

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Amerilab Technologies, Inc.  
First Named Inventor: Kyle M. Johnson  
Serial No.: 13/113,174  
Filed: May 23, 2011  
Title: EFFERVESCENT COMPOSITION FOR FORMING A GELLED  
COMPOSITION, TABLET FOR FORMING A GELLED COMPOSITION, AND  
METHOD OF MAKING A GELLED COMPOSITION

Art Unit: 1616  
Examiner: Branson  
Confirmation No.: 9118  
Customer No.: 27791

**MAIL STOP APPEAL BRIEF-PATENTS**

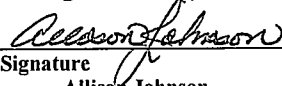
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

REPLY BRIEF

Appellant submits the following Reply Brief in response to the Examiner's  
Answer dated October 5, 2015.

CERTIFICATE OF TRANSMISSION

I hereby certify under 37 CFR §1.8(a) that this correspondence is being electronically transmitted to the United States Patent and Trademark Office, by EFS-Web, on November 18, 2015.

  
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Signature

Allison Johnson

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I. Status of Claims

Claims 1-20 and 28-39 are withdrawn from consideration.

Claims 21-27 and 40-42 are rejected.

II. Grounds of Rejection to be Reviewed on Appeal

A. Whether claims 21-27 and 40-42 are patentable under pre-AIA 35 U.S.C. § 103 over Wehling in view of Silvestrini and Bonanomi et al. and further in view of Pam?

### III. Argument

#### A. Terms

The following explanations of terms are provided to assist the Board in carefully reviewing the cited references and the statements set forth in both the Examiner's Answer, this Reply Brief, and Appellant's Appeal Brief.

Gelatin is a gelatin that forms a gel.

Native Gelatin is a gelatin that forms a gel.

Non-hydrolyzed gelatin is a gelatin that forms a gel.

Partly-hydrolyzed gelatin is a gelatin that does not form a gel and is the type of gelatin used in the Bonanomi et al. examples

Hydrolyzed gelatin is a gelatin that does not gel and is used in the compositions of Pam.

"Gelatin as an active agent" is a term used in Pam to denote gelatin that is either in the form of hydrolyzed gelatin or in the form of a mixture of hydrolyzed gelatin and gelatin.

#### B. Response to the Examiner's Positions

The MPEP 1207.2 states that an examiner must use headings and subheadings that parallel the headings and subheadings utilized in the Appellant's Appeal brief. Here, the Examiner has not followed this requirement. Instead the Examiner's Answer refers to the references "as a whole." The Examiner puts forth his position in general terms that rely on hindsight, hand waiving, and misleading assertions. The Examiner takes this approach because, if he were to use the headings and subheadings in Appellant's Appeal Brief and if he were to directly address Appellant's positions, it would become uncontrovertibly evident that a *prima facie* case of obviousness of claims 21-27 and 40-42 under pre-AIA 35 U.S.C. § 103 over Wehling in view of Silvestrini and Bonanomi et al. and further in view of Pam does not exist and cannot be made.

The Examiner cannot escape the fact that there is nothing in the cited references that teaches or suggests or provides a reason for selectively picking and choosing from among the disclosures in the various cited references to arrive at Appellant's claimed invention. The Examiner's cataloging (in some instances in a misleading way) of various disclosures in the cited references does not supplant the need for identifying a suggestion,

motivation, or reason for selecting from the cited references in such a way so as to arrive at the claimed invention. Here, the only way for a skilled artisan to even attempt to arrive at the effervescent composition of claim 21 from the cited references, would be if he or she used Appellant's Specification as a road map to get there. This is what the Examiner has done. Since this approach constitutes impermissible hindsight, a *prima facie* case of obviousness of claims 21-27 and 40-42 under pre-AIA 35 U.S.C. § 103 over Wehling in view of Silvestrini and Bonanomi et al. and further in view of Pam has not been made. For at least this reason the rejections of record must be overruled.

The rejections of record also must be overruled for at least the following additional reasons. The Examiner's Answer contains numerous references to gelatin. By failing to specify the type of gelatin being discussed by a reference, the Examiner's Answer leaves the reader with the impression that each mention of gelatin refers to the same type of gelatin --a type of gelatin that gels. This is not the case. The gelatins disclosed in the cited references are not the same and are not all of a type that gels. The lack of specificity in the Examiner's Answer obfuscates these differences and borders on misrepresentation.

A careful reading of Appellant's Appeal Brief, Bonanomi et al. and Pam demonstrates the following. Bonanomi et al. and Pam have found that partly-hydrolyzed and hydrolyzed gelatin (both of which are non-gelling gelatins) achieve benefits that are not found in non-hydrolyzed gelatin (i.e., gelling gelatin). Bonanomi et al. intentionally chose to use a gelatin that does not gel because 1) gelatin that gels has been found to cause gastric intolerance, and 2) they wanted to administer amino acids to combat disease associated with a lack of amino acids and had found that a gelatin that gels does not achieve this goal (see, Bonanomi et al., para. [0028]). Bonanomi et al. describe experimental results that demonstrate that the uptake of amino acids from a gelatin that does not gel is about twice as great as compared to the uptake of amino acids from a gelatin that does gel (see, *Id.*, para. [0047] and p. 8, Graphic No. 1).

The Examiner implies that Bonanomi et al. teach including 2500 mg of gelatin that gels in an effervescent tablet (Examiner's Answer, p. 4, l. 3). This is not the case. The gelatin referred to in Bonanomi et al. is partly-hydrolyzed gelatin, which is a gelatin that does not gel (Bonanomi et al., para. [0015]).

The Examiner takes the position that Bonanomi et al. would not have discouraged the skilled artisan from utilizing native gelatin in an effervescent tablet, because Silvestrini discloses that native gelatin can be added to a food product. As demonstrated below, the disclosure of Silvestrini pertaining to gelatin is of no moment in light of the disclosures of Bonanomi et al. and Pam. Bonanomi et al. disclose using their partly-hydrolyzed gelatin as a food additive (see, Bonanomi et al. para. [0026]). Bonanomi et al. also disclose that their partly-hydrolyzed gelatin can be administered in formulations such as effervescent tablets and ready-dissolution granular powders (*Id.*, para. [0048]). In addition, Bonanomi et al. disclose that their partly-hydrolyzed gelatin has the following advantages over native gelatin: 1) it improves treatment acceptability by the patient avoiding the feeling of gastric swelling due to gelation, and 2) it reduces the required doses for obtaining the desired effects (*Id.*, para. [0023]). Therefore the skilled artisan would understand Bonanomi et al. as teaching away from using native gelatin, such as the gelatin used in Silvestrini, as a food additive. Moreover, the skilled artisan would have no reason to ignore the teachings of Bonanomi et al.

The Examiner takes the position that, “ex [vivo] hydration of gelatin would have avoided the negative side effects mentioned in Silvestrini” (Examiner’s Answer, p. 4, para. “(3)”). There is no evidence of record supporting this assertion. Moreover, the skilled artisan would not come to this conclusion because Example 1 of Bonanomi et al. refers to a ready-dissolution granular powder (see Bonanomi et al., para. [0049]; see also, *Id.*, paras. [0051]-[0056]). A ready dissolution granular powder implies that the powder is to be dissolved, and the skilled artisan would further understand that it is to be dissolved prior to administration. Thus, Bonanomi et al. contemplate ex vivo hydration for their composition and expressly teach using a non-gelling gelatin for the same.

Regarding Pam, the statements in the Examiner’s Answer at the paragraph bridging pages 3 and 4 leave the reader with the impression that Pam teaches that a gelatin that gels should be used as a protein active that treats hair thinning and hair loss. Pam contains no such teaching. Rather, Pam discloses that the protein in gelatin is not suitable form for mammalian nutrition (see Pam, p. 2, ll. 18-29). According to Pam,

Although gelatin has been publicized for decades as a good source of protein, there is little hard scientific evidence to support the statements made for gelatin

products. For example, gelatin contains protein, but in an incomplete form for mammalian nutrition.

*Id.* Pam also states that there is no solid evidence that gelatin will help maintain healthy hair and nails (*Id.*).

Gelatin has been promoted as a food supplement to improve hair and nail appearance and growth. In fact, the body already manufactures abundant amounts of the amino acids that gelatin provides and no solid experimental evidence has proven whether extra supplies of these nutrients will help build or maintain healthy hair and nails.

*Id.*

Pam further discloses that it is the hydrolyzed gelatin, also known as non-gelling gelatin, that is the active ingredient that treats hair thinning and hair loss (see, Pam, p. 5, ll. 6-12). In particular, Pam states:

The art has provided inconsistent and conflicting reports regarding the usefulness of gelatin in preventing or reducing hair loss and in promoting hair and nail growth and health. The inventors of the present invention now show, in contradistinction to the hitherto known art, that a daily low oral dose of gelatin is [*sic*] in the form of **hydrolyzed** gelatin or a mixture of hydrolyzed gelatin and gelatin, and in particular, in the form of a malleable edible composition, is able to reduce or prevent hair loss in mammals.

*Id.*, p. 5, ll. 3-12. (Emphasis added.) Thus, Pam found that it was hydrolyzed gelatin and in particular hydrolyzed gelatin in the form of a malleable edible composition that reduces or prevents hair loss in mammals.

Pam also does not disclose administering from 500 mg to 7000 mg of a gelatin that gels, notwithstanding the Examiner's Assertions to the contrary (see, Examiner's Answer, p. 3). Rather, Pam discloses that "the overall dose of the active agent is in the range of from about 0.5 grams to 7.0 grams gelatin per day" (Pam, p. 7, ll. 9-18). As established above, Pam expressly states that the term "gelatin as an active agent" is used to denote gelatin that is either in the form of hydrolyzed gelatin (i.e., non-gelling gelatin) or in the form of a mixture of hydrolyzed gelatin and gelatin. Thus, the most skilled

artisan can glean from this passage is that the overall dose of the non-gelling gelatin could be from 0.5 grams to 7.0 grams.

Pam also expressly comments on the deficiencies of the prior art including those of Silvestrini. In particular Pam notes, “Several dietary supplements and topical formulations are commercially available for treatment of hair loss and the promotion of hair growth. None of the so-called ‘hair growth stimulants’ have proven to be very efficacious,” (*Id.*, p. 1, ll. 13-25). Pam asserts, “[Silvestrini] discloses that lower dosages of gelatin are not sufficient to produce an effect on hair growth. Furthermore, the gelatin, when administered in capsular form, was found to be irritating to the subjects, and was therefore provided in yogurt” (*Id.*, p. 3, ll. 1-5). Pam’s solution is to use a hydrolyzed gelatin, or a mixture of hydrolyzed gelatin and gelatin, and to administer the same in a Gummy Bear-like candy. Therefore Pam does not lead the skilled artisan to the effervescent composition of claim 21.

As has been established in Appellant’s Appeal Brief and in this Reply Brief, there is nothing in the cited references of Wehling, Silvestrini, Bonanomi et al. and Pam that would lead the skilled artisan to decide to include a gelatin that gels in an effervescent composition. The only way the skilled artisan would even think to make such a combination would be if he or she were aware of Appellant’s Specification and used the same as a road map to reconstruct the effervescent composition of claim 21. This would constitute hindsight reconstruction and is impermissible. For at least these additional reasons, the proposed combination of Wehling, Silvestrini, Bonanomi et al. and Pam thus fails to render obvious the composition of claim 21. As such, the rejection of claim 21 under pre-AIA 35 U.S.C. § 103 over Wehling in view of Silvestrini and Bonanomi et al. and further in view of Pam is unwarranted and cannot stand. Appellant again respectfully requests that it be overruled.

Claims 22-27 and 40-42 depend either directly or indirectly from claim 21 and are distinguishable under pre-AIA 35 U.S.C. § 103 over Wehling in view of Silvestrini and Bonanomi et al. for at least the same reasons set forth above. Appellant again respectfully requests that the Patent Trial and Appeal Board overrule these rejections as well.

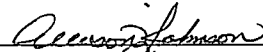


The claims now pending in the application are in condition for allowance and such action is respectfully requested. Appellant requests that the Board overrule the rejections of Record with directions to the Examiner pass the application on to issue.

Please charge any fees or credit any over payments to Deposit Account No. 50-1171.

Respectfully submitted,

Date: November 17, 2015

  
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