain sudden outflows of stomal discharge.

BRIEF SUMMARY

[0005] A mini ostomy pouch according to various embodiments is sufficiently small to provide a higher degree of discretion for the user, yet configured to expand to provide
collection capacity of a full size ostomy pouch to accommodate sudden outflows of stomal discharge, thereby providing the user with added security.

[0006] In one aspect, an ostomy appliance includes a pouch and a tear-away panel. The pouch includes an inlet and two walls, to wit, a body side wall and an outer wall, which are sealed together along their peripheral edges to define a cavity for collecting body waste. The ostomy appliance has a compacted state and a deployed state. The ostomy appliance in the deployed state has a surface area, which is greater than that of the ostomy appliance in the compacted state. The ostomy appliance is configured to change from the compacted state to the deployed state by removing the tear-away panel.

[0007] In another aspect, an ostomy appliance includes a pouch and a tear-away panel. The pouch includes an inlet and two walls, to wit, a body side wall and an outer wall, which are sealed together along their peripheral edges to define a cavity for collecting body waste. The ostomy appliance has a compacted state and a deployed state. In the compacted state, the peripheral edges of the pouch walls are hidden behind the tear-away panel.

[0008] Any of above described ostomy appliances can further include a skin barrier arranged about the inlet. The skin barrier includes a barrier backing and an adhesive for attaching the ostomy appliance on a user, such that the body waste flows into the cavity through the inlet. The barrier backing is laminated on the pouch side surface of the adhesive. The body side wall of the pouch is attached to the barrier backing proximate the inlet, and the tear-away panel is attached along peripheral edges of the barrier backing. The pouch is folded or gathered such that the pouch is contained between the barrier backing and the tear-away panel in the compacted state.

[0009] Any of above described ostomy appliances can further include a pull-tab arranged proximate a peripheral edge of the tear-away panel. The pull-tab may be integrally formed with the tear-away panel or may be a separate piece arranged between the tear-away panel and the barrier backing. The tear-away panel can be peelably attached to the barrier backing such that the tear-away panel is peeled away from the barrier backing by pulling on the pull-tab. In one embodiment, the tear-away panel is peelably attached to the barrier backing by
heat sealing. In another embodiment, the tear-away panel is peelably attached to the barrier
baking by an adhesive.

[0010] In some embodiments, the ostomy appliance can include a two-piece ostomy pouch including a pouch side coupling ring and a body side coupling ring, wherein the pouch is folded or gathered behind the tear-away panel when in the compacted state.

[0011J Any of the above described ostomy appliances can include the tear-away panel formed of a non-woven sheet.

[0012J Any of the above described ostomy appliances has a first body waste collection capacity when in the compacted state and a second body waste collection capacity when in the deployed state, wherein the second body waste collection capacity is greater than the first body waste collection capacity. In one embodiment, the second body waste collection capacity is at least three times greater than the first body waste collection capacity.

[0013J Any of the above described ostomy appliances can include a single use disposable pouch without an outlet, or a pouch including an outlet with a closure mechanism.

[0014J Other aspects, objectives and advantages will become more apparent from the following detailed description when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0015] The benefits and advantages of the present embodiments will become more readily apparent to those of ordinary skill in die relevant art after reviewing the following detailed description and accompanying drawings, wherein:

[0016] FIG. 1 is a perspective view of an ostomy appliance including a one-piece ostomy pouch in a compacted state according to an embodiment;

[0017] FIG. 2 is an exploded view of the ostomy appliance of FIG. 1;

[0018] FIG. 3 is a cross-sectional view of the ostomy appliance of FIG. 1 taken along line A--A;
FIG. 4 is a perspective view of the ostomy appliance of FIG. 1 in a deployed state;

FIG. 5 is a cross-sectional view of the one-piece ostomy pouch of FIG. 4 taken along line B--B; and

FIG. 6 is a cross-sectional view of an ostomy appliance including a two-piece ostomy pouch according to another embodiment.

DETAILED DESCRIPTION

While the present disclosure is susceptible of embodiment in various forms, there is shown in the drawings and will hereinafter be described a presently preferred embodiment with the understanding that the present disclosure is to be considered an exemplification and is not intended to limit the disclosure to the specific embodiment illustrated.

Referring now to the figures, FIGS. 1-4 show an embodiment of an ostomy appliance 10. FIGS. 1 and 2 illustrate the ostomy appliance 10 in a compacted state 11, and FIG. 4 illustrates the ostomy appliance 10 in a deployed state 13. The ostomy appliance 10 generally includes a pouch 12, a skin barrier 14, and a tear-away panel 16. As shown in FIG. 4, the pouch 12 is a full size ostomy pouch, which can be provided in different sizes.

As shown in an exploded view in FIG. 3 and a cross-sectional view in FIG. 2, the pouch 12 is folded and secured in place with the tear-away panel 16, such that the pouch 12 is completely contained within a cavity 15 defined between the tear-away panel 16 and the skin barrier 14. The tear-away panel 16 is peelably attached to the pouch side surface 17 of the skin barrier 14 to form the ostomy appliance 10 in the compacted state 11, as shown in FIGS. 1 and 2. The ostomy appliance 10 in the compacted state 11 is significantly smaller in size when compared to the ostomy appliance 10 in the deployed state 13 (FIG. 4), in which the pouch 12 is fully deployed.

The ostomy appliance 10 in the compacted state 11 is also referred to herein as a mini pouch or a mini ostomy appliance due to the significant reduction in size when compared to the fully deployed, full size ostomy pouch. The mini pouch in the illustrated
embodiment has substantially the same surface area as the peel-away panel. The mini pouch can come in many different sizes, preferably in a size similar to ostomy caps. When a large capacity pouch is needed, the user can remove the tear-away panel 16 to deploy the pouch 12. Thus, the user can wear the mini pouch when more discretion is desired, such as in public, without concern about conditions due to leakage caused by, for example, a sudden outflow of stoma discharge.

[0026] With the ostomy appliance 10, generally described, additional structural details of the ostomy appliance 10 will be described. As shown FIGS. 2 and 5, the pouch 12 includes a body side wall 18, an outer wall 20, and a non-woven sheet 22. The body side wall 18 and the outer wall 20 are sealed together along their outer peripheral edges 21 to define a cavity 24 for collecting stoma discharge. The non-woven sheet 22 is attached on the outer surface of the outer wall 20. The non-woven sheet is optional, thus some embodiments may not include the non-woven sheet or may include the non-woven sheet only on the outer surface of the body side wall or on the outer surfaces of both walls.

[0027] The pouch 12 of this embodiment is designed for a single use, thus has a closed end 34 without a discharge outlet. In other embodiments, the pouch may include a discharge outlet which may be closed during collection of the stoma discharge and opened for periodic draining of the stoma discharge from the pouch. For example, the pouch may include an outlet with a fold-up type closure, such as those disclosed in Villefrance, et al., US Patent No. 7,879,015, and Mandzij, et al.; US Patent No. 7,879,016, both of which are commonly assigned with the present application and are incorporated herein by reference. In such embodiments, the discharge opening is closed before the pouch is folded and secured with the tear-away panel to form the mini ostomy appliance.

[0028] The body side wall 18 is provided with an inlet opening 26 to receive a stoma. The skin barrier 14 is arranged about the inlet opening 26 for attachment around the stoma. The skin barrier 14 includes an adhesive 28, a barrier backing 30, and a release liner 32. The barrier backing 30 is laminated on the pouch side surface of the adhesive 28. The body side wall 18 is attached to the barrier backing 30 proximate the inlet opening 26. The body side wall 18 can be attached to the barrier backing 30 via any suitable methods, such as an adhesive or heat sealing. Preferably, the body side wall 18 is heat sealed to the barrier backing 30. The body
side wall 18 and the outer wall 20 can be formed of the same material or different materials, which can be a single layer film or a multilayer film. The barrier backing 30 may also be formed of a single layer film or a multilayer film. Preferably, the body side wall 18 and the barrier backing 30 are formed of films, which include a heat scalable surface layer, such that the body side wall 18 and the barrier backing 30 can be heat sealed together.

[0029] The pouch 12 may also be provided with a filter 36, such as those disclosed in Nolan, US 3,952,727, and Botten, US 7,559,922, both of which are commonly assigned with the present application and are incorporated herein by reference. The filter 36 is strategically arranged on the pouch 12 such that flatus gases in the pouch 12 can still exit via the filter 36 when the ostomy appliance 10 is in the compacted state 11. Although, the filter 36 of the illustrated embodiment is attached to an inner surface of the pouch 12, in other embodiments, the filter may be attached on an outer surface of the pouch, or the pouch may not include a filter.

[0030] The tear-away panel 16 is shaped and sized such that an outer periphery 42 of the tear-away panel 16 generally matches an outer periphery 44 of the skin barrier 14, as shown in FIGS. 2 and 3. The tear-away panel 16 includes a pull-tab 60 extending from a peripheral edge 62. The pull-tab 60 is integrally formed with the tear-away panel 16 in this embodiment, however, the pull-tab may be a separate member arranged between the tear-away panel 16 and the barrier backing 30 in other embodiments, such that the pull-tab extends out of the sealed peripheral edges of the tear-away panel and the barrier backing. Although the pull-tab 60 is arranged on the top peripheral edge 62 of the tear-away panel 16 in the illustrated embodiment, the pull-tab can be arranged in different peripheral locations, such as at a corner or on a bottom peripheral edge, as long as the user can grasp the pull-tab and apply a pulling force to remove or peel away the tear-away panel 16 from the barrier backing 30.

[0031] To form the ostomy appliance 10 in a compacted state 11, the pouch 12 is folded or gathered toward a center 64 on the barrier backing 30, such that the peripheral edges 21 of the pouch 12 do not extend beyond the outer periphery 44 of the skin barrier. The pouch 12 is folded or gathered to leave a sealing space 50 proximate the outer periphery 44 of the skin barrier 14 for the attachment of the tear-away panel 16. When folding or gathering the pouch 12, the folds or gathers are formed such that the filter 36 is not obstructed by the folds or gathers to
allow flatus gasses in the pouch 12 to exit the ostomy appliance 10 via the filter 36 and through the tear-away panel 16 when in the compacted state 11.

[0032] The tear-away panel 16 is peelably attached to the barrier backing 30 such that the tear-away panel 16 can be removed or peeled away from the barrier backing 30 without ripping or damaging the skin barrier 14. Further, the peelable attachment between the tear-away panel 16 and the barrier backing 30 is configured such that the tear-away panel 16 can be easily removed from the barrier backing 30 without interrupting a seal between the adhesive 28 and user’s skin. Such peelable attachment between the tear-away-panel 16 and the barrier backing 30 can be obtained via any suitable method, such as peelable adhesives or heat sealing. The tear-away panel 16 can be formed of any suitable material, such as a polymeric film or a non-woven sheet, preferably, a non-woven sheet. Preferably, the tear-away panel 16 is formed of a material, which can form a peelably seal with the barrier backing 30 by heat sealing.

[0033] In the illustrated embodiment, the pouch 12 is folded in four ways, such that the peripheral edges 21 of the pouch 12 are folded toward the center of the barrier backing 30 to form the ostomy appliance 10 in the compacted state 11. In other embodiments, the pouch 12 can be folded less than four times or greater than four times as long as the pouch 12 is contained within the cavity 15 formed between the barrier backing 30 and the tear-away panel 16 when their peripheries 42, 44 are sealed together. For example, the pouch 12 can be gathered on the barrier backing 30 with multiple gathers to fit between the barrier backing 30 and the tear-away panel 16.

[0034] The pouch 12 can come in various sizes. In one embodiment, the pouch 12 has a surface area 37 with a length 38 of about 9 inches and a width 40 of about 6 inches when fully deployed, as shown in FIG.4. The tear-away panel 16 has a generally a rectangular shape with rounded corners, and has a surface area 51 with a length 52 of about 4 inches and a width 54 of about 4 inches. The skin barrier 14 has a corresponding shape and sizes such that the outer peripheries of the tear-away panel 16 and the skin barrier 14 generally match when sealed together to form the mini pouch. The pouch 12 is folded or gathered, and secured in place by attaching the tear-away panel 16 on the peripheral edges of the barrier backing 30 to form the ostomy appliance 10 in the compacted state 11. As such, the ostomy appliance 10 in the
compacted state 11 has a surface area equal to that of the tear-away panel 16. The appliance
10 in the deployed state 13 has a surface area 37, which is the same as that of the fully deployed
pouch 12. The mini pouch can come in various shapes and sizes. For example, the mini pouch
can have a circular shape with a diameter of about 3 inches.

When in use, the user attaches the ostomy appliance 10 in the compacted
state 11 around the stoma by peeling off the release liner 32 and placing the exposed adhesive
around the stoma, such that the stoma is received in the inlet opening 26 to allow stoma
discharge to flow into the cavity 24. The ostomy appliance 10 in the compacted state 11
provides the user with a higher degree of discretion with a significant reduction in the ostomy
appliance size when compared to the fully deployed pouch 12 in the deployed state 13.

However, since the pouch 12 is folded or gathered, and contained within the cavity 15 between
the tear-away panel 16 and the barrier backing 30, a collection capacity of the pouch 12 is also
significantly reduced as the pouch can only expand within the cavity 15 to hold the stoma
discharge. Although, the collection capacity is smaller when compared to the fully deployed
pouch 12, the mini pouch can still contain some stomal discharge and allow flatus gasses to exit
via the filter 36, while the user enjoys the higher degree of discretion. When the user desires to
increase the collection capacity, for example to accommodate sudden outflows of stomal
discharge, the user can pull on the pull-tab 60 to remove the tear-away panel 16 to deploy the
pouch 12. In the deployed state 13, the fully deployed pouch 12 provides the user with an
increased collection capacity to contain the stomal discharge without leakage. In one
embodiment, the collection capacity of the ostomy appliance in the deployed state is greater than
that of the ostomy appliance in the compacted state by at least 2 times, and preferably by at least
3 times. Thus, the ostomy appliance 10 provides the user with a desirable mini pouch with the
capability to increase the collection capacity.

FIG. 6 shows a cross-sectional view of a mini pouch 70 according another
embodiment. Similar to the ostomy appliance 10, the mini pouch 70 includes a pouch 72 and a
tear-away panel 74. However, the pouch 72 is a two-piece pouch with a pouch side coupling
ring 78, instead of the skin barrier 14 of the ostomy appliance 10. The pouch side coupling ring
78 is configured to mate with a body side coupling ring (not shown) on a skin barrier (not
shown). In this embodiment, the skin barrier is first attached to the user around a stoma, and the
mini pouch 70 is attached to the skin barrier by coupling the pouch side coupling ring 78 with the body side coupling ring (not shown.)

[0037] The mini pouch 70 also includes a backing panel 76. The pouch 72 is attached on a first surface 80 of the backing panel 76 about an inlet opening 84, and the pouch side coupling 78 is attached on a second surface 82 of the backing panel 76. Other aspects of the pouch 72 are the same as pouch 12 of the previously described embodiment. The mini pouch 70 includes a pull-tab 86, which is arranged between the tear-away panel 74 and the backing panel 76 proximate their peripheral edges. The pull-tab 86 is attached at least to the tear-away panel 74 or attached both to the tear-away panel 74 and the backing panel 76. Preferably, the pull-tab 86 is permanently attached to the tear-away panel 74, such that the pull-tab 86 remains attached to the tear-away panel 74 as the user pulls on the pull-tab to remove the tear-away panel 74 to deploy the pouch 72. As it was with the ostomy appliance 10, the mini pouch 70 is formed by folding and gathering the pouch 72. The folded or gathered pouch 72 is secured in place by sealing the peripheral edges of the tear-away panel 74 and the backing panel 76 together. The collection capacity of the mini pouch 70 can be increased by removing the tear-away panel 74 and deploying the pouch 72, as described in detail above with regard to the ostomy appliance 10.

[0038] All patents referred to herein, are hereby incorporated herein in their entirety, by reference, whether or not specifically indicated as such within the text of this disclosure.

[0039] In the present disclosure, the words "a" or "an" are to be taken to include both the singular and the plural. Conversely, any reference to plural items shall, where appropriate, include the singular.

[0040] From the foregoing it will be observed that numerous modifications and variations can be effectuated without departing from the true spirit and scope of the novel concepts of the present disclosure. It is to be understood that no limitation with respect to the specific embodiments illustrated is intended or should be inferred. The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims.
CLAIMS

What is claimed is:

1. An ostomy appliance, comprising:

   a pouch, the pouch including an inlet, a body side wall, and an outer wall, wherein the body side wall and the outer wall are sealed together along their peripheral edges to define a cavity for collecting body waste;

   a tear-away panel;

   wherein the ostomy appliance has a compacted state having a first surface area, and a deployed state having a second surface area, the second surface area being greater than the first surface area, and wherein the ostomy appliance is configured to change from the compacted state to the deployed state by removing the tear-away panel.

2. The ostomy appliance of claim 1, further including a skin barrier arranged about the inlet, the skin barrier including a barrier backing and an adhesive for attaching the ostomy appliance on a user such that the body waste flows into the cavity through the inlet, the barrier backing being laminated on a pouch side surface of the adhesive, wherein the body side wall is attached to the barrier backing proximate the inlet, and wherein the tear-away panel is attached along peripheral edges of the barrier backing.

3. The ostomy appliance of claim 2, wherein the pouch is folded or gathered such that the pouch is contained between the barrier backing and the tear-away panel in the compacted state.

4. The ostomy appliance of claim 2, further including a pull-tab arranged proximate a peripheral edge of the tear-away panel, wherein the tear-away panel is peelably attached to the barrier backing such that the tear-away panel is peeled away from the barrier backing by pulling on the pull-tab.

5. The ostomy appliance of claim 4, wherein the tear-away panel is peelably attached to the barrier backing by heat sealing.
6. The ostomy appliance of claim 4, wherein the tear-away panel is peelably attached to the barrier baking by an adhesive.

7. The ostomy appliance of claim 1, wherein the ostomy pouch is a two-piece ostomy pouch including a pouch side coupling ring and a body side coupling ring, wherein the pouch is folded or gathered behind the tear-away panel when in the compacted state.

8. The ostomy appliance of claim 1, wherein the tear-away panel comprises a non-woven sheet.

9. The ostomy appliance of any of claims 1-8, wherein a body waste collection capacity of the pouch is greater in the deployed state than in the compacted state.

10. An ostomy appliance, comprising:

   a pouch, the pouch having an inlet, a body side wall, and an outer wall, wherein the body side wall and the outer wall are sealed together along their peripheral edges to define a cavity for collecting body waste;

   a tear-away panel; and

   wherein the ostomy appliance has a compacted state and a deployed state, wherein the peripheral edges of the pouch walls are hidden behind the tear-away panel in the compacted state.

11. The ostomy appliance of claim 10, wherein the pouch is a one-piece pouch including a skin barrier arranged about the inlet, the skin barrier including a barrier backing and an adhesive for attaching the ostomy appliance on a user such that the body waste flows into the cavity through the inlet, the barrier backing being laminated on a pouch side surface of the adhesive, wherein the body side wall is attached to the barrier backing proximate the inlet, and wherein the tear-away panel is attached along peripheral edges of the barrier backing.

12. The ostomy appliance of claim 11, wherein the pouch has a larger surface area than the tear-away panel, and the pouch is folded or gathered such that the pouch is covered by
the tear-away panel without any portion of the pouch extending beyond the peripheral edges of
the tear-away panel.

13. The ostomy appliance of claim 12, further including a pull-tab arranged proximate
a peripheral edge of the tear-away panel, wherein the tear-away panel is peelably attached to
the barrier backing such that the tear-away panel is peeled away from the barrier backing by pulling
on the pull-tab.

14. The ostomy appliance of claim 10, wherein the tear-away panel is removed from
the ostomy appliance when in the deployed state, wherein the pouch is fully deployed to provide
a maximum body waste collection capacity in the deployed state.

15. The ostomy appliance of claim 10, wherein the ostomy pouch is a two-piece
ostomy pouch including a pouch side coupling ring and a body side coupling ring, wherein the
pouch is folded or gathered behind the tear-away panel when in the compacted state.

16. The ostomy appliance of claim 10, wherein the tear-away panel comprises a non-
woven sheet.

17. The ostomy appliance of any of claims 10-16, wherein the ostomy appliance has a
first body waste collection capacity when in the compacted state and a second body waste
collection capacity when in the deployed state, wherein the second body waste collection
capacity is at least three times greater than the first body waste collection capacity.

18. The ostomy appliance of any of claims 1-17, wherein the pouch is a single use
disposable pouch without an outlet.

19. The ostomy appliance of any of claims 1-17, wherein the pouch includes an outlet
with a closure mechanism.
## INTERNATIONAL SEARCH REPORT

**International application No.**

PCT/US 12/27215

### A. CLASSIFICATION OF SUBJECT MATTER

<table>
<thead>
<tr>
<th>IPC(8)</th>
<th>A61F 5/44 (201.2.01)</th>
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<td>USPC</td>
<td>604/339</td>
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According to International Patent Classification (IPC) or to both national classification and IPC

### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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<tr>
<th>IPC(8)</th>
<th>A61F 5/44 (2012.01)</th>
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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<td>604/327, 332-344</td>
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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWEST (PGPB, USPT, EPAB, JPAB); Google (Patents, Scholar, Web)

Search Terms: Ostomy, pouch, bag, inlet, stoma, cavity, chamber, pocket, waste, tear, peel, away, off, frangible, panel, layer, portion, sheet, nonwoven, tab, pull, surface area, volume, increase, enlarge, expand, compact, grow, deploy, backing, structure, support, skin

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<tbody>
<tr>
<td>Y</td>
<td>US 2004/0171999 A1 (ANDERSON et al.) 02 September 2004 (02.09.2004) Fig. 1-4; Para [0019], [0021H0022], [0031]-[0032], [0034]-[0035], [0037]-[0039], [0041]-[0042], [0044]</td>
<td>1-17</td>
</tr>
<tr>
<td>Y</td>
<td>US 5,865,819 A1 (CISKO et al.) 02 February 1999 (02.02.1999) Fig. 2-3, 5-8; col 4, in 63 to col 5, in 47, col 6, in 47 to col 7, in 6</td>
<td>1-17</td>
</tr>
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</table>

Further documents are listed in the continuation of Box C.

- Special categories of cited documents:
  - “A” document defining the general state of the art which is not considered to be of particular relevance
  - “E” earlier application or patent but published on or after the international filing date
  - “L” document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  - “O” document referring to an oral disclosure, use, exhibition or other means
  - “P” document published prior to the international filing date but later than the priority date claimed
  - “T” later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  - “X” document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
  - “Y” document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
  - “Z” document member of the same patent family

**Date of the actual completion of the international search**

18 June 2012 (18.06.2012)

**Date of mailing of the international search report**

06 JUL 2012

**Name and mailing address of the ISA/US**

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

**Facsimile No.**

571-273-3201

**Authorized officer:**

Lee W. Young

PCT HelpDesk: 571-272-4300

PCT OSP: 571-272-7774

Form PCT/ISA/2 10 (second sheet) (July 2009)
Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. □ Claims Nos.:
   because they relate to subject matter not required to be searched by this Authority, namely:

2. □ Claims Nos.:
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. □ Claims Nos. '18-19
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. □ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. □ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. □ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. □ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

□ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

□ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

□ No protest accompanied the payment of additional search fees.