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The opinion in support of the decision being entered today  
(1) was not written for publication in a law journal and  
(2) is not binding precedent of the Board.

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* ARTHUR L. VELLUTATO  
and

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Appeal No. 1996-1801  
Application 08/142,049<sup>1</sup>

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HEARD: December 9, 1999

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Before JOHN D. SMITH, WARREN and LIEBERMAN, *Administrative Patent Judges*.

WARREN, *Administrative Patent Judge*.

*Decision on Appeal*

This is an appeal under 35 U.S.C. § 134 from the decision of the examiner refusing to allow claims 1,4, 5, 8, 9, 13 through 17 and 19. Claim 1 is illustrative of the claims on appeal:

1. A method of sterilization comprising the steps of:
  - (a) providing a chemical composition to be sterilized;
  - (b) filtering particulates from said chemical composition;
  - (c) charging a container with said chemical composition, said step of charging said container

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<sup>1</sup> Application for patent filed October 28, 1993.

including the step of pressurizing an internal volume of said container and hermetically sealing said container with a closure;

(d) encasing said container within a first sealing layer forming a single layer hermetically sealed container enclosure;

(e) encasing said single layer hermetically sealed container enclosure within a second sealing layer forming a second layer hermetically sealed container enclosure;

(f) inserting said second layer sealed container enclosure into a carton member lined with a third sealing layer, tying one end section of said third sealing layer to form a closed interior volume therein, and closing said carton member to form a closed shipping package; and,

(g) externally irradiating said closed shipping package at a predetermined radiation level for a predetermined time interval for combinedly and simultaneously sterilizing said chemical composition, said first and second hermetically sealed container enclosures and said closed interior volume defined by said third sealing layer.

The appealed claims as represented by claim 1<sup>2</sup> are drawn to a method of sterilization in which a container containing a chemical composition under pressure is successively hermetically enclosed within two enclosures to form a multi-enclosure package that is inserted into the liner of a carton, which liner is closed to form a third enclosure. The carton is closed to form a shipping package which is externally irradiated at a predetermined level to sterilize each of the enclosures and the chemical composition contained therein. According to appellant, the method provides, *inter alia*, “a carton containing sterilized containers may be shipped to a relatively contaminated area and removed to a relatively contamination free area while still maintaining a double hermetic seal around the sterilized containers” (specification page 2; see also, e.g., pages 7-8).

The references relied on by the examiner are:

Pomerantz et al. (Pomerantz)	2,904,392	Sep. 15, 1959
Falciani et al. (Falciani)	4,700,838	Oct. 20, 1987
Anthony et al. (Anthony)	4,714,595	Dec. 22, 1987
Anderson	4,896,768	Jan. 30, 1990
Bacehowski et al. (Bacehowski)	4,968,624	Nov. 6, 1990

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<sup>2</sup> Appellant states in the brief (page 6) that the appealed claims “define a single group rejected under § 103.” Thus, we decide this appeal based on appealed claims 1 and 14 with respect to the respective grounds of rejection under 35 U.S.C. § 103 advanced by the examiner on appeal. 37 CFR § 1.192(c)(7) (1995).

The examiner has rejected appealed claims 1, 4, 5, 8, 9, 13, 16, 17 and 19 under 35 U.S.C. § 103 as being unpatentable over Falciani in view of Anthony and Bacehowski. The examiner has also rejected appealed claims 14 and 15 under 35 U.S.C. § 103 as being unpatentable over Falciani in view of Anthony and Bacehowski as applied to claim 13, and further in view of Pomerantz and Anderson. We affirm.

Rather than reiterate the respective positions advanced by the examiner and appellant, we refer to the examiner's answer and to appellant's brief for a complete exposition thereof.

*Opinion*

We have carefully reviewed the record on this appeal and based thereon find ourselves in agreement with the examiner that the claimed sterilization method encompassed by appealed claim 1 would have been obvious over the combined teachings of Falciani, Anthony and Bacehowski, and that the claimed sterilization method encompassed by appealed claim 14 would have been obvious over the combined teachings of Falciani, Anthony, Bacehowski, Pomerantz and Anderson, to one of ordinary skill in this art at the time the claimed invention was made. We agree with the position advanced on appeal by the examiner, including the response to appellant's arguments in the brief, adding the following for emphasis.

We find from the combined teachings of Falciani, Anthony and Bacehowski that it was known in the art to employ a multi-enclosure package, which can be inserted into a shipping package, to maintain the sterility of various biological materials under various levels of contamination, wherein the various enclosures surrounding such materials can be peeled away as necessary to maintain the desired level of sterilization of the surface of the presented outer enclosure of the package in the area in which the package is to be placed. See, e.g., Bacehowski, col. 7, lines 17-33. Each of Falciani, Anthony and Bacehowski utilize gamma radiation to sterilize a multi-enclosure package, with only Bacehowski performing the sterilization step prior to filling the multi-layer container **10** with a biological solution (col. 6, lines 46-49). In Falciani, the pharmaceutical product was sterilized via "ã-rays" "*in bag 1*" which was hermetically sealed (col. 2, lines 41-44; emphasis supplied), prior to insertion of "*bag 1*" into further hermetically sealed enclosures and encasing the resulting multi-enclosure package for shipping

(e.g., col. 3, lines 17-21). In Anthony, the biological tissue was successively hermetically enclosed by at least two enclosures to form a multi-enclosure package, which package and all of the contents thereof were then sterilized by radiation (e.g., col. 2, lines 29-32; col. 3, lines 55-57; col. 5, lines 27-32; and col. 8, lines 13-19).

Based on the objective evidence in the combined teachings of Falciani, Anthony and Bacehowski, we find that one of ordinary skill in this art would have recognized that irradiation of enclosed biological material with gamma radiation, including material surrounded by multi-enclosures, as well as the irradiation of a multi-enclosure package prior to insertion of the biological material, is a result effective step in a sterilization method comprising preparing, enclosing, transporting and storing sterilized biological material, which irradiation step can be performed at various points in the process.<sup>3</sup>

Accordingly, we find that, *prima facie*, one of ordinary skill in this art would have been motivated to irradiate the final package containing the biological material with gamma radiation, whether that package was for storage or for shipping, with the reasonable expectation of sterilizing each of the enclosures constituting the package and the biological material contained therein in order to obtain the desired level of sterilization to meet the conditions that the final package would encounter. Thus, *prima facie*, one of ordinary skill in this art following the combined teachings of Falciani, Anthony and Bacehowski would have arrived at the claimed method encompassed by appealed claim 1. *In re Gorman*, 933 F.2d 982, 986-87, 18 USPQ2d 1885, 1888-89 (Fed. Cir. 1991) (“The extent to which such suggestion [to select elements of various teachings in order to form the claimed invention] must be explicit in, or may be fairly inferred from, the references, is decided on the facts of each case, in light of

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<sup>3</sup> It is axiomatic that in evaluating the teachings of a reference, we must consider the specific teachings thereof and the inferences one of ordinary skill in this art would have reasonably been expected to draw therefrom. *In re Fritch*, 972 F.2d 1260, 1264-65, 23 USPQ2d 1780, 1782-83 (Fed. Cir. 1992); *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). Thus, the definition of a term or the meaning of a phrase in a reference must be construed within the context of the reference as interpreted by one of ordinary skill in this art. *See In re Salem*, 553 F.2d 676, 682-83, 193 USPQ 513, 518 (CCPA 1977). In evaluating the relevance of the various teachings of the reference, we must presume skill on the part of those of ordinary skill in this art. *See In re Sovish*, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985).

the prior art and its relationship to the applicant's invention."); *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981)("The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.").

We reach the same result with respect to the ground of rejection of appealed claim 14, which rejection is principally founded on the same combination of references.

Accordingly, since the examiner has established a *prima facie* case of obviousness, we have again evaluated all of the evidence of obviousness and nonobviousness based on the record as a whole, giving due consideration to the weight of appellant's arguments. *See generally In re Johnson*, 747 F.2d 1456, 1460, 223 USPQ 1260, 1263 (Fed. Cir. 1984); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984).

We have carefully considered all of appellant's arguments in the brief and agree with the examiner's response thereto set forth in the answer. As pointed out by the examiner, and as we have set forth above, it is the combined teachings of the references, and not appellant's disclosure, which provides the objective evidence that one of ordinary skill in this art would have been motivated to irradiate the final package containing the biological material with the reasonable expectation of obtaining the desired level of sterilization. *Gorman, supra; Keller, supra; compare generally, Fritch*, 972 F.2d at 1265-66, 23 USPQ2d at 1783-84. We fail to find in the record any evidence that the claimed method of sterilization provides a new or unexpected result.

Accordingly, based on our consideration of the totality of the record before us, we have weighed the evidence of obviousness found in the combined teachings of Falciani, Anthony and Bacehowski, with respect to appealed claims 1, 4, 5, 8, 9, 13, 16, 17 and 19, and the combined teachings of Falciani, Anthony, Bacehowski, Pomerantz and Anderson, with respect to appealed claims 14 and 15, with appellant's countervailing evidence of and argument for nonobviousness and conclude that the claimed invention encompassed by appealed claims 1,4, 5, 8, 9, 13 through 17 and 19 would have been obvious



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