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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GUISHENG PAN, PRAKASARAO MANDADI, LIN FEI, and SUMAN KUMAR CHOPRA

Appeal 2019-005101
Application 15/101,153
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant[1] seeks our review, under 35 U.S.C. § 134(a), of the Examiner's decision to reject claims 1–3 and 5–20 (Appeal Brief filed March 18, 2019) ("App. Br.") 3, 5.)

We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the Real Party in Interest as Colgate-Palmolive Company. (*See* App. Br. 2.)

INTRODUCTION

Appellant's Specification provides a teeth cleaning and whitening dentifrice containing a stabilized peroxide, particularly hydrogen peroxide ("H_2O_2") complexed with polyvinylpyrrolidone ("PVP"). (Specification filed January 16, 2018 ("Spec.") ¶¶ 1, 2.) PVP-H_2O_2 complexes are described in US Pat. No. 5,122,370, which the Specification incorporates by reference. (*Id.*) The Specification describes phase separation and bloating as significant challenges for gel dentifrices containing peroxides. (*Id.* ¶ 3.) Unacceptable phase separation can be observed by the unaided eye after storage for 24 hours. (*Id.* ¶ 12.) The Specification describes single-phase dentifrices that are stable during long term storage and include a crosslinked PVP complexed with H_2O_2 and a fatty amphiphile, e.g., stearyl alcohol or cetyl alcohol. (*Id.* ¶ 5.)

Appellant's claim 1 recites:

> A phase separation stable dentifrice composition comprising:
>
> a whitening complex comprising a water insoluble crosslinked polyvinylpyrrolidone complexed with hydrogen peroxide;
>
> a fatty amphiphile selected from fatty C_{12} to C_{28} alcohols or mixtures thereof in an amount of about 0.1 to about 20% by weight of the composition; and
>
> an ethylene oxide-propylene oxide block copolymer.

(App. Br. 8.)

The Examiner rejects the claims as follows:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Final Office Action
1–3, 5–20	112(a)	Written Description	2–4
1–3, 5–20	103	LeBlanc,[2] Zaidel[3]	4–8

ANALYSIS

35 U.S.C. § 112(a), Written Description

The Examiner finds the instant claims recite new matter not supported by the original disclosure, specifically "a water insoluble crosslinked polyvinylpyrrolidone . . . ." (Final Action dated October 18, 2018 ("Final Act.") 3, emphasis added.) The Examiner finds the disclosure of Polyplasdone XL-10 in the original disclosure does not support the instant claims because Polyplasdone XL-10 is only one species of water insoluble crosslinked polyvinylpyrrolidone. (*Id.*) The Examiner finds that Polyplasdone XL-10 is not representative of the genus of water insoluble crosslinked polyvinylpyrrolidone due to variation within the genus in grade, particle size, peroxide specification, bulk density and tap density. (Examiner's Answer dated April 17, 2019 ("Ans.") 4–5.)

Additionally, the Examiner finds Appellant's incorporation by reference of US Pat. No. 5,122,370 ("the '370 patent")[4] does not provide written description support for the instant claims. (*Id.* at 4.) The Examiner finds that the '370 patent teaches PVP-H_2O_2 complexes for treating acne vulgaris and not for whitening teeth. (*Id.*) The Examiner finds the '370

[2] LeBlanc et al., US 2009/0246151 A1, published Oct. 1, 2009.
[3] Zaidel et al., US 2008/0145321 A1, published June 19, 2008.
[4] Merianos et al., US 5,122,370, issued June 16, 1992.

patent discloses a method of making an insoluble PVP-H_2O_2 complex and does not mention crosslinking. (*Id.*) Thus, the Examiner finds that a skilled artisan would not have understood that the inventor possessed the claimed invention based on an objective inquiry of the Specification. (*Id.*)

Appellant argues the Specification discloses water-insoluble polyvinylpyrrolidones used in PVP-H_2O_2 complexes as a class by incorporating the '370 patent by reference. (App. Br. 3., citing Spec. ¶ 2.) Appellant argues the '370 patent discloses both water-soluble and water-insoluble polyvinylpyrrolidones, as well as a method of forming a water-insoluble PVP-H_2O_2 complex. (*Id.*, citing the '370 patent, 2:32–41.)

Appellant argues further that the original specification as filed discloses a whitening complex formed of H_2O_2 and commercially available crosslinked polyvinylpyrrolidone, i.e., Polyplasdone XL-10. (*Id.* at 4.) Appellant argues that Polyplasdone XL-10 was known in the art as a water insoluble crosslinked polyvinylpyrrolidone, as shown by extrinsic evidence. (*Id.*, citing Polyplasdone Product Overview.[5]) Appellant argues that, in view of the known composition of Polyplasdone XL-10 at the time the application was filed, the originally filed application reasonable conveyed possession to those of ordinary skill in the art. (*Id.*)

We are persuaded by Appellant. "What is required to meet the written description requirement 'varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.'" *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005). Both

[5] Ashland Inc., *Polyplasdone™ crospovidone superdisintegrants, Product Overview* (2012), made of record in the Response filed August 3, 2018.

Appellant's Specification and the prior art cited by the Examiner establish that water insoluble crosslinked PVP-H_2O_2 complexes were well known and commercially available in the art. The Specification as a whole refers to whitening complexes comprising "crosslinked polyvinylpyrrolidone." (*See* Spec. *supra*.) The Specification provides a specific example of crosslinked polyvinylpyrrolidone, Polyplasdone XL-10. (*Id.* ¶¶ 15–16.) Appellant established that a person of ordinary skill in the art would have recognized crosslinked Polyplasdone XL-10 as water-insoluble, as shown by the Polyplasdone Product Overview. (Polyplasdone Product Overview 1.) Notably, despite all of the varying grades of Polyplasdone, the species are commonly referred to as "synthetic, insoluble, crosslinked homopolymers of N-vinyl-2-pyrrolidone." (*Id.*)

The prior art confirms what would have been understood by a person of ordinary skill in the art at the time the application was filed. The '370 patent, incorporated by reference, discloses a PVP-H_2O_2 complex including "crospovidone XL10 (water-insoluble cross polymerized PVP)." (*See* Reply Brief filed June 17, 2019 ("Reply Br.") 2, citing '370 patent, 4:25–35.) More generally, the '370 patent explains that "[c]rospovidone is an example of an available water-insoluble PVP material." ('370 patent, 2:56–57.) Moreover, Zaidel, cited by the Examiner to reject the claims, teaches that PVP-H_2O_2 complexes preferably include "insoluble crosslinked" polyvinylpyrrolidone homopolymers, referred to as "cross-povidone, and cPVP." (Zaidel ¶ 34.)

As shown by the Specification and the prior art, water-insoluble crosslinked PVP-H_2O_2 complexes were well known and described in the art.

The compounds were not new or unknown materials that ordinarily skilled artisans would easily miscomprehend. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003). Because we find that the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor possessed the claimed subject matter as of the filing date, we reverse the Examiner's rejection for lack of written description.[6]

35 U.S.C. § 103, Obviousness over LeBlanc and Zaidel

The Examiner finds LeBlanc teaches oral care compositions, e.g., dentifrices, containing a fatty amphiphile, e.g., cetyl alcohol and stearyl alcohol, in an amount of about 0.05% to about 30%. (Final Act. 5, citing LeBlanc Abstr.; ¶¶ 13, 32.) The fatty amphiphile forms a dispersed gel network that may aid in stabilizing a peroxide whitening agent. (*Id.*, citing LeBlanc ¶ 68.) The Examiner finds that LeBlanc teaches oral compositions must have a desired shelf stability as well as be viscous enough to fill into a container. (*Id.*, citing LeBlanc ¶ 4.) The Examiner finds that LeBlanc's oral compositions include two phases, a fatty amphiphile dispersed gel network phase and an oral carrier phase, that "cannot be distinguished" by the naked eye. (*Id.* at 9–10, citing LeBlanc ¶ 20.)

The Examiner acknowledges that LeBlanc does not teach a dentifrice including a crosslinked PVP-H_2O_2 complex and an ethylene oxide-propylene

[6] We do not address the Examiner's objection to the Specification as amended. Final Act. 2. "The propriety of 'objections' and other procedural requirements is solely within the jurisdiction of the Commissioner of Patents." *Ex parte C*, 27 USPQ2d 1492, 1494 n.3 (BPAI 1992).

oxide block copolymer. (*Id.* at 7.) The Examiner finds these claimed components are taught by Zaidel. (*Id.*) Particularly, the Examiner finds Zaidel teaches oral compositions including crosslinked PVP-H_2O_2 complexes, wherein the PVP polymer is preferably an insoluble crosslinked homopolymer. (*Id.*, citing Zaidel ¶¶ 27, 34, 37.) The Examiner also finds that Zaidel teaches the composition may include nonionic block copolymers of ethylene oxide and propylene oxide, which are useful for providing viscosity for the composition. (*Id.*, citing Zaidel ¶ 50.)

The Examiner finds that it would have been obvious to a person of ordinary skill in the art to combine Zaidel's whitening agent and ethylene oxide-propylene oxide copolymer with LeBlanc's compositions based on the recognized suitability of the ingredients for their intended use. (*Id.* at 7–8.) Accordingly, the Examiner concludes the claims would have been *prima facie* obvious over the prior art. (*Id.* at 8.)

Appellant argues "LeBlanc does not teach that the fatty amphiphiles may impart phase-separation stability to the oral care composition." (App. Br. 6.) Rather, Appellant argues that LeBlanc teaches fatty amphiphiles provide storage stability by preventing unwanted increases in viscosity over long periods of time. (*Id.* at 5–6.)

We are not persuaded by Appellant's argument. LeBlanc teaches oral compositions containing fatty amphiphiles that are stable with respect to viscosity and contain multiple phases that are indistinguishable to the naked eye. (*See* LeBlanc ¶¶ 4, 20.) Thus, LeBlanc teaches fatty amphiphile-containing compositions that are phase-separation stable. Moreover, the Examiner has established the combined prior art teaches a composition

substantially similar or identical to the claimed composition. Therefore, the PTO can require an applicant to prove that the prior art products do not necessarily possess the characteristics of the claimed product as the PTO cannot manufacture products or obtain and compare prior art products. *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). Appellant does not provide evidence that contradicts the Examiner's findings.

Appellant argues that a person of ordinary skill in the art would have recognized that water-insoluble PVP would not have been suitable in LeBlanc's compositions because LeBlanc teaches water-soluble PVP as a dispersing agent. (App. Br. 6.) Appellant argues that "the presence of water-soluble polyvinylpyrrolidone directly impacts the resulting surface tensions between components in the oral care composition." (*Id.*)

We are not persuaded by Appellant's argument. LeBlanc teaches numerous fatty amphiphile-dispersing surfactants, including *inter alia*, water soluble alkylated polyvinylpyrrolidone, such as butylated polyvinylpyrrolidone. (LeBlanc ¶ 47.) Appellant provides no evidence that this dispersing surfactant is incompatible with Zaidel's water insoluble, crosslinked PVP-H_2O_2 complex. "An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness." *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997). Moreover, that LeBlanc teaches a number of various optional components, e.g., water-soluble polyvinylpyrrolidone, does not constitute a teaching away from the combination with Zaidel, absent any criticism or discouragement of the combination. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

Appellant argues that the Specification demonstrates "unexpected increase in phase-separation stability." (App. Br. 6; *see also* Reply Br. 3.) Appellant points to Examples 2-4 of the Specification which reportedly show that when fatty amphiphiles are used in an oral care composition in combination with water-insoluble, cross-linked polyvinylpyrrolidone, the fatty amphiphiles impart an unexpected increase in phase-separation stability not taught in LeBlanc. (*See* App. Br. 6–7.) According to Appellant, "the data described in Examples 2-4 demonstrates the unexpected advancement over the cited art, provided by the claimed invention." (App. Br. 7.)

The Specification discloses working Examples 2–4, each containing crosslinked PVP-H_2O_2 and an ethylene oxide-propylene oxide block copolymer, among other components. (Spec. ¶¶ 52–54.) Examples 2 and 3 each contain 7% (w/w) fatty amphiphile, i.e., stearyl alcohol and cetyl alcohol, respectively. (*Id.* ¶¶ 52, 53.) Example 4 contains 0% (w/w) fatty amphiphile. (*Id.* ¶ 54.) The Specification discloses "Examples 2 and 3 . . . are stable in that no phase separation is observed. Example 4 is not stable in that a separation into two distinct phases is observed." (*Id.* ¶ 55.) The Specification does not provide any other data.

Appellant does not explain why phase separation is a significant challenge for gel dentifrices containing peroxides, particularly water insoluble crosslinked PVP-H_2O_2 complexes. Contrary to Appellant's characterization, the Examiner finds that because the compositions of LeBlanc contain fatty amphiphiles one of ordinary skill in the art would have expected the same compositions to be stable against phase separation. (Ans. 8.)

Appellant's argument about unexpected results is not persuasive. Evidence of unexpected results must establish an unexpected difference between the results and the closest prior art. *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991). We begin with what would have been expected in view of the prior art. As discussed above, LeBlanc teaches fatty amphiphiles may aid in stabilizing peroxide whitening agents in tooth whitening dentifrices. (LeBlanc ¶ 68.) Moreover, LeBlanc teaches the need for a composition with acceptable rheology and shelf stability, containing multiple phases that cannot be visually distinguished. (LeBlanc ¶¶ 4, 20.) Likewise, Zaidel teaches a teeth whitening composition including a water-insoluble crosslinked PVP-H_2O_2 complex and an ethylene oxide-propylene block copolymer that remains stable under accelerated aging conditions. (*See* Zaidel ¶ 109.) Although the references do not directly address phase-separation stability, Appellant fails to direct us to any statements in the Specification or to any other evidence that phase-separation stability would have been unexpected. *See Geisler*, 116 F.3d at 1470.

Moreover, the prior art cited by the Examiner includes fatty amphiphiles, unlike Example 4, which is not stable. Therefore, the comparison is not against the closest prior art. *See Baxter Travenol*, 952 F.2d at 392. Rather, in view of the prior art's teachings of stable compositions having non-distinct phases, we agree with the Examiner that it seems likely that the prior art compositions would also have been stable against phase separation. (*See* Ans. 8.) "Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention." 952 F.2d at 392.

Accordingly, we affirm the Examiner's rejection of claim 1. Appellant does not provide separate arguments for the rejection of the dependent claims. (*See* App. Br. 5–7.) Appellant does not provide any separate arguments against the rejection of dependent claims 2, 3, and 5–20. We also affirm the rejection of these dependent claims as being obvious under 35 U.S.C. § 103.

CONCLUSION

Upon consideration of the record and the reasons given, the rejection of claims 1–3 and 5–20 under 35 U.S.C. § 112(a), written description, is not sustained.

The rejection of claims 1–3 and 5–20 under 35 U.S.C. § 103 is sustained.

In summary:

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
1–3, 5–20	112(a)	Written Description		1–3, 5–20
1–3, 5–20	103	LeBlanc, Zaidel	1–3, 5–20	
Overall Outcome			1–3, 5–20	

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

AFFIRMED