

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DONALD S. KAPLAN, MATTHEW E. HERMES,
ROSS R. MUTH, DAVID L. BROWN and HENRY A. HOLZWARTH

Appeal No. 1997-3712
Application 08/474,340

ON BRIEF

Before GARRIS, OWENS and SPIEGEL, *Administrative Patent Judges*.

OWENS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal from the examiner's final rejection of claims 81-100, which are all of the claims remaining in the application.

THE INVENTION

Appellants' claimed invention is directed toward packaging of synthetic absorbable sutures. Claim 81 is

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illustrative and reads as follows:

81. The combination of

a) a peelable substantially moisture-impervious pouch made of a metal foil laminate defining an enclosure which constitutes a sealed pocket and which is accessible by peeling;

b) a suture retainer disposed within said sealed pocket and sealed therewithin; and

c) a synthetic absorbable suture situated within said retainer.

THE REFERENCES

Granowitz et al. (Granowitz) 1968	3,376,973	Apr. 9,
Glick 1974	3,815,315	Jun. 11,
Miller et al. (Miller) 1976	3,939,969	Feb. 24,

THE REJECTIONS

Claims 81-100 stand rejected under 35 U.S.C. § 103 over Granowitz in view of appellants' admitted prior art, and also

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over Glick in view of Miller.^{1,2}

OPINION

We have carefully considered all of the arguments advanced by appellants and the examiner and agree with appellants that the aforementioned rejections are not well founded. Accordingly, we reverse these rejections. We need to address only the broadest claim, i.e., claim 81.

*Rejection over Granowitz in view of
appellants' admitted prior art*

Granowitz discloses a suture (32) wound around a reel (11) placed in a sealed inner envelope (34) which is enclosed in a strippable, i.e., peelable, outer envelope (36). Granowitz teaches (col. 4, lines 41-42) that the package can be of the type disclosed by Buccino (U.S. 2,949,181). Buccino's inner envelope is made of polyethylene or polyvinyl film and his outer envelope is made of polyester or other film

¹Obviousness-type double patenting rejections in the final rejection (pages 2-3) have been overcome by the filing of a terminal disclaimer (communication from the examiner filed June 27, 1997, paper no. 18).

²Appellants and the examiner should address whether there is sufficiently clear antecedent basis for "said sealed pocket" in claim 88.

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forming polymer such as polymers of polyhydric alcohols and polycarboxylic acids (col. 1, lines 49-51 and col. 1, line 63 - col. 2, line 11). Granowitz's suture can be either natural catgut or regenerated collagen, packed in a conditioning liquid in the inner envelope (col. 1, lines 46-50; col. 4, lines 36-38). Such a suture is designated as being absorbable (col. 1, line 50). The suture also can be a natural fiber or a synthetic fiber such as nylon, polyester, isotactic polypropylene or linear polyethylene (col. 1, lines 50-56). A synthetic fiber suture is packed dry in the inner envelope (col. 1, lines 50-52).

The acknowledged prior art relied upon by the examiner is the disclosure that 1) synthetic absorbable sutures typically are packaged in moisture impervious foil laminate envelopes with the suture wound in a figure 8 pattern on a paper card retainer (specification, page 5), 2) molded suture packages having convoluted passageways were known (specification, page 6), and 3) tearable foil laminate envelopes were conventional (specification, page 27) (final rejection, pages 3-4; answer, page 8).

The examiner argues that it would have been obvious to

one of ordinary skill in the art to use a metal foil laminate pouch in Granowitz's package because such a pouch is conventional, and to make the pouch peelable if difficulty of opening the pouch is of concern (final rejection, page 4).

Appellants argue, in reliance upon the Kaplan declaration,³ that the prior art relied upon by the examiner would not have been interpreted by one of ordinary skill in the art as teaching that a peelable metal foil laminate pouch can be used for packaging an absorbable suture (brief, pages 15-17).

Kaplan argues that in the prior art, absorbable sutures placed in foil laminates could be opened only by tearing because they had weld seals produced by plastic flow (page 5). The reason why the weld seals were used, Kaplan argues, is that the thinnest heat seal possible and minimal linear seal length were desired to minimize the permeation of moisture into the package which would degrade the sutures (pages 4 and 11). Kaplan argues that appellants' peel-open package

³The Kaplan declaration was filed in parent application no. 07/911,981 and included in the present application with the preliminary amendment filed June 7, 1995, paper no. 3.

includes an adhesive layer between the thermoplastic layers to permit the package to be peeled open, and that this adhesive layer increases the thickness of the seal and the linear distance of the seal (pages 11-12). Because both of these features would increase the potential for moisture absorption through the package, Kaplan argues, one of ordinary skill in the art would not have interpreted the applied prior art as teaching that such a package is suitable for packaging absorbable sutures.⁴ See *id.*

The examiner merely argues, without explanation, that the Kaplan declaration, when considered with appellants' arguments, does not overcome the evidence of obviousness (answer, page 11).⁵

⁴Appellants disclose that because their synthetic absorbable suture is filled with a stabilizing agent, it need not be packaged under the extremely dry conditions required by prior art packaged synthetic absorbable sutures (brief, pages 8-9).

⁵Appellants' claims do not require any duration of storage of the absorbable suture in the package. The examiner, however, has not established that one of ordinary skill in the art would have been led by the applied references to package an absorbable suture in a peelable envelope for a storage period which is sufficiently short that the moisture permeation discussed by Kaplan would be acceptable.

Appellants have presented credible evidence in the form of the Kaplan declaration that one of ordinary skill in the art would not have interpreted the prior art relied upon by the examiner as indicating that a peelable metal foil laminate pouch is suitable for packaging an absorbable suture, and the examiner has presented no evidence or technical reasoning to the contrary. On this record, therefore, we conclude that the examiner has not established a *prima facie* case of obviousness of appellants' claimed invention over Granowitz in view of appellants' admitted prior art. Consequently, the rejection over this prior art is reversed.

Rejection over Glick in view of Miller

Glick discloses an air-tight sealed envelope which is substantially impervious to water vapor, may be made of a laminate film having a metallic foil layer, and contains a dry absorbable synthetic suture (abstract). A strippable outer envelope, which can be made of various plastic, paper and metallic foil materials such as those of Buccino, can be formed around the water-impervious sealed envelope (col. 10,

lines 38-49).⁶ Glick teaches that an inner envelope traditionally used to hold tubing fluid is not needed a dry suture is packaged (col. 16, lines 15-18), but indicates that if a single envelope is used to package the suture, it is to be a moistureproof envelope (col. 15, lines 6-8 and 49-51; col. 16, lines 5-7). Glick's moistureproof envelope is a sealed laminate which is not disclosed as being strippable (abstract; col. 7, lines 41-53; col. 9, lines 4-24).

Miller discloses a "package for sutures in which an inner suture retainer is intimately connected to the sealed outer envelope so that when the outer envelope is opened, the suture end in the inner retainer is exposed for immediate pick-up" (abstract). "The pulling force exerted when the envelope is opened may occur both in envelopes which are opened by tearing and in envelopes which are opened by stripping" (col. 1, lines 54-57). The sealed outer envelope preferably is made of

⁶As discussed regarding the rejection over Granowitz in view of appellants' admitted prior art, the materials disclosed by Buccino are a polyethylene or polyvinyl film as the inner layer and, as the outer layer a film of a polyester or other film forming polymer such as polymers of polyhydric alcohols and polycarboxylic acids (col. 1, lines 49-51 and col. 1, line 63 - col. 2, line 11).

laminated plastic-aluminum foil (col. 3, lines 24-26). The sutures "may be natural or synthetic in origin and be absorbable or non-absorbable" (col. 8, lines 11-12).

The examiner argues that Glick discloses most of the elements of the claims but does not disclose that the inner pouch is peelable, and that the teaching by Miller of using either a tearable or peelable pouch to hold a suture retainer would have rendered obvious, to one of ordinary skill in the art, making Glick's inner foil laminate pouch peelable to facilitate ease of use (final rejection, page 4). The examiner argues that Glick's teaching (col. 16, lines 5-9) that the suture and retainer could be in a single strippable envelope⁷ directly undercuts appellants' argument that where there are double envelopes, the art would not have recognized that the inner one could be strippable (answer, page 10).⁸

⁷The disclosure relied upon by the examiner does not state that the single envelope is strippable.

⁸ The examiner argues as though the limitations of appellants' claim 81 are not met unless Glick's inner envelope is strippable. Claim 81, however, is open to a peelable, substantially moisture-impervious outer pouch which contains therein a sealed inner envelope having therein a retainer with a synthetic absorbable suture within it. The sealed pocket in the pouch would be accessible by peeling, and the retainer

When a determination is made whether references would have fairly suggested a claimed invention to one of ordinary skill in the art, the references necessarily must be interpreted as they would have been understood by one of ordinary skill in the art. Appellants rely upon the declaration of Kaplan as evidence of how one of ordinary skill in the art would have interpreted Miller and U.S. 3,728,938 to Glick, of which the Glick patent applied by the examiner is a continuation (brief, pages 12-16).

Kaplan argues that one of ordinary skill in the art reading Miller would have understood that synthetic absorbable sutures could be packaged only in tear-open packages due to the extreme moisture sensitivity of those sutures (page 14).

within the inner sealed envelope would be disposed within the sealed pocket. The examiner has not established, however, that the applied references would have fairly suggested, to one of ordinary skill in the art, using as Glick's outer envelope a peelable, substantially moisture impervious pouch made of a metal foil laminate as recited in appellants' claim 81. Glick discloses (col. 10, lines 43-48) that various plastic, paper and metallic foil materials are suitable for use as the outer strippable envelope, particularly the plastic films of Buccino, but the examiner has not explained why this disclosure would have fairly suggested, to one of ordinary skill in the art, use of a metal foil laminate such that the pouch formed is substantially moisture impervious.

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The strippable packages disclosed by Miller, Kaplan argues, would have been considered by one of ordinary skill in the art to be suitable only for other types of sutures. *See id.* Similarly, Kaplan argues that the Glick patents would have been interpreted by one of ordinary skill in the art as requiring a tear-open package for packaging a synthetic absorbable suture to minimize moisture permeation into the package (page 11).

Kaplan has presented plausible reasoning as to why one of ordinary skill in the art would not have interpreted the applied prior art in the manner proposed by the examiner. The examiner provides no evidence or technical reasoning to the contrary but, rather, merely states that the declaration and appellants' arguments do not overcome the evidence of obviousness (answer, page 11). Accordingly, on this record, we conclude that the examiner has not established that, *prima facie*, the combined teachings of Glick and Miller would have fairly suggested appellants' claimed invention to one of ordinary skill in the art. We therefore reverse the rejection over these references.

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DECISION

The rejections of claims 81-100 under 35 U.S.C. § 103 over Granowitz in view of appellants' admitted prior art, and over Glick in view of Miller, are reversed.

REVERSED

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BRADLEY R. GARRIS)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
TERRY J. OWENS))
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
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CAROL A. SPIEGEL)	
Administrative Patent Judge)	

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