UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROBERT K. YANG, RICHARD C. FUISZ,
GARY L. MYERS, and JOSEPH M. FUISZ

Appeal 2007-4225
Application 10/074,272
Technology Center 1700

Decided: February 21, 2008

Before BRADLEY R. GARRIS, THOMAS A. WALTZ, and
CATHERINE Q. TIMM, *Administrative Patent Judges*.

WALTZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the Primary Examiner's final rejection of claims 91, 93-104, 106, 108-112, 114, 116, 117, and 119 (*see* the Amendment dated May 9, 2006, subsequent to the final rejection, which amended claims 91, 101, 104, 106, 108, 110-112, 114, 116, 117, and 119; according to the Advisory Action dated May 22,

2006, this Amendment was entered and overcomes the rejection of these claims under 35 U.S.C. § 112, second paragraph; Br. 2-3).[1] The remaining claims pending in this application are claims 54, 55, 62-78, 80, 81, and 83-90, which stand withdrawn from further consideration (Br. 2). We have jurisdiction pursuant to 35 U.S.C. § 6(b).

According to Appellants, the invention is directed to a process for making a self-supporting edible film having a substantially uniform distribution of components including the steps of providing, combining and/or mixing an edible water-soluble polymer component, water, and an active component to form an edible matrix, deaerating the matrix by mixing, forming a wet film from the deaerated matrix, rapidly forming a visco-elastic film by applying hot air currents to the bottom of the film with substantially no top air flow, and further drying the visco-elastic film to form the self-supporting edible film (Br. 3-4). Independent claims 91, 104, 110, and 117 are illustrative of the invention and a copy of these claims is reproduced below:

91. A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) mixing an edible water-soluble polymer component, water and an active component to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by mixing;

(c) forming a wet film from said deaerated matrix;

(d) providing a surface having top and bottom sides;

[1] We refer to and cite from the amended Appeal Brief dated Mar. 16, 2007.

(e) feeding said film onto said top side of said surface;

(f) rapidly forming a visco-elastic film by applying hot air currents to said bottom side of said surface with substantially no top air flow to prevent flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and

(g) drying said visco-elastic film to form a self-supporting edible film.

104. A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, an active component selected from the group consisting of pharmaceutical actives, cosmetic actives and combinations thereof and water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by mixing to prevent cavitation of the matrix, thereby reducing formation of air bubbles;

(c) forming a wet film from said deaerated wet matrix, said film having a top surface, a bottom surface and a depth between said top and bottom surfaces;

(d) rapidly forming a visco-elastic film by applying hot air currents to said film to prevent flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and

(e) drying said visco-elastic film to form a self-supporting edible film, said dried film having a uniform distribution of said polymer and said solvent components, a uniform weight and a uniform thickness.

110. A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) providing a wet matrix having a uniform distribution of edible components, said components comprising a water-soluble polymer component, a pharmaceutical active component and water to form an edible matrix with a compositionally uniform distribution of said components;

(b) deaerating said matrix by mixing;

(c) forming a wet edible film from said deaerated wet matrix, said film having a top surface, a bottom surface and a depth of at least about 500μm between said top and bottom surfaces;

(d) rapidly forming a visco-elastic film by applying hot air currents to said film, wherein said air currents are less than that which cause surface rippling or skinning prior to drying of the depth of said film, to prevent flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components; and

(e) drying said visco-elastic film to form a self-supporting edible film.

117. A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:

(a) forming a masterbatch premix of an edible water-soluble polymer component and water;

(b) deaerating said premix by mixing;

(c) feeding a predetermined amount of said deaerating premix to at least one mixer;

(d) adding an active component to said at least one mixer;

(e) mixing said active component and said predetermined amount of said premix to form a matrix having a uniform distribution of components;

(f) forming a wet film from said matrix;

(g) providing a surface having top and bottom sides;

(h) feeding said film onto said top side of said surface;

(i) rapidly forming a visco-elastic film by applying hot air current to said bottom side of said surface with substantially no top air flow to prevent air flow migration and intermolecular forces from creating aggregates or conglomerates thereby maintaining the compositional uniform distribution of components;

(j) drying said visco-elastic film to form a self-supporting edible film; and

(k) removing said self-supporting film from said surface.

The Examiner has relied on the following prior art references as evidence of obviousness:

Wittwer	US 4,478,658	Oct. 23, 1984
Yuhki	US 5,044,761	Sep. 3, 1991
Horstmann	US 5,629,003	May 13, 1997
Mehra	US 5,733,575	Mar. 31, 1998
Strobush	US 5,881,476	Mar. 16, 1999
Zerbe ‘957	US 6,231,957 B1	May 15, 2001
Zerbe ‘292	US 6,660,292 B2	Dec. 9, 2003

ISSUES ON APPEAL

Claim 119 stands provisionally rejected on the judicially created doctrine of obviousness-type double patenting over claim 1 of co-pending Application No. 10/768,809 in view of Yuhki (Ans. 3).

The following rejections under 35 U.S.C. § 103(a) have been presented for review in this appeal:

(1) claims 91, 93, 97, 100, 101, 106, 108, 109, 111, 112, 114, 117, and 119 over Zerbe '292 in view of Strobush and Yuhki (Ans. 5);

(2) claims 94 and 95 over Zerbe '292 in view of Strobush, Yuhki, and Horstmann (Ans. 7);

(3) claim 96 over Zerbe '292 in view of Strobush, Yuhki, and Wittwer (Ans. 8);

(4) claims 98, 99, 102, and 103 over Zerbe '292 in view of Strobush, Yuhki, and Zerbe '957 (Ans. 9);

(5) claims 104 and 110 over Zerbe '292 in view of Strobush, Horstmann, and Yuhki (Ans. 10); and

(6) claim 116 over Zerbe '292 in view of Strobush, Mehra, and Yuhki (Ans. 12).

Appellants contend that Strobush is non-analogous art since this reference bears no relevance to the pharmaceutical field, nor is it related to Appellants' problem of safe and effective film dosage formulations but is solely concerned with reducing surface defects such as mottle (Br. 10-15, citing the Rounds Declaration under 37 C.F.R. § 1.132). Appellants further contend that the Examiner's definition of the problem is erroneous, and this definition in the Answer is inconsistent with the Examiner's previous definition (Reply Br. 3, 6-7).

Appellants contend that the Examiner is incorrect regarding the definition of "mottle" as a uniformity defect, but actually "mottle" is a surface defect (Br. 8; Reply Br. 7-8, citing the Rounds Declaration).

Appellants contend that there is no motivation to combine Zerbe '292, Strobush, and Yuhki, specifically noting that Zerbe '292 generally mentions

drying but does not suggest any concerns with conventional drying means (Br. 16-18; Reply Br. 16).

Appellants contend that Strobush "teaches away" from water-based ingestible self-supporting films, and it is improper to only use the bottom drying element from the complicated drying disclosure of Strobush (Br. 18-24; Reply Br. 13).

Appellants also present separate contentions regarding the thickness of the film (claims 94-95; Br. 27; Reply Br. 15) and the specific pre-mix steps required by claim 117 (Br. 25-26; Reply Br. 17-18).

The Examiner contends that Strobush is analogous prior art since it is reasonably pertinent to the particular problem with which Appellants were concerned, namely drying a coated film (Ans. 16-17).

The Examiner contends that Strobush defines "mottle" not as a surface defect but as a problem of non-uniform density (Ans. 19-20). The Examiner further contends that to maintain uniform distribution of components throughout a film would require uniform concentration or density or thickness (Ans. 15-16).

The Examiner contends that Strobush discloses water-based systems (Ans. 18), and teaches the use of conventional drying ovens, as used by Zerbe '292, causes coating defects (Ans. 20, 23). The Examiner further notes that the claims are "open" to include other components, such as those included in the additional drying procedure taught by Strobush (Ans. 22).

Accordingly, we determine the following issues presented from the record in this appeal (1) Have Appellants established that the Examiner reversibly erred in applying Strobush as analogous prior art; and (2) if Strobush is analogous prior art, have Appellants established, through

argument and the Rounds Declaration, that the Examiner reversibly erred in combining the teachings of Strobush with Zerbe '292 and Yuhki?

We determine that the Examiner has properly established a prima facie case of obviousness in view of the reference evidence, which prima facie case has not been adequately rebutted by Appellants' arguments and evidence. Therefore, we AFFIRM all grounds of rejection based on § 103(a) essentially for the reasons stated in the Answer, as well as those reasons set forth below. Since Appellants have not contested the Examiner's rejection for obviousness-type double patenting (Br. 6, fn 2), we summarily AFFIRM this rejection. Accordingly, the decision of the Examiner is AFFIRMED.

OPINION

A. The Rejection for Obviousness-type Double Patenting

Claim 119 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of co-pending Application No. 10/768,809 in view of Yuhki (Ans. 3). Appellants have not disputed this rejection, nor stated that they will submit the appropriate terminal disclaimer. Appellants only state that this rejection is not being addressed on appeal since the rejection is provisional (Br. 6, fn 2; Reply Br. 3, fn 1). Accordingly, we summarily affirm this rejection for the reasons of record (e.g., Ans. 3-5).

B. The Rejection over Zerbe '292, Strobush, and Yuhki

We determine the following Factual Findings (FF) from the record in this appeal:

(1) Zerbe '292 discloses rapidly dissolving flavored film strips containing hydroxypropyl cellulose, a modified starch, and a flavor ingredient, advantageously employed for uniformity

and reproducibly flavoring food items (Abstract; col. 1, ll. 25-26; col. 3, ll. 30-33; and col. 5, ll. 23-30);

(2) Zerbe '292 discloses that the flavored films may be prepared by mixing the ingredients in water to produce a solution that is coated onto a suitable carrier substrate, and dried to form a flavored film (col. 5, ll. 36-44);

(3) Zerbe '292 teaches that the film is dried by hot air in a drying oven, but pre-drying by infrared radiators may also be suitable (col. 6, ll. 42-54);

(4) Zerbe exemplifies using various premixes of the ingredients with high speed stirring or mixing (col. 6, ll. 1-21);

(5) Strobush discloses an apparatus and method for evaporating a coating solvent from a coating on a first substrate surface of a substrate while minimizing formation of mottle during evaporation (Abstract; col. 1, ll. 9-18 and 27-29);

(6) Strobush teaches that the process of applying a coating to and drying that coating on a substrate can inherently create defects such as mottle, where "mottle" is defined as "an irregular pattern or non-uniform density defect that appears blotchy when viewed," and the usual cause of mottle is air movement over the coating before it enters the dryer, as it enters the dryer, or in the dryer (col. 1, l. 43-col. 2, l. 5);

(7) Strobush teaches that mottle is a problem when the coating solution contains a volatile organic solvent "but can also occur to a significant extent even with aqueous coating compositions" (col. 2, ll. 10-15);

(8) Strobush teaches that the prior art substrates which have been coated are often dried using a drying oven which contains a drying gas such as air (col. 2, ll. 20-22);

(9) Strobush discloses the drying of coated substrates without introducing significant mottle while running at higher web speeds by supplying drying gas (heated air) toward the bottom surface of the coated substrate such that the substrate rides on a cushion of drying gas, while the top side receives little or no drying gas, and where the coating comprises any film-forming material dispersed in any evaporable liquid vehicle (col. 6, ll. 20-27; col. 9, ll. 1-11 and 47-50; col. 11, ll. 1-6 and 16-27; col. 12, ll. 14-21, 27-31, and 48-55; and col. 19, ll. 43-46);

(10) Strobush teaches that the maximum allowable heat transfer rate for a particular coating varies proportionately to the viscosity and the thickness of the coating (col. 13, ll. 13-17);

(11) Strobush teaches that his apparatus and method are suitable for a "wide variety of coatings" (col. 9, l. 9), with materials particularly suited for drying by this apparatus including "[a]ny mottle-susceptible material" such as graphic arts materials, magnetic media, and photothermographic imaging constructions (col. 16, ll. 60-66); and

(12) Yuhki discloses a method of minimizing the bubbles in a solution of a powder and solvent by high speed stirring of the solution (Abstract; col. 4, l. 17-col. 5, l. 6).

Determination that a reference is from non-analogous art is two-fold; first, we must decide if the reference is within the field of the inventor's endeavor; if it is not, then we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. *See In re GPAC Inc.,* 57 F.3d 1573, 1577 (Fed. Cir. 1995); *In re Wood,* 599 F.2d 1032, 1036 (CCPA 1979).

Under 35 U.S.C. § 103, the factual inquiry into obviousness requires a determination of: (1) the scope and content of the prior art; (2) the differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations, if any. *See Graham v. John Deere Co. of Kansas City,* 383 U.S. 1, 17-18 (1966). Often it will be necessary to look to interrelated teachings of multiple patents and the background knowledge possessed by a person having ordinary skill in the art. *See KSR Int'l Co. v. Teleflex, Inc.,* 127 S. Ct. 1727, 1740-41 (2007). "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR,* 127 S. Ct. at 1740. During examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification. *See In re Graves,* 69 F.3d 1147, 1152 (Fed. Cir. 1995).

Applying the preceding legal principles to the factual findings (FF) in the record of this appeal, we determine that Strobush is analogous prior art and that the Examiner has properly combined Zerbe '292, Strobush, and Yuhki to establish a prima facie case of obviousness, which prima facie case

has not been adequately rebutted by Appellants' arguments and evidence (the Rounds Declaration).

First, we address the determination of whether Strobush is analogous prior art. Appellants state, under "Field of the Invention," that the invention relates to rapidly dissolving films with active ingredient evenly distributed throughout the film, where this uniform distribution is achieved by controlling such parameters as the drying process to reduce aggregation or conglomeration of the components (Specification 1, ¶ [0001]). Appellants further distinguish over conventional prior art drying means such as drying ovens using forced hot air since such drying means produce surface defects (Specification 3-4, ¶¶ [0008] and [0010]). Appellants teach that one of the advantages of their drying means is a more uniform surface of the film (Specification 12, ¶ [0039]). As shown by FF (5) through (8) listed above, we determine that Strobush relates to drying aqueous systems to achieve more uniform distribution (uniform density) of the active component (the flavor ingredient), while distinguishing over the conventional drying oven systems of the prior art which produce surface and density defects such as mottle. Accordingly, we determine that Strobush is not only pertinent to the problem facing Appellants (improving drying of coated films over conventional drying ovens to produce films with reduced surface defects and more uniform distribution of components), but Strobush may also reasonably be considered to be within the field of Appellants' endeavor (as stated under the "Field of the Invention" on page 1 of the Specification). Therefore, we determine that Strobush is analogous prior art.

Appellants argue that Strobush bears no relevance to the pharmaceutical field, nor the problem of safe and effective film dosage

formulations (Br. 9-11, citing the Rounds Declaration; Reply Br. 7-8). Appellants' argument is not persuasive for several reasons. First, the claims and the Specification are not limited to the pharmaceutical field (with the exception of claims 104 and 110). The "active component" recited in the claims (e.g., claim 91) may be a flavor component, as well as a pharmaceutical component (Specification 18, ¶ [0060]). Second, as discussed above, this argument is contrary to Appellants' own Specification which defines the "Field of the Invention" as including control of the drying process to achieve uniform distribution of the active component (Specification 1, ¶ [0001]). Third, as also discussed above, the problem Appellants were concerned with was drying of an active component film to achieve uniform distribution, and a result of the solution of this problem was safe and effective film dosage formulations. Fourth, we note that the Rounds Declaration is primarily concerned with the specific examples of Strobush, which are directed to non-aqueous photothermographic systems (*e.g., see* ¶¶ 7, 13, 14, and 16 of the Rounds Declaration). Although Rounds quotes from the portion of Strobush defining "mottle" as a "non-uniform density defect" (¶ 9), the Rounds Declaration never specifically explains why non-uniform density differs from the non-uniform distribution of components desired by Appellants (*see* ¶¶ 18 and 21-26 of the Rounds Declaration).

Since we have determined that Strobush is analogous prior art, we now turn to the Examiner's combination of Zerbe '292, Strobush, and Yuhki to show the obviousness of claims 91, 93, 97, 100, 101, 106, 108, 109, 111, 112, 114, 117, and 119. As shown by FF (1) listed above, we determine that Zerbe '292 discloses a method of forming an active component film

including an edible water soluble polymer component (starch), water, and an active component which is a flavor, with the desire to achieve uniformity of the flavor ingredient throughout the film. As shown by FF (2) and (4) listed above, we determine that Zerbe '292 discloses a method including the steps of mixing the components, with further mixing which will deaerate the film at least to some extent, forming a wet film over a carrier substrate having a top and bottom surface, and drying the film to form an edible film. As shown by FF (3) listed above, we determine that Zerbe '292 teaches drying by forced hot air in a conventional drying oven, although pre-drying by infrared radiators may also be used.[2] As shown by FF (5) through (9) and (11) listed above, we determine that Strobush teaches that the use of conventional drying ovens for drying aqueous coated film systems results in non-uniform density defects, and the solution to this problem is to apply hot air currents to only the bottom side of the coated film.[3] As shown by FF (12) listed above, we determine that Yuhki teaches that deaeration of a solution may be accomplished by high speed mixing. We also determine that Yuhki is not necessary to the rejection since Zerbe '292 teaches high speed mixing of the various components, thus resulting in some degree of deaeration, however large or small, which is all that the claims require. Accordingly, we determine that it would have been well within the ordinary

[2] We note that Appellants teach that "[a]nother drying technique for obtaining the films of the present invention is controlled radiation drying" such as infrared frequency radiation (Specification 11, ¶ [0037]).
[3] As correctly stated by the Examiner (Ans. 22), and contrary to Appellants' argument (Br. 19), the claims on appeal recite "comprising" and thus are "open" to include any other elements or steps that might be included in Strobush's disclosure. *See Vehicular Techs. V. Titan Wheel Int'l, Inc.,* 212 F.3d 1377, 1383 (Fed. Cir. 2000).

skill in this art to apply the drying method taught by Strobush to the film formation method disclosed by Zerbe '292 to achieve uniformity in density of the active component.

With regard to claim 117, Appellants argue that the combination of references do not show all the limitations of this claim, specifically forming a premix and deaerating it prior to adding the active component (Br. 25-26; Reply Br. 17-18). As shown by FF (4) listed above, we determine that the use of premixes, deaeration by mixing (at least to some extent), and adding the active component at the end of this mixing, were all well known in this art. We also determine that the particular order of adding components would have been well within the ordinary skill in this art, absent some showing of criticality.

For the foregoing reasons and those stated in the Answer, we affirm the rejection of claims 91, 93, 97, 100, 101, 106, 108, 109, 111, 112, 114, 117, and 119 under § 103(a) over Zerbe '292 in view of Strobush and Yuhki.

C. The Remaining Rejections based on § 103(a)

Regarding the rejection of claims 94 and 95, Appellants argue that the thickness of films disclosed by Strobush is only about 100 microns (Br. 27). This argument is not persuasive for several reasons. First we must note that claim 94 only requires a thickness of more than 30 microns, thus including thicknesses exemplified by Strobush. Although Zerbe '292 is silent regarding the film thickness, we note that Strobush teaches that drying depends on the thickness of the film (*see* FF (10) listed above). Therefore, with respect to claim 95 which requires a thickness of 500 microns or more, we determine that any thickness would have been obvious depending on the drying time needed to produce the final film. The disclosure of Strobush

cannot be limited to its examples but is available for all that it suggests to one of ordinary skill in the art. *See In re Widmer,* 353 F.2d 752, 757 (CCPA 1965). We also note that the Examiner applies Horstmann as evidence that films with drug actives, food, or cosmetics, have been known to have thicknesses above 500 microns (Ans. 11).

With regard to the rejection of claims 104 and 110, the only claims limited to pharmaceutical actives, we note that Appellants present no specific arguments other than to state that the additional reference to Horstmann does not overcome the deficiencies of Zerbe '292, Strobush, and Yuhki (Br. 29-30). We additionally note that Horstmann teaches the formation of edible films permitting the individual dosages of drugs, cosmetics, confectionary, and other food (Ans. 11; Horstmann, Abstract; col. 3, ll. 20-24). Furthermore, we determine that giving the claimed term "pharmaceutical actives" its broadest reasonable interpretation consistent with the Specification (¶¶ [0060] and [0061]) includes flavors as taught generally by Zerbe '292 that can also have pharmaceutical action, i.e., honey for a cold, garlic for health benefits, etc. Accordingly, we determine that the use of "pharmaceutical actives" within the scope of claims 104 and 110 in the process of Zerbe '292, as modified by Strobush, would have been obvious to one of ordinary skill in this art.

With regard to the remaining rejections and references, we note that Appellants merely present the same argument as discussed above, namely that the additional reference(s) does not overcome the deficiencies of Zerbe '292, Strobush, and Yuhki (Br. 28-30). Accordingly, we adopt the Examiner's findings of fact and conclusions of law for the rejections involving Wittmer, Zerbe '957, and Mehra, as stated in the Answer.

D. Summary

For the foregoing reasons and those stated in the Answer, we affirm all rejections presented for review in this appeal. The decision of the Examiner is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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