

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte FLOYD S. SMITH and MARK E. CRIM

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Appeal No. 1996-3860  
Application 08/312,819

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ON BRIEF

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Before DOWNEY, WILLIAM F. SMITH and ELLIS, Administrative Patent Judges,  
DOWNEY, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 9 -18, all the claims remaining in the application.

The subject matter on appeal is directed to methods for covering a caplet with hard-shell gelatin capsule halves (claim 9), manufacturing a capsule-shaped medicament (claim 13) and manufacturing a gelatin covered caplet (claim 16).

Claims 9, 13 and 16 are illustrative of the subject matter on appeal and are set forth

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in the appendix attached to this decision.

The references relied upon by the examiner are:

Talbot	1,937,468	Nov. 28, 1933
Weidenheimer et al (Weidenheimer)	2,770,553	Nov. 13, 1956
Wai	3,444,290	May 13, 1969
Barshay et al (Barshay)	4,928,840	May 29, 1990
Boardman et al (Boardman)	5,188,688	Feb. 23, 1993
Sauter	5,317,849	Jun. 7, 1994

The rejections before us are:

- I. Claims 9, 11-13, 16 and 18 stand rejected under 35 U.S.C. ' 103 over Talbot in view of Barshay and Weidenheimer;
- II. Claims 14 -15 and 17 stand rejected under 35 U.S.C. ' 103 over Talbot in view of Barshay and Weidenheimer taken further with Wai;
- III. Claim 10 stands rejected under 35 U.S.C. ' 103 over Talbot in view of Barshay, Weidenheimer and Boardman;
- IV. Claim 9 -11, 13 -14, and 17-18 stand rejected under 35 U.S.C. ' 102(e)/103 over Sauter; and
- V. Claims 12 and 15 stand rejected under 35 U.S.C. ' 103 over Sauter in view of Barshay.

After careful consideration of the rejections before us, the applied prior art, the arguments of appellants and the examiner, we find ourselves in complete agreement with appellants and accordingly, we reverse each of the above rejections.

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Discussion

In proceedings before the PTO, the examiner has the burden of establishing the prima facie case of unpatentability. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); citing In re Spada, 911 F.2d 705, 707, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990), In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984) and In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976). See also In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992).

The examiner's position has been difficult to review since the Examiner's Answer contains neither a statement of any of the rejections nor a reference to where we might find a statement of the rejections. The final rejection does not help us; it does not contain a statement of any prior art rejection. Rather, it is only the first Office action which contains a statement of a rejection based upon prior art. Since the time of the first Office action, most of the claims have been amended in a substantial manner. Logically, one would expect that the examiner would need to restate the rejection to take into account the new claims. This has not happened here.

This Board serves as a board of review. 35 U.S.C. § 7(b). The manner in which the examiner has presented his case on appeal does not facilitate a review process. Rather,

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it forces the merits panel to resort to surmise and conjecture as to the examiner's reasoning as to why the amended claims are considered to be

unpatentable. Our review of the examiner's rejection is premised upon the statements of rejection made in the first Office action.

Rejection IV.

IV. Claim 9 -11, 13 -14, and 17 -18 stand rejected under 35 U.S.C. § 102(e)/103 over Sauter. We reverse.

Anticipation is established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984).

The examiner relies upon Sauter to show a process of forming an encapsulated or wrapped medicinal caplet by shrinking two moistened gelatin capsule halves on the end of each caplet to form a smooth, no-overlap capsule. It is the examiner's position that all the limitations of the claims are satisfied by the reference. However, as correctly noted by the appellants, there are a number of differences between the

claimed invention and the reference disclosure.<sup>1</sup>

The examiner has not addressed each of the differences with respect to Sauter. This is error. In order to have a viable 35 U.S.C. § 102 rejection, “[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art in the field of the invention.” Scripps Clinic & Research Found. V. Genentech, Inc., 927 F.2d 1565, 1576, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). Claim limitations cannot be ignored, but rather every limitation must be given effect. In re Angstadt, 537 F.2d 498, 501, 190 USPQ 214, 217 (CCPA 1976) and In re Wilder, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970).

Here in view of the detailed arguments presented by appellants as to the

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<sup>1</sup>. With respect to claim 9, appellants urge that Sauter does not disclose a caplet with hard-shell gelatin capsule halves. In addition, appellants urge that Sauter does not (a) provide a first and second holding means for the caplet (b) insert the first end of the caplet into the first caplet holding means while leaving the second end exposed; (c) place a hard-shell gelatin capsule half on the second exposed end of the caplet (d) dip the hard-shell capsule covered second exposed end of the caplet into a hot water bath to plasticize the hard-shell half; (e) permit the plasticized hard-shell capsule to dry to form a shrink-wrapped hard-shell covered second end; (f) displace the caplet from the first holding means; (g) insert the hard-shell capsule covered second end of the caplet into the second caplet holding means while leaving the first end of the caplet exposed (h) place a hard-shell gelatin capsule half on the first exposed end of the caplet; (i) dip the hard-shell capsule covered first exposed end of the caplet into a hot water bath to plasticize the hard-shell capsule half (j) permit the plasticized hard-shell capsule half to dry to form a shrink-wrapped hard-shell covered first end and (k) displace the caplet from the second holding means. And with respect to claim 13, appellants urge that Sauter does not place first and second hard-shell gelatin capsule halves on first and second ends of a caplet, and does not plasticize the hard-shell gelatin capsule halves by exposing the halves to moisture. See appellant’s brief, pages 10-11.

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differences between the claims and the disclosure of Sauter, one would expect the examiner to set forth a detailed statement of a rejection explaining why Sauter exactly describes the rejected claims. This has not happened. Accordingly, we reverse the rejection under 35 U.S.C. § 102(b) based upon Sauter.

The examiner has not begun to establish a credible basis for the alternative §103 rejection. The examiner stated at page 6 of the first Office action (Paper No. 4, March 6, 1995) that “any conceivable differences which might exist between the claimed/envisioned invention and sauter[sic] being held/seen NOT to constitute patentable differences.” Suffice it to say the Examiner’s Answer does not further explain the examiner’s position.

The alternative rejection under 35 U.S.C. § 103 is reversed.

Rejection V.

Claims 12 and 15 stand rejected under 35 U.S.C. § 103 over Sauter in view of Barshay. We reverse.

Obviousness is a legal conclusion based upon underlying factual inquiries. Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966); In re Fritch, 972 F.2d at 1265, 23 USPQ2d at 1783.

For us to review a rejection under 35 U.S.C. § 103, it is incumbent upon the

examiner to make an initial analysis as to what the claimed invention is and a proper analysis of the claims and prior art as required by Graham, supra. See also MPEP 706.02(j) wherein it states that:

...[A]fter indicating that the rejection is under 35 U.S.C. § 103, the examiner should set forth in the Office action (1) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate, (2) the difference or differences in the claim over the applied reference(s), (3) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and (4) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.

As noted previously, appellants, in their brief, have pointed out a number of differences between the claimed process and the Sauter process. The examiner has not disputed that these differences exist. Rather, as explained above, the examiner curtly dismissed any differences. This is error. As part of the analysis under 35 U.S.C. § 103, it is the examiner's burden to consider whether the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in

the art. In re Clay, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060 (Fed. Cir. 1992). This the examiner has failed to do.

Rejections I, II, and III.

We reverse these rejections.

Each of these rejections relies upon Talbot. Talbot discloses a process for wrapping articles with two moistened cup shaped regenerated cellulose materials that are telescopically joined with an adhesive and then dried and shrunk to fit about the article. See Figure 6 and page 2, lines 3-11. The wrapper protects the article from any adverse conditions to which it is exposed.

Barshay discloses the application of adhesive to the end of caplets that are encased in gelatin capsules that are telescopically joined. Weidenheimer describes preparing a soft gelatin capsule by treating the gelatin with a small amount of plasticizer (because of its toxicity to humans) to hydrate the gelatin. Wai discloses a process for forming a medicament gelatin capsule with formaldehyde in order that the prepared capsule will swell without breaking, when in contact with gastric juices. Boardman discloses a process of employing a polymeric sealant to seal gelatin capsules joined telescopically.

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It is the examiner's position that it would have been obvious to one of ordinary skill in this art to wrap the caplet of Barshay with gelatin, gelatin being a known hydrophilic/hydratable material as taught by Weidenheimer, using the process of Talbot; and that it further would have been obvious to make the caplet structure that described in Wai and to use color for one half of the capsule as in Boardman.

The examiner's position is untenable. In determining the propriety of an examiner's case for obviousness, it is necessary to ascertain whether or not the reference teachings would have suggested to one of ordinary skill in the relevant art to make the proposed substitution, combination or modification. ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). Here, the examiner has only pointed to isolated teachings in each of the applied references.

The examiner has not provided a fact-based explanation why one having ordinary skill in the art would have found it obvious to combine the references in the manner suggested by the examiner.

In stating these rejections in the first Office Action, the examiner merely listed the

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elements of the claims he believed were described in the various references, followed by a pro forma statement of what would have been obvious to a person of ordinary skill in the art. What has been missing from the examiner's analysis under 35 U.S.C. 103 throughout this case is the concept that the examiner must explain why it would have been obvious to this hypothetical person to combine the identified teachings so as to arrive at the "subject matter as a whole." As stated in Pro Mold and Tool Co., v. Great Lakes Plastics Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996):

It is well-established that before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion, or motivation to lead an inventor to combine those references. (citation omitted)

Here the only reference to this requirement set forth in the Examiner's Answer is contained in the single sentence which spans pages 7-11 of the answer. This sentence is so jumbled and confusing that it is not susceptible to meaningful review. While the examiner is correct in observing that Talbot indicates that the method described therein is useful for wrapping "articles" broadly, that does not give the examiner license to

substitute any “article” into the reference. When we view the references apart from appellants’ disclosure of the present invention, as we must, it is not apparent why one of ordinary skill in the art would have found it obvious to modify the process in order to arrive at the claimed subject matter. Absent a fact-based explanation from the examiner why it would have been obvious to rearrange Talbot in the manner needed to arrive at the claims on appeal, he has not set forth his initial burden of establish prima facies case of obviousness. In re Oetiker, *supra*.

REVERSED

MARY F. DOWNEY	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
WILLIAM F. SMITH	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
JOAN ELLIS	)	
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#### APPENDIX

A method for covering a caplet with hard-shell gelatin capsule halves to produce a simulated capsule-like medicament comprising:

providing a first holding means and a second holding means for said caplet;

inserting a first end of said caplet into said first caplet holding means while leaving a second end of said caplet exposed;

placing a hard-shell gelatin capsule half on said second exposed end of said caplet;

dipping said hard-shell capsule covered second exposed end of said caplet into a hot water bath to plasticize said hard-shell capsule half;

permitting said plasticized hard-shell capsule half to dry to form a shrink-wrapped hard-shell covered second end;

displacing said caplet from said first holding means;

inserting said hard-shell capsule covered second end of said caplet into said second caplet holding means while leaving said first end of said caplet exposed;

placing a hard-shell gelatin capsule half on said first exposed end of said caplet;

dipping said hard-shell capsule covered first exposed end of said caplet into a hot water bath to plasticize said hard-shell capsule half;

permitting said plasticized hard-shell capsule half to dry to form a shrink-wrapped hard-shell covered first end, said shrink-wrapped hard-shell gelatin capsule half coverings on said first and second ends substantially covering said caplet;

displacing said caplet from said second holding means.

A method of manufacturing a capsule-shaped medicament comprising:

placing a first hard-shell gelatin capsule half on a first end of a solid caplet having a first and a second end, plasticizing said first hard-shell capsule half by exposing said first hard-shell capsule half to moisture, and shrink-wrapping said first hard-shell gelatin capsule half on said first end; and

placing a second hard-shell gelatin capsule half on said second end of said caplet, plasticizing said second hard-shell capsule half by exposing said second hard-shell capsule half to moisture, and shrink-wrapping said second hard-shell gelatin capsule half on said second end.

A method of manufacturing a gelatin covered caplet comprising:  
plasticizing a first and second hard-shell gelatin capsule shell half and positioning said first and second plasticized shell halves on opposite ends of a solid caplet; and

drying said plasticized shell halves once on said caplet to shrink said gelatin shell halves onto said caplet.

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