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for publication and is not binding precedent of the Board.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. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOHN H. LEE, JOSEPH D. HAHN and ROBERT C. MUSSER

Appeal No. 2003-2147
Application No. 09/392,243

ON BRIEF

Before SCHEINER, MILLS, and GREEN Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 21-27 and 36-54, which are all of the claims pending in this application.

Claims 21, 36 and 42 are illustrative of the claims on appeal and read as follows:

21. A method for preserving mucosa tissue comprising mixing a quantity of mucosa tissue with a preserving agent selected from the group consisting of hydrogen peroxide and phosphoric acid to yield the preserved mucosa tissue.

36. A method of treating mucosa tissue, the method comprising combining the mucosa tissue and a peroxide-containing compound to form an intermediate.

42. The method of claim 36, the method further comprising mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product, the concentration of the peroxide-containing compound remaining in the mucosa product being undetectable when the concentration of the peroxide-containing compound in the mucosa product is determined using $KMnO_4$ titration.

The prior art references cited by the examiner are:

Van Gorp et al (Van Gorp)	5,607,840	Mar. 4, 1997
Balslev et al (Balslev)	4,438,100	Mar. 20, 1984
Oles	4,415,451	Mar. 20, 1979

Reference cited by the Merits Panel:

Hiles et al. (Hiles)	6,666,892	Dec. 23, 2003 (filed May 27, 1999)

Grounds of Rejection

Claim 42 stands rejected under 35 U.S.C. §112, second paragraph for indefiniteness.

Claims 21-27 and 36-54 stand rejected under 35 U.S.C. §103(a), as obvious over Van Gorp in view of Balslev and Oles.

We reverse these rejections.

DISCUSSION

35 U.S.C. §112, second paragraph

Claim 42 stands rejected under 35 U.S.C. §112, second paragraph for indefiniteness.

As set forth in Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991):

> The statute requires that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." A decision as to whether a claim is invalid under this provision requires a determination whether those skilled in the art would understand what is claimed. See Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985) (Claims must "reasonably apprise those skilled in the art" as to their scope and be "as precise as the subject matter permits.").

Furthermore, claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971).

The examiner argues that claim 42 is confusing because "the claim initially recites addition of a peroxide-containing compound to a composition, but then recites that the added product must become undetectable when the amount of added product is measured. It is therefore unclear how much peroxide-containing product can be added, if any." Answer, page 3.

Appellants argue that claim 42 is not indefinite. Brief, page 38. Appellants argue that

> [i]f the concentration of the peroxide containing compound remaining in the mucosa product, when determined using $KMnO_4$ titration, is not "undetectable" (i.e. is "detectable") or if the particular subject matter does not entail "mixing the peroxide containing compound and the mucosa tissue to form a mucosa product" as claim 42 requires, then the person knows the particular subject matter falls outside the literal scope of claim

> 42. If, on the other hand, the concentration of the peroxide-containing compound remaining in the mucosa product, when determined using $KMnO_4$ titration, is "undetectable" and the particular subject matter does entail "mixing the peroxide-containing compound and the mucosa tissue to form a mucosa product," as claim 42 requires, then the person knows the particular subject matter falls within the literal scope of claim 42.

Brief, page 39.

In our view the examiner has failed to establish a prima facie case of indefiniteness. In our view, the examiner has failed to fully analyze the claim 42 language in view of the application disclosure.

For example, Example 1 of the specification states that first porcine mucosa was heated. A specific amount of hydrogen peroxide was added to the solution followed by mixing for 10 minutes. "The color of the solution changed so that it was similar to the color of a whey protein solution. The solution was analyzed to determine whether there was any hydrogen peroxide remaining. This was carried out by adding 0.01 M $KMnO_4$ to the diluted solution (1:150) and observing whether a color change took place. This test indicated that there was no hydrogen peroxide remaining in the product." Specification, page 5.

Upon review of this portion of the specification, and the other examples 2-8 set forth in the specification, in our view, one of ordinary skill in the art would have been provided with an amount of hydrogen peroxide and an equivalent, to be added to the solution. This amount of hydrogen peroxide, according to the examples, provides for an

amount which, in some instances, is undetectable by $KMnO_4$ titration.[1]

Furthermore, appellants concede that "if the concentration of the peroxide containing compound remaining in the mucosa product, when determined by $KMnO_4$ titration, is not "undetectable" (i.e. is "detectable") ..., then the person knows the particular subject matter fall outside the literal scope of claim 42." Brief, page 39.

In view of the above, when claim 42 is read in view of the specification the claim language is not indefinite. The rejection of claim 42 for indefiniteness is reversed.

35 U.S.C. §103(a)

Claims 21-27 and 36-54 stand rejected under 35 U.S.C. §103(a), as obvious over Van Gorp in view of Balslev and Oles.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). It is well-established that the conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

---

[1] The examiner also appears to understand that the prior art, Balslev, Column 6, lines 39-68, teaches that hydrogen peroxide continuously decomposes over time, eventually to a concentration of zero. Answer, page 11.

According to the examiner, Van Gorp teaches a process wherein mucosal protein hydrolysate is added to protein-containing food or feed. Van Gorp also discloses the preservation of the mucosa starting material using well known preservatives. Answer, page 4; Final Rejection, page 3. The examiner finds that Van Gorp differs from the claimed invention in that Van Gorp does not use the claimed peroxide or phosphoric acid as a preservative. Id.

To make up for this deficiency in Van Gorp, the examiner relies on Balslev and Oles for the teaching that both phosphoric acid and peroxide were well known preservatives in food and/or pharmaceutical applications. Thus, according to the examiner, the claimed substitution of well known preservatives for those used in Van Gorp must be considered an obvious substitution of one known equivalent preservative for another. Id, at 4. The examiner continues that, “the artisan of ordinary skill at the time of applicant's invention would have had a reasonable expectation from Oles and Balslev that phosphoric acid and/or peroxide would have functioned equivalently to the preservatives disclosed by Van Gorp, the artisan of ordinary skill would have been motivated to have substituted Oles' phosphoric acid and/or Balslev's peroxide for the preservatives disclosed by Van Gorp.” Answer, pages 4-5.

Appellants respond, arguing, “there is no teaching or suggestion in the Van Gorp patent to use any preservative other than an oxygen scavenger, an antioxidant, or in low acidity environments, calcium propionate. ... In this regard, the Van Gorp patent principally mentions use of sodium metabisulfite as an oxygen scavenger, while also

referencing use of calcium propionate, BHT, and BHA as alternatively acceptable preservatives..." Brief, page 13. Appellants argue that "[t]he Van Gorp patent suggests the use of oxygen scavengers as preservatives. The Van Gorp patent does not suggest the incorporation of either an oxidizer (such as hydrogen peroxide) or an acidifier (such as phosphoric acid) in the process disclosed in the Van Gorp patent." Brief, page 14.

In addition, appellants provide evidence, Exhibit D, Jay, James M., Modern Food Microbiology, pages 259-296 (1986), which according to appellants, demonstrates there is no support for the position that the Oles phosphoric acid "would have functioned equivalently to the preservatives disclosed by Van Gorp..." Brief, page 14.

Appellants argue that Oles relies on a synergistic combination of acidifying agents (a combination of (1) acetic acid or other organic acid and (2) phosphoric acid), whereas the Van Gorp patent principally relies on an oxygen scavenging stabilizer ... [and] demonstrates the wide difference in operating function between the preservatives of the Van Gorp patent and the preservatives of the Oles patent. Brief, page 14.

Finally, appellants argue that Balslev "actually teaches away from using hydrogen peroxide as a preservative in the process disclosed in the Van Gorp patent. The Van Gorp patent principally teaches preservation by scavenging oxygen from the mucosa tissue with oxygen scavengers. ... According to the Balslev patent the hydrogen peroxide serves an oxidizing bactericide. ... An oxidizing agent provides oxygen to an active site via a chemical reaction. Providing oxygen to mucosa tissue is exactly the opposite result of that desired by the preservatives principally employed in

the Van Gorp patent, namely scavenging oxygen." Brief, page 16.

In response, the examiner finds with respect to Oles, that the claims are open ended and do not exclude the combination of acetic acid and phosphoric acid as a preservative. While the examiner is correct in his interpretation of the scope of claim 21, what is missing from the examiner's analysis is why one of ordinary skill in the art would have been motivated to select the specific phosphoric acid and acetic acid preservative in combination with mucosa tissue. Oles provides that the combination of acetic acid and phosphoric acid has specific application to low acid food products. See abstract. The examiner has not established that mucosa tissue would be considered an equivalent to a low acid food product.

In view of the above, we agree with appellants that the examiner has failed to establish a prima facie case of obviousness on the prior art evidence before us. "To establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant." In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000). An adequate showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075 (Fed. Cir. 2000).

In the present case, the examiner has failed to provide sufficient evidence that one of ordinary skill in the art would readily substitute one preservative for another, in view of evidence present in the record that preservatives of the prior art in fact function differently than the claimed preservative. Moreover, the evidence of record reasonably appears to reasonably show that specific preservatives are for required for specific applications and thus one of ordinary skill in the art would not readily substitute one preservative for another. We particularly note appellants' Exhibit D, Tables 11-1 and 11-3, provides evidence that preservatives have distinct applications. From the examiner's perspective Table 11-1 of Exhibit D provides that certain preservative have multiple applications (Answer, page 7), but th examiner does not acknowledge the reference's teaching that other preservatives do not have general application or provide evidence that the specific claimed preservatives are known in the art to have general application, or particular application to the preservation of mucosa tissue.

In view of the above, we reverse the rejection of the claims over Van Gorp in view of Balslev and Oles.

Other Issue

Upon return of the application to the examiner, it is recommended that the examiner carefully review the disclosure of Hiles, U.S. Patent No. 6,666,892 (attached) and determine its relevance under 35 U.S.C. § 102(e) or 103(c), if any, to the claimed subject matter. In particular, Hiles would appear to have a filing date, May 27, 1999,

prior to the filing date of the present application, September 9, 1999. Hiles discloses the treatment of tissue mucosa with a disinfecting agent which is desirably an oxidizing agent, and preferably hydrogen peroxide. Col. 4, lines 44-67. Hiles states that the process will eliminate contaminants but will also produce a tissue which "exhibits no substantial degradation of physical and mechanical properties," i.e., the tissue will be preserved. (Col. 7, lines 1-8).

CONCLUSION

The rejection of claim 42 under 35 U.S.C. §112, second paragraph for indefiniteness is reversed. The rejection of claims 21-27 and 36-54 under 35 U.S.C. §103(a), as obvious in view of Van Gorp in view of Balslev and Oles is reversed.

The application is returned to the examiner to determine the relevance of Hiles to the claimed subject matter.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED

TONI R. SCHEINER Administrative Patent Judge	)
DEMETRA J. MILLS Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
LORA M. GREEN Administrative Patent Judge	)

WESTMAN CHAMPLIN & KELLY, P.A.
Suite 1800 International Centre
900 Second Avenue South
Minneapolis, MN 55402-3319