

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte HORST G. ZERBE and
FADIA AL-KHALIL

Appeal No. 2006-0442
Application No. 10/123,142

ON BRIEF

Before ADAMS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a breath-freshening composition, which the examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 134. We reverse.

Background

“Water-soluble films for oral administration of therapeutic agents are well known in the art. It is also known in the art to use such films for administering a breath freshening agent, e.g., menthol. The known films for administering breath freshening agents and/or active pharmaceutical agents are generally comprised of at least one water-soluble polymer suitable for human consumption and at least one compound that enhances the

wettability of the water-soluble polymer, typically selected from polyalcohols, surfactants and plasticizers.” Specification, page 1.

The specification discloses that “flavored films which disintegrate more rapidly than previously known flavored films can be obtained by replacing the polymers used in the known flavored films with hydroxypropyl cellulose and modified starch.” Page 2.

“Hydroxypropyl cellulose is . . . a nonionic, water-soluble, film-forming polymer. . . . Conveniently, hydroxypropyl cellulose is commercially available in a variety of molecular weights.” Page 3.

“Modified starches include any of several water-soluble polymers derived from a starch (e.g., corn starch, potato starch, tapioca starch) such as by acetylation, halogenation, hydrolysis (e.g., such as w[ith] an acid), or enzymatic action. . . . Maltodextrins are a preferred class of modified starches obtained by hydrolysis.”

Page 4.

Discussion

1. Claim construction

Claims 1-3, 5-13, 15-23, 25-33, and 35-40 are pending and on appeal. Claims 1, 2, and 11 are representative and read as follows:

1. A breath freshening comestible comprising:

a film containing at least one hydroxypropyl cellulose;

at least one modified starch;

at least one surfactant; and

at least one flavor ingredient, the amounts of the hydroxypropyl cellulose, modified starch, surfactant, flavor ingredient, and any optional ingredients selected to provide a film that rapidly disintegrates in water without leaving a noticeable residue.

2. The breath freshening comestible of claim 1, wherein the modified starch is maltodextrin.

11. A multiple layer breath freshening film comprising:

a first layer including at least one hydroxypropyl cellulose, at least one modified starch, at least one surfactant and at least one flavor ingredient; and

at least one other layer including a water-soluble polymer and a second flavor ingredient.

Thus, claim 1 is directed to a comestible (i.e., an edible composition) comprising a film, where the film comprises the specified components. The claim language makes clear that the starch, surfactant, and flavoring are components of the film itself, not components of the comestible that are separate from the film: the claim requires that the starch, surfactant, and flavoring be “selected to provide a film that rapidly disintegrates in water without leaving a noticeable residue.”

Claim 2 adds the limitation that the modified starch is maltodextrin.

Claim 11 is directed to a multi-layer film having, among other things, a first layer that includes hydroxypropyl cellulose, a modified starch, a surfactant, and a flavoring ingredient.

2. Obviousness based on Zerbe and Leung

The examiner rejected claims 1, 3, 5-10, 31, 33, and 35-40 under 35 U.S.C. § 103 as obvious in view of Zerbe¹ and Leung.² As the examiner noted, Zerbe teaches a film that contains a water-soluble polymer, which can be hydroxypropyl cellulose (column 2, lines 38-41), a surfactant, and a flavoring agent such as a breath-freshener (column 2,

¹ Zerbe et al., U.S. Patent 5,948,430, issued September 7, 1999.

² Leung et al., U.S. Patent 6,596,298, issued July 22, 2003 (application filed September 14, 1999).

lines 14-23; and column 3, lines 32-35). See the Examiner's Answer, page 4. However, "Zerbe . . . [does] not teach the use of modified starch in the film." Id., page 6.

The examiner relied on Leung to make up for this deficiency. The examiner characterized Leung as "teach[ing] fast dissolving, orally consumable, edible films comprising suitable film-forming agents of high amylose starch, modified starch such as hydroxypropylated high amylose starch, in combination with dextrin, hydroxypropyl cellulose, various surfactants and flavorants . . . (see reference column 4, line 64 – col. 5, line 22)." Id.

The examiner concluded that it would have been obvious

to use the combined reference teachings of Leung et al. within Zerbe et al. because the reference of Leung et al. shows the use of modified starches, such as hydroxypropylated high amylose starch in combination with hydroxypropyl cellulose, dextrin and surfactants and flavorants to obtain a fast dissolving film that provides breath-deodorizing properties and similarly Zerbe et al. teach a water-soluble film for oral administration comprising film-forming substances, surfactants and flavorants whereby the film provides instant wettability, rapid dissolution and rapid disintegration upon oral administration in the oral cavity. The expected result would be an effective, fast-dissolving film preparation beneficial for treating oral hygiene conditions.

Examiner's Answer, page 7.

Appellants argue that Leung's "lengthy list of possible ingredients, especially when considered in view of the preference for pullulan and the 39 examples (containing pullulan or polyvinyl pyrrolidone), none of which contains either hydroxypropyl cellulose or a modified starch, is merely an invitation to experiment with the use of film-forming agents other than the preferred pullulan. An invitation to try various combinations that are not preferred is nothing more than a starting point for experimentation." Appeal Brief, pages 6-7. Appellants argue that the film-forming agents disclosed by Leung can be

combined in billions of different ways, and the prior art would not have led those skilled in the art to combinations containing hydroxypropyl cellulose and a modified starch.

Appeal Brief, page 7.

The examiner bears the burden of showing that a claimed invention would have been obvious to a person of ordinary skill in the art. In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). As part of the prima facie case, the examiner must establish, by evidence or sound scientific reasoning, “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, 1076 (Fed. Cir. 2000). See also In re Kahn, 441 F. 3d 977, 988, 78 USPQ2d 1329, 1337 (Fed. Cir. 2006) (“[T]he ‘motivation-suggestion-teaching’ test asks not merely what the references disclose, but whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims.”).

In this case, we agree with Appellants that the examiner has not shown that the cited references would have suggested the instantly claimed composition. The examiner has established that Zerbe teaches a composition lacking only the modified starch recited in claim 1, and that Leung teaches that hydroxypropylated high amylose starch (a modified starch) was a known film-forming agent used in edible films.

However, the examiner has not provided any evidence or reasoning that would have led those skilled in the art to add the modified starch taught by Leung to the film

composition taught by Zerbe. Zerbe expresses a preference for cellulose derivatives such as hydroxypropyl cellulose, and suggests that “[o]ther optional polymers” could also be added. See column 2, lines 38-47. The listed polymers do not include any starches or modified starches.

Leung expresses a preference for pullulan in the disclosed films and suggests that “[t]he film . . . can further comprise . . . additional film-forming agents,” among other things. See column 5, lines 14-22. The film-forming agents taught by Leung include all of the optional polymers suggested by Zerbe, and also include “amylose, high amylose starch, hydroxypropylated high amylose starch, dextrin, pectin, chitin, chitosan, levan, elsinan, collagen, gelatin, zein, gluten, soy protein isolate, whey protein isolate, casein, and mixtures thereof.” Column 4, line 64 to column 5, line 8.

Thus, Zerbe suggests addition of any of fourteen “optional polymers” in the disclosed, hydroxypropyl cellulose-containing composition, none of which is a modified starch, while Leung discloses thirty-three film-forming agents, expresses a preference for pullulan, and suggests that the film-forming agents can be used in combination. The examiner has pointed to nothing in either reference that would have led those skilled in the art to single out the only modified starch listed by Leung as a film-forming agent and combine that modified starch with the Zerbe’s composition.

We conclude that the examiner has not adequately explained why the cited references would have suggested the instantly claimed composition to a person of ordinary skill in the art. We therefore reverse the rejection of claims 1, 3, 5-10, 31, 33, and 35-40 under 35 U.S.C. § 103.

3. Obviousness based on Zerbe and Schmidt

The examiner rejected claims 11, 13, 15-21, 23, and 25-30 under 35 U.S.C. § 103 as obvious in view of Zerbe and Schmidt.³ Claim 11 is directed to a multi-layer film having, among other things, a first layer that includes hydroxypropyl cellulose, a modified starch, a surfactant, and a flavoring ingredient.

The examiner relied on Zerbe for its disclosure of a “film contain[ing] a water-soluble cellulose derivative, hydroxypropyl cellulose (between 20-75%) in combination with surfactants (0.1-5%), flavors and flavor enhancers.” Examiner’s Answer, page 12. The examiner relied on Schmidt for its teaching of “an oral and dental hygiene multiple-layered film comprising water-soluble or water-swellaable film-forming agents, such as starch[,] in combination with various surfactants and flavorants.” Id. The examiner concluded that the cited references would have made the multi-layer film of claim 11 prima facie obvious.

Appellants argue that the rejection should be reversed because, among other things, “neither patent discloses a modified starch.” Appeal Brief, page 9.

We agree with Appellants’ position. The examiner has pointed to no teaching in either Zerbe or Schmidt that would have suggested the inclusion of a modified starch in a multi-layer film. Therefore, the examiner has not adequately explained how the references would have suggested a multilayer film comprising a modified starch. The rejection of claims 11, 13, 15-21, 23, and 25-30 is reversed.

³ Schmidt, U.S. Patent 5,354,551, issued October 11, 1994.

4. Obviousness based on Leung and Cherukuri

The examiner rejected claims 2, 12, 22, and 32 as obvious in view of Leung and Cherukuri.⁴ The rejected claims are limited to compositions in which the modified starch is maltodextrin.

The examiner characterized Leung as teaching

fast dissolving, orally consumable, edible films comprising suitable film-forming agents of high amylose starch, hydroxypropylated high amylose starch (modified starch), dextrin, hydroxypropyl cellulose, surfactants and flavorants/flavor ingredients. . . . Leung et al. does not teach maltodextrin as the modified starch.

Examiner's Answer, page 15. The examiner cited Cherukuri as teaching "a multiple encapsulated flavor delivery system" comprising "modified starches, maltodextrin, hydroxypropyl cellulose and mixtures thereof," for use in "confections, pharmaceutical preparations and denture products." Id.

The examiner concluded that it would have been obvious

to use the combined teachings of Cherukuri et al. within Leung et al. because Cherukuri et al. teach oral hygiene and dentifrice products comprising modified starches, maltodextrin and hydroxypropyl cellulose, which are taught to be effective hydrocolloids and film-forming carbohydrates and similarly Leung et al. teach fast dissolving, orally consumable, edible films comprising suitable modified starches (i.e., hydroxypropylated high amylose starch). The expected result would be an improved and effective film composition for oral hygiene applications.

Id., pages 15-16.

Appellants argue that Cherukuri "teaches that maltodextrin may be used in an encapsulation matrix coated onto a core of a free-flowing particulate delivery system. . . . A protective coating on a particulate material . . . and a free standing film . . . are not the

⁴ Cherukuri et al., U.S. Patent 5,004,595, issued April 2, 1991.

same, and require different physical properties, such that the use of maltodextrin [sic] on a protective film coating on a particulate core material would not be considered relevant to those skilled in the art attempting to make a rapidly disintegrating free standing film.”

Appeal Brief, page 10.

We will reverse this rejection as well. We will assume that a person of ordinary skill in the art would have found it obvious, based on Leung, to make an edible film comprising hydroxypropyl cellulose, a surfactant, and a flavoring agent. That composition differs from the one defined by claim 2 because claim 2 requires that the composition also contain maltodextrin.

Cherukuri teaches that maltodextrin is one of a number of hydrocolloids that can be used to form either the core or encapsulating matrix (col. 8, lines 40-55) of a spray-dried flavor-delivery system (col. 5, lines 28-38) in which the “encapsulating matrix protects the flavor in the core and permits higher concentrations of flavor to be included without imparting bitterness” (col. 5, lines 15-17). Cherukuri teaches that the disclosed flavor delivery system is “a particulate free-flowing material” (col. 6, lines 53-55) that is suitable for use in “hard and soft candies, chewing gums and particularly, low calorie, low moisture formulations” (col. 6, lines 4-6).

The examiner has not adequately explained how the cited references would have suggested the claimed composition. In particular, the examiner has not adequately explained what would have led a skilled worker to choose maltodextrin from the list of twenty-six specific hydrocolloids taught by Cherukuri, and then combine either maltodextrin itself or maltodextrin-containing flavor delivery particles with a rapidly dissolving film such as that taught by Leung.

The examiner has not shown that the teachings of the references or knowledge of those skilled in the art would have led a skilled worker to expect that maltodextrin would be useful as a film-forming agent in edible films, or that the skilled worker would have found it obvious to incorporate a particulate flavor-delivery material in edible films. Since the examiner has not made out a prima facie case of obviousness, we reverse the rejection of claims 2, 12, 22, and 32 under 35 U.S.C. § 103.

Summary

The examiner has not adequately explained why the prior art would have suggested the claimed compositions and therefore we reverse the rejections on appeal.

REVERSED

Donald E. Adams)	
Administrative Patent Judge)	
)	
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)	BOARD OF PATENT
Eric Grimes)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Lora M. Green)	
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