

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte SIDNEY T. SMITH, DAVID V. BACEHOWSKI,  
WILLIAM KOLANKO, LARRY A. ROSENBAUM,  
STEPHEN L. SMITH, JAMES G. BENDER,  
LECON WOO and MICHAEL T.K. LING

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Appeal No. 1998-1382  
Application No. 08/330,717

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ON BRIEF

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Before JOHN D. SMITH, LIEBERMAN, and DELMENDO, Administrative Patent Judges.

DELMENDO, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 through 4, 6 through 8, 11 through 22, 25 through 27, 30 through 42, and 45.<sup>1</sup> Claims 9, 10, 28, 29, 43, and 44, which are the only

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<sup>1</sup> In response to the final Office action, the appellants filed a response on November 25, 1996, in which amendments to claims 1, 21, and 34 were proposed. (Paper 13.) The examiner

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other claims pending in the application, are indicated as allowable if rewritten in independent form.<sup>2</sup> (Final Office action, page 10; advisory action; appeal brief, page 3.)

Claims 1, 21, 32, 34, 36, and 38, which are all the independent claims, are reproduced below:

1. A multi-layer, flexible, gas-permeable film suitable for forming a cell culture container, the film comprising:

a first layer composed of a polystyrene having a thickness within the range of 0.0001 inches to about 0.0010 inches, the first layer defining an inner cell growth surface; and,

a second outer layer adhered to the first layer composed of a polymer alloy blend having multiple components, the second layer having a thickness within the range of 0.004 inches to about 0.015 inches.

21. A multi-layer, flexible, gas-permeable film suitable for forming a cell culture container, the film comprising:

a first layer composed of a polystyrene having a thickness within the range of 0.0001 inches to about 0.0010 inches, the first layer defining a cell growth surface;

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indicated in an advisory action mailed December 19, 1996 that these amendments will be entered upon the filing of a notice of appeal and appeal brief. (Paper 14.)

<sup>2</sup> Contrary to the appellants' statement regarding the claims on appeal (appeal brief, page 3), our jurisdiction under 35 U.S.C. § 134 is limited to rejections of claims. Accordingly, claims 9, 10, 28, 29, 43, and 44 are not involved in this appeal.

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a second layer adhered to the first layer composed of a polymer alloy blend having multiple components; and,

wherein the film having physical properties within the range:

a > 10,000 but < 30,000

b > 9 but < 15

c > 40 but < 80

d > 10 but < 100

e < 20

wherein:

a is the flexural modulus in psi of the film measured according to ASTM D-790;

b is the oxygen permeability in Barrers;

c is the carbon dioxide permeability in Barrers;

d is the nitrogen permeability in Barrers; and

e is the water vapor transmission rate in (g mil/100 in<sup>2</sup>/day).

32. A flexible, gas-permeable cell culture container suitable for culturing cells, the container comprising:

a first and second side wall each having edges, the first and second side walls being sealed together at their respective side wall edges to provide a containment area, wherein at least the first side wall is composed of a first layer of polystyrene having a thickness within the range of 0.0001 inches to about 0.0010 inches the first layer facing an interior of the container to define a cell growth surface, and, a second layer adhered to the first layer of a polyolefin, the second layer having a thickness within the range of 0.004 inches to about 0.015 inches.

34. A method for fabricating a multi-layered film suitable for forming a container for culturing cells comprising the steps of:

providing a polystyrene cell growth surface;

providing a polymer alloy blend having multiple components; and,

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coextruding the polystyrene and the polymer alloy blend producing a layered film having a gas permeability to promote cell growth.

36. A flexible, gas-permeable cell culture container suitable for culturing cells, the container comprising:

a first side wall of the container being suitable for growing adherent cells, the first side wall comprises a first layer of polystyrene having a thickness within the range of 0.0001 inches to about 0.0010 inches, and, a second layer adhered to the first layer of a polymer alloy having multiple components, the second layer having a thickness within the range of 0.004 inches to about 0.015 inches;

a second side wall attached to the first side wall for growing non-adherent cells; and,

means associated with the container for distinguishing the first side wall from the second side wall.

38. A method for culturing cells comprising the steps of:

providing a flexible cell culture container having at least one side wall of a film having a first layer of a polystyrene having a thickness from 0.0001 inches to about 0.0010 inches, and a second layer adhered to the first layer of a polymeric material having a thickness from 0.004 inches to about 0.015 inches, the first layer faces an interior of the container to provide a cell growth surface;

adding to the container a cell growth medium;  
and

seeding the container with cells to be grown.

The subject matter on appeal relates to (i) a multi-layer, flexible, gas-permeable film suitable for forming a

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cell culture container (claims 1 and 21), (ii) a flexible, gas-permeable cell culture container (claims 32 and 36), (iii) a method for fabricating a multi-layered film suitable for forming a container for culturing cells (claim 34), and (iv) a method for culturing cells (claim 38). The film comprises a first layer composed of a polystyrene and a second outer layer adhered to the first layer and composed of a polymer alloy blend (claims 1, 21, 34, and 36), a polyolefin (claim 32) or a polymeric material (claim 38), with the first and second outer layers having the recited thicknesses. According to the appellants, the present invention provides a layer of polystyrene as part of a layered film without rendering the film too stiff to fabricate a flexible container and too impermeable to allow the passage of certain gases necessary to sustain cell growth in an unvented, flexible container.

(Appeal brief, pages 4-5.)

The examiner relies upon the following prior art references as evidence of unpatentability:

Erb 1971	3,589,976	Jun. 29,
Stanley et al. 11, 1972	3,655,503	Apr.

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(Stanley)

Bonis 1984	4,440,824	Apr. 3,
Keilman et al. 5, 1988 (Keilman)	4,717,668	Jan.
Bacehowski et al. 1990 (Bacehowski)	4,939,151	Jul. 3,
Akazawa (Sumitomo) (published JP patent application)	59-83651	May 15, 1984

Appealed claims 1 through 4, 6 through 8, 11, 12, 20 through 22, 25 through 27, 30 through 42, and 45 stand rejected under 35 U.S.C. § 103 as unpatentable over Keilman in view of Erb, Sumitomo,<sup>3</sup> and Bacehowski. (Examiner's answer, pp. 4-6.) Additionally, appealed claims 11 through 14 and 45 stand rejected under 35 U.S.C. § 103 as unpatentable over Keilman in view of Erb, Sumitomo, Bacehowski, and Bonis. (Id. at pp. 6-7.) Further, appealed claims 15 through 19 stand rejected under 35 U.S.C. § 103 as unpatentable over Keilman in

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<sup>3</sup> In our decision, we refer to the English language translation of Sumitomo as provided by the USPTO. (Reply brief, pp. 2-3.)

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view of Erb, Sumitomo, Bacehowski, and Stanley. (Id. at pp. 7-8.)

We reverse the aforementioned rejections.

Keilman, the principal prior art reference, teaches that various means for venting of a conventional culture bottle generally provide a source of contamination of the culture. (Column 1, lines 15-17.) As a solution to this problem, Keilman describes a potentially disposable plastic roller bottle, which does not require a mechanical vent to provide high enough levels of oxygen and carbon dioxide transfer into and out of the container for aerobic culturing processes. (Column 1, lines 32-47.) According to Keilman, the bottle has flexible plastic walls, which may be made of a plastic formulation, preferably a polymer blend. (Column 1, lines 50-53; column 2, lines 4-5 and 25-44.)

The examiner appears to admit that Keilman does not teach the multi-layer film as recited in the appealed claims. (Examiner's answer, page 4.) To account for this difference, the examiner relies on the teachings of Erb, Sumitomo, and Bacehowski. (Id. at pages 4-6.)

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Notwithstanding the examiner's arguments, we cannot agree with the examiner that Erb, Sumitomo, and Bacehowski, either individually or in combination, would have led one of ordinary skill in the art to modify Keilman in the manner as suggested on page 5 of the answer. Specifically, Erb teaches composite films of coextruded polystyrene and polyolefins, which are said to exhibit a favorable balance of the stiffness of polystyrene and other tensile properties of polyolefins. (Column 1, lines 12-14.) Erb further teaches that the films "find their greatest utility" as wrapping and packaging materials, that thinner films are used in flexible packaging such as plastic bags, and that thicker films are used in thermoforming applications to form rigid packages such as butter tubs, ice cream cartons, and freezer packs. (Column 2, lines 63-72.) No mention is made in Erb of using the film as part of a cell culture container as in Keilman. Nor does Erb teach or suggest that the film possesses the sufficient oxygen and carbon dioxide permeabilities required for use in Keilman's cell culture container to sustain the growth of cells without the use of a mechanical vent.

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Sumitomo does teach a packing film consisting of a layer (A) of polystyrene resin, polyethylene phthalate resin, or vinyl chloride resin, an adhesive layer (B) of ethylene-vinyl acetate copolymer, denatured polyolefin, styrene-butadiene copolymer, or a mixture of these polymers, and a polyolefin resin layer (C). (Page 2.) Further, Sumitomo teaches that the polyolefin resin layer (C) may be made of a mixture of two or more of polyethylene, polypropylene, ethylene-propylene copolymer, and ionomer. (Page 6.) According to Sumitomo, the film may be used for packaging drugs. (Pages 2-3.) Like Erb, however, Sumitomo does not teach that the film can be used as part of a cell culture container. Although Sumitomo states that the film has "excellent gas permeability" (page 3), the reference does not provide any indication as to any specific oxygen and carbon dioxide permeability properties for the film such that one of ordinary skill in the art would have considered using it for Keilman's purpose, i.e., to sustain cell growth without the use of a mechanical vent. (Reply brief, page 4.) Thus, there is no evidence in the record to indicate that Sumitomo's film would be suitable for Keilman's purpose.

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The examiner has cited Bacehowski for describing what is already admitted by the appellants as prior art on page 2 of the present specification, namely a cell culture flask made of polystyrene. (Examiner's answer, page 5.) Similarly, Bonis and Stanley have been applied for the use of a tie layer and skin layer, respectively. (Id. at pp. 6-8.) However, none of these prior art references remedy what is fundamentally lacking in Erb and Sumitomo. In particular, there is no teaching or suggestion in these references that the multi-layer film of Erb or Sumitomo would possess the properties required for Keilman's purpose.

Absent the benefit of the appellants' specification as a template, we determine that there is no teaching, suggestion, or motivation to combine the prior art references in the manner as proposed by the examiner. In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985).

For these reasons and those expressed in the appellants' briefs, we hold that the examiner has failed to establish a prima facie case of obviousness as to appealed independent

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claims 1, 21, 32, 34, 36, and 38. In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984).

Since the remaining appealed claims all directly or indirectly depend from these independent claims, it follows that these dependent claims would also not have been prima facie obvious to one of ordinary skill in the art. In re Fine, 837 F.2d 1071, 1076, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

In summary, we reverse the examiner's § 103 rejections of (i) appealed claims 1 through 4, 6 through 8, 11, 12, 20 through 22, 25 through 27, 30 through 42, and 45 as unpatentable over Keilman in view of Erb, Sumitomo, and Bacehowski, (ii) appealed claims 11 through 14 and 45 as unpatentable over Keilman in view of Erb, Sumitomo, Bacehowski, and Bonis, and (iii) appealed claims 15 through 19 as unpatentable over Keilman in view of Erb, Sumitomo, Bacehowski, and Stanley.

The decision of the examiner is reversed.

REVERSED

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JOHN D. SMITH	)	
Administrative Patent Judge	)	
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	)	BOARD OF PATENT
PAUL LIEBERMAN	)	APPEALS
Administrative Patent Judge	)	AND
	)	INTERFERENCES
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ROMULO H. DELMENDO	)	
Administrative Patent Judge	)	

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