

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 41

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte DAVID ROLF

Appeal No. 2000-0890
Application No. 08/345,215

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and MILLS, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 13-33, all the claims pending in the application.

Claims 13, 19, 26 and 33 are representative of the subject matter on appeal and read as follows:

13. A mixing and dispensing package for applying a wound dressing product to a patient, comprising:

a flexible container-body formed from superimposed upper and lower flexible walls that form a flexible pouch having first and second edges on opposite sides of the package,

said flexible walls comprising two different sheets located in two portions of the package for permitting the introduction of different sterilizing agencies into said portions of the package where said two different sheets are located,
said sheets including
(a) a first flexible sheet for allowing the introduction therethrough of a first sterilizing agency,
(b) a second sheet for allowing the introduction therethrough of a second sterilizing agency, and
(c) said second sheet has a different composition from said first sheet,
a pressure-rupturable seal between the superimposed walls of said package, said seal extending from the first edge of the package to the second edge to divide said package into two separate compartments,
a dry wound dressing in one compartment,
water in the other compartment,
said pressure-rupturable seal being able to be forced open by manual pressure applied to the exterior of the package by pressing on the water-containing compartment of the package with the hands to increase the hydrostatic pressure in the water-containing compartment and thereby force the water through the rupturable seal into the dry wound dressing contained in said one compartment to form a fluid dispersion for being dispensed from the package onto the wound,
whereby said dry wound dressing is sterilized by a first sterilizing agency introduced into the package through the first sheet and the water sterilized by a second sterilizing agency introduced into the package through the second sheet.

19. A mixing and dispensing package for applying a wound dressing product to a patient, comprising:
a flexible container-body formed from superimposed upper and lower flexible walls that comprise a flexible pouch having first and second edges on opposite sides of the package,
the upper and lower flexible walls of the package have an ionomer coating on an inside surface thereof,
a rupturable seal in the package comprising a heat seal wherein the ionomer coating is bonded to itself to define a pressure-rupturable seal between the superimposed walls of said package with the ionomer coating, said seal extending from the first edge of the package to the second edge to divide said package into two separate compartments,
a dry wound dressing in one compartment,
water in the other compartment,
said pressure-rupturable seal comprising the ionomer being able to be forced open by manual pressure applied to the exterior of the package by pressing on the water-containing compartment of the package with the hands to increase the hydrostatic pressure in the water-containing compartment and therefore the water through the rupturable seal into the dry wound dressing contained in the second compartment,
a portion of the package being removable to provide an opening through which the dressing can be dispensed for being applied onto the wound,

whereby the rupture of said heat seal wherein the ionomer is bonded to itself allows communication between the compartments and permits contact between the contents of the separate compartments of said package.

26. A sterilizable mixing and dispensing package for a natural or synthetic hydratable solid in particulate form comprising,
a flexible container body having first and second compartments,
a rupturable barrier between the compartments for allowing communication therebetween when the barrier is eliminated to permit mixing of contents within the package,

a natural or synthetic hydratable solid in particulate form in the first compartment,
said first compartment having a wall formed from a porous polymeric sheet for allowing the entry of a gas into the first compartment through the pores in the sheet for sterilizing the particulate solid in said first compartment when the gas contacts the particulate solid therein,

the second compartment has walls formed from a plastic resin that provides a watertight enclosure,

water stored in said second compartment,

said rupturable barrier being constructed and arranged to be opened by a person to allow the water in the second compartment to mix with the particulate solid in the first compartment for dispersing the particulate solid in the water to thereby form an aqueous dispersion with the package, and

the porous polymeric sheet and plastic resin confine the aqueous dispersion within the package after mixing whereby the aqueous dispersion can be expelled from the package onto a surface through an outlet in the package other than the pores in the porous polymeric sheet.

33. A sterilizable mixing and dispensing package for a wound dressing, comprising,

a flexible pouch having a pair of compartments with a rupturable barrier between the compartments to allow mixing of material contained in the compartments after the barrier is ruptured,

said compartments include a water-containing compartment formed from plastic film and,

a hydrocolloid-containing compartment comprising a porous flexible sheet adapted to admit a sterilizing gas through pores in the flexible sheet for sterilizing the hydrocolloid contained therein, and

after the barrier is ruptured the porous sheet and plastic film confine the hydrocolloid and water within the package, allowing a wound dressing formed from the mixture of the hydrocolloid and water to be expelled from the package onto a wound through an opening in the package.

The references relied upon by the examiner are:¹

U. K. Pat. App. (GB'144)	2,194,144	Mar. 2, 1988
U. K. Pat. App. (GB'443)	2,229,443	Sep. 26 1990

Two patents discussed by this merits panel are:

Rolf	5,804,213	Sep. 8, 1998
Rolf	6,406,712	Jun. 18, 2002

Claims 13 through 33 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon the combined disclosures of GB'443 and GB'144.² We reverse. We also raise other issues for the examiner and appellants to consider upon return of the application to the jurisdiction of the examiner.

DISCUSSION

1. Claims 13-18

In relevant part, the package of claim 13 requires flexible walls, which comprise two different sheets located in two portions of the package for permitting the introduction of different sterilizing agencies. The first flexible sheet allows the introduction of a first sterilizing agency while the second sheet allows for the introduction of a second sterilizing agency. The second sheet has a different composition from the first sheet.

¹ The examiner also makes reference to disclosures appearing at pages 7-7a of the specification at pages 3-4 of the Examiner's Answer. However, did not rely upon these passages in rejecting the claims in the final Office action (Paper No. 33). The propriety of the examiner relying upon new evidence during an appeal proceedings is not apparent. Accordingly, we have limited our consideration of the examiner's position as it relies upon GB'144 and GB'443.

² The examiner states at page 3 of the Examiner's Answer that the claims are rejected on the basis of GB'443 alone. We consider this to be an inadvertent mistake on the part of the examiner as it is clear from the record that the examiner relies upon the two documents together.

The examiner relies upon GB'144 for the details of the claimed package. The examiner asserts at the top of page 4 of the Examiner's Answer that the material of the package and the laminated plastic films, apparently is required by the claims on appeal are described at page 3 of GB'144. The examiner states at page 5 of the Examiner's Answer that making a package of "two distinct sheets" is also "within the scope of the cited art." In support of this assertion, the examiner cites GB'144 page 2, lines 43-46 which states "[t]he selection in any particular case of the plastics film material, thickness of film, and so on, will be governed in part by the substances to be contained within the envelope...."

We have reviewed GB'144 in its entirety paying close attention to the portions of the reference cited by the examiner but do not find that it teaches or suggests the specific requirements set forth in claim 13 on appeal. We do not find any disclosure in GB'144 that the flexible walls of the package described in the reference should comprise of two different sheets located in two portions of the package for permitting the introduction of different sterilizing agencies as required by claim 13 on appeal. The "so on" portion of the reference relied upon by the examiner does not provide an adequate evidentiary basis for the examiner's ultimate conclusion of obviousness.

Absent a fact-based analysis from the examiner explaining precisely where in GB'144 the requirements of claim 13 are found, we do not find the examiner has satisfied his initial burden of providing reasons of unpatentability. Accordingly, we reverse the rejection of claims 13 through 18.

2. Claims 19-25

In relevant part, these claims require that the upper and lower flexible walls of the package have an ionomer coating on an inside surface thereof. The pressure-rupturable seal of the claimed package comprises the ionomer.

The examiner does not point to any passage in GB'144 which describes the package of that reference having an ionomer coating on the inside surfaces of the upper and lower flexible walls as required by claim 19 on appeal.

Absent a fact-based explanation from the examiner as to specifically how GB'144 teaches or suggests the requirements of claim 19, especially those involving the presence of an ionomer coating on the inside surface of the upper and lower flexible walls of the package, the examiner has not satisfied his initial burden of establishing a prima facie case of unpatentability. Accordingly, we reverse the rejections of claims 19 through 25.

3. Claims 26-32

In relevant part, claim 26 requires that the flexible container have a first compartment having a wall form from a porous polymer sheet, which allows entry of a gas while the second compartment has walls formed from a plastic resin that provides a watertight closure. Again, the examiner has failed to point to any specific passage in GB'144, which describes this aspect of the subject matter set forth in claim 26 on appeal. Absent a fact-based explanation by the examiner why GB'144 teaches or suggests the specific requirements of claim 26 on appeal, we again find the examiner

has failed to establish his initial burden of providing reasons of unpatentability.

Accordingly, the rejection of claims 26-32 is reversed.

4. Claim 33

Claim 33 is similar to claim 26 in that the claimed package requires two compartments, one including a water-containing compartment formed from plastic film and a second compartment which comprises a porous flexible sheet adapted to admit a sterilizing gas through pores in the flexible sheet for sterilizing the contents. In other words, claim 33 requires that the claimed package be constructed of porous and non-porous materials in order to form the two compartments. Again, the examiner has not explained on the record how GB'144 teaches or suggests the specific package required by claim 33. Absent such an explanation from the examiner we do not find that he has adequately explained why claim 33 is unpatentable. The rejection of claim 33 is reversed.

OTHER ISSUES

1. Admitted prior art

As set forth above, the examiner belatedly referred to appellant's admission of prior art which appears on pages 7-7(a) of the specification. Specifically, appellant states at page 7(a) that the five-layer laminate useful in the present invention, which includes an inner coating of an ionomer, is commercially available from a packaging company.

Upon return of the application, appellant and the examiner should cooperate and make of record relevant prior art which documents this admission. It may be that the commercially available packaging material referred to by appellant in the specification

when view in combination with the teachings of GB'144 may suggest the subject matter of claim 19 on appeal. In this regard, appellant and examiner should note that claim 19 does not appear to require that separate portions of the flexible package be composed of porous and non-porous materials. Appellant and examiner should also take note that GB'144 appears to describe a two-compartment package which contains a dry wound dressing in one compartment (the Varidase (trade mark) material which is used in GB'144 is described at page 1 line 25 of the reference as being a "dry sterile powder") and the second compartment which contains water (second compartment can contain a water solution of a gel forming polymer, page 3 lines 28-29).

2. Obviousness-type double patenting

We make of record U.S. Patent 5,804,213 and U.S. Patent 6,406,712 which each list present inventor David Rolf as sole inventor. We note that in parent application 07/913,151, appellant filed a terminal disclaimer in response to an obviousness-type double patenting rejection by the examiner based in part upon the application, which subsequently issued as U.S. Patent 5,804,213. For reasons which are not clear from this record, when this application was filed neither the examiner nor appellant revisited this obviousness-type double patenting issue.

Upon return of the application, the examiner should take a step back and consider U. S. Patent 5,804,213 and U.S. Patent 6,406,712 and determine whether double patenting issues exist and, if so, take appropriate action. The examiner and appellant should work together and ensure that all related applications or patents have been made of record and are properly considered by the examiner.

The decision of the examiner is reversed.

REVERSED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

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