

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. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DUDLEY W. C. SPENCER

Appeal No. 2000-0605
Application No. 08/803,779

ON BRIEF

Before McQUADE, BAHR and LAZARUS, Administrative Patent Judges.
BAHR, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 2, 7-10 and 13-17.¹ Claims 3-6, the only other claims pending in the application, stand withdrawn from further consideration under 37 CFR § 1.142(b) as being directed to a non-elected invention.

¹ The amendment filed April 28, 1999 (Paper No. 9) after the final rejection has not been entered (see Paper No. 10).

Appeal No. 2000-0605
Application No. 08/803,779

BACKGROUND

The appellant's invention relates to a container for use in medical applications where a medical fluid is transferred through tubing communicating with the container. Claim 13 is illustrative of the invention and is reproduced in the appendix to appellant's brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Hillier et al. (Hillier) 1977	4,048,254	Sep. 13,
Kobayashi et al. (Kobayashi) 1987	4,670,510	Jun. 2,
Mueller et al. (Mueller) 1989	4,816,343	Mar. 28,

The following rejections are before us for review.

(1) Claims 2, 7-10 and 13-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hillier in view of Kobayashi.

(2) Claims 2, 7-10 and 13-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kobayashi in view of Mueller.

Reference is made to the brief and reply brief (Paper Nos. 13 and 15) and the answer (Paper No. 14) for the

Appeal No. 2000-0605
Application No. 08/803,779

respective positions of the appellant and the examiner with regard to the merits of these rejections.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. For the reasons which follow, we cannot sustain the examiner's rejections.

The prior art

Hillier discloses thermoplastic polymers comprising nonvulcanized radial block copolymers of the diene-aryl substituted olefin butadiene-styrene type blended with other polymeric or copolymeric materials, such as polyesters, polyester urethane polymers and polyether urethane polymers, to form plastic compositions which have sufficient clarity, hardness, tensile strength and elongation to be readily adaptable for use in composing plastic materials for contact with parenteral fluids. Hillier teaches that the disclosed compositions have such a high degree of clarity that they can replace polyvinylchloride (PVC) as a material in the forming

Appeal No. 2000-0605
Application No. 08/803,779

of medical plastic products such as tubing, drip chambers, injection reseal devices and other parenteral administration equipment. Additionally, Hillier intimates that the disclosed composition will have low alkaline extraction values so that ingredients in the composition are not extracted into the fluids to be administered. See col. 1, lines 7-42.

Kobayashi discloses a polyester type copolymer composition comprising a polyester ether mixed with a copolymer of ethylene with methacrylic acid neutralized with a metallic ion to a methacrylate salt (col. 1, lines 33-40; col. 3, lines 22-43). The resulting composition has greatly improved moldability, mechanical characteristics (strength, elongation and frictional characteristics), heat resistance and transparency (col. 5, lines 1-13). Consequently, according to Kobayashi, the composition can be used for various utilities, such as injection moldings, blow moldings and extrusion moldings useful as parts of various machines (e.g., name plates, automobile parts, switches, holders, hooks, packings, etc.), coatings and the like (col. 5, lines 14-19).

Appeal No. 2000-0605
Application No. 08/803,779

Mueller discloses a multi-layer flexible film for use as a replacement for PVC in forming pouches to supply liquids such as medical solutions for parenteral administration. These pouches should be collapsible, transparent, strong and capable of resisting high temperatures required for heat sterilization of their contents. The film comprises a sealant layer of an ethylene propylene copolymer or modified ethylene propylene copolymer, a core layer of a very low density polyethylene and an outer layer of a flexible polyester or copolyester (copolymer of polyether and polyethylene terephthalate; a poly-ether-ester). Mueller discloses blending a high molecular weight stabilizer such as Irganox™ 1010 available from Ciba-Geigy Corporation into the polyester or copolyester outer layer prior to extrusion of the film to limit the migration of extractables from the outer layer into a medical solution contained in the pouch (col. 3, lines 52-61).

Rejection (1)

Claim 13, the sole independent claim on appeal, recites a container for use in an assembly adapted for transferring medical fluid, wherein the container is made from a

Appeal No. 2000-0605
Application No. 08/803,779

composition consisting essentially of an ionomeric modified poly-ether-ester material containing from 1% to 50% by weight ionomer, said poly-ether-ester being a block copolymer containing both polyether and ester blocks modified by an ionomer, said ionomer being a copolymer of ethylene with a 1-10% by weight methacrylic acid converted to methacrylate salt.

The examiner concedes that the composition disclosed by Hillier is not the composition recited in independent claim 13. However, the examiner takes the position that it would have been obvious to one of ordinary skill in the art at the time of appellant's invention to use the improved polyester type copolymer composition taught by Kobayashi in the polyester medical containers and devices disclosed in Hillier in order to provide containers and devices with improved moldability, mechanical properties and transparency (answer, pages 3-4).

The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art. See In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991) and In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Indeed, a prima

Appeal No. 2000-0605
Application No. 08/803,779

facie case of obviousness is established where the reference teachings would appear to be sufficient for one of ordinary skill in the art having those teachings before him to make the proposed combination or modification. See In re Lintner, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

In establishing a prima facie case of obviousness, it is incumbent upon the examiner to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. See Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellant's disclosure. See, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988).

We recognize that Kobayashi teaches that the polyester type block copolymer composition disclosed therein possesses several desirable characteristics, such as improved moldability, mechanical characteristics (strength, elongation

Appeal No. 2000-0605
Application No. 08/803,779

and frictional characteristics), and transparency, which are also recognized by Hillier as desirable for materials for medical products used in administration of medical fluids. We also appreciate that the composition taught by Hillier may include polyesters, polyether or polyester urethane polymers, or mixtures thereof, in substantial amounts. However, viewing the teachings of Hillier and Kobayashi as a whole, as we are obliged to do, we fail to perceive any teaching, suggestion or incentive therein which would have motivated an artisan to substitute the composition taught by Kobayashi for the composition taught by Hillier in making medical products for administration of parenteral fluids. In particular, we note that the applications taught by Kobayashi for the disclosed composition are quite divergent from the medical applications taught by Hillier and that Kobayashi in no way teaches or suggests that the composition disclosed therein is suitable as a substitute for PVC or for making medical products of any kind.² From our perspective, the only suggestion for putting

² We note in this regard that the examiner's statement (answer, page 5) that the material disclosed by Kobayashi is already well known in the medical field is not supported by evidence. In making an obviousness rejection, the examiner has the initial duty of supplying the requisite factual basis and may

(continued...)

Appeal No. 2000-0605
Application No. 08/803,779

the selected pieces from the references together in the manner proposed by the examiner is found in the luxury of hindsight accorded one who first viewed the appellant's disclosure. This, of course, is not a proper basis for a rejection. See In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

Accordingly, we shall not sustain the examiner's rejection of independent claim 13, or of claims 2, 7-10 and 14-17 which depend from claim 13, as being unpatentable over Hillier in view of Kobayashi.

Rejection (2)

In making this rejection, the examiner implicitly concedes that Kobayashi does not teach or suggest the use of the disclosed composition for use in containers of the type recited in claim 13. The examiner, however, finds suggestion, in the teaching by Mueller of blending a high molecular weight stabilizer into the copolyester outer layer of a multi-layer

²(...continued)
not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 177-78 (CCPA 1967).

Appeal No. 2000-0605
Application No. 08/803,779

film pouch for containing medical fluids to limit the migration of extractables from the outer layer, to (1) add a high molecular weight stabilizer to the Kobayashi composition to limit the extractables and (2) use the modified Kobayashi composition to construct medical containers of the type discussed by Mueller (answer, page 4). We find no such suggestion.

In particular, we see no teaching or suggestion in either Kobayashi or Mueller to use the particular composition taught by Kobayashi in a container or pouch for administration of medical fluids. Likewise, in the absence of any teaching or suggestion to use the Kobayashi composition in an environment where migration of extractables is a problem, it is not apparent to us why one of ordinary skill in the art would have been motivated to blend a high molecular weight stabilizer in the Kobayashi composition.

In light of the above, we also shall not sustain the examiner's rejection of claim 13, or of claims 2, 7-10 and 14-17 which depend from claim 13, as being unpatentable over Kobayashi in view of Mueller.

Appeal No. 2000-0605
Application No. 08/803,779

We note appellant's reference on page 13 of the brief to the Spencer declaration (Paper No. 7) filed December 11, 1998. However, as we have determined, supra, that, with regard to both rejection (1) and rejection (2), the applied references are not sufficient to establish a prima facie case of obviousness of the claimed subject matter, it is not necessary for us to discuss the Spencer declaration herein.

CONCLUSION

To summarize, the decision of the examiner to reject claims 2, 7-10 and 13-17 under 35 U.S.C. § 103(a) is reversed.

REVERSED

JOHN P. McQUADE)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
JENNIFER D. BAHR)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
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Appeal No. 2000-0605
Application No. 08/803,779

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