Trials@uspto.gov
571.272.7822

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

J. KYLE BASS and ERICH SPANGENBERG,
Petitioners,

v.

ALPEX PHARMA SA,
Patent Owner.

Case IPR2016-00245
Patent 8,440,170 B2

Before TONI R. SCHEINER, LORA M. GREEN, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Messrs. J. Kyle Bass and Erich Spangenberg ("Petitioner") filed a Corrected Petition requesting an *inter partes* review of claims 1–9 of U.S. Patent No. 8,440,170 B2 (Ex. 1001, "the '170 patent"). Paper 5 ("Pet."). Alpex Pharma SA ("Patent Owner") filed a Corrected Preliminary Response to the Petition. Paper 12 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon considering the Petition and the Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–3, 5, 6, 8, and 9. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

Neither Petitioner nor Patent Owner identifies any related matters. *See*, *e.g.*, Pet. 2 ("Petitioner is unaware of any other matter related to the '170 patent").

B. The '170 Patent (Ex. 1001)

The '170 patent issued on May 14, 2013, with Federico Stroppolo and Shahbaz Ardalan as the listed co-inventors. Ex. 1001. As set forth in the '170 patent, "the invention relates to orally disintegrating tablets with speckled appearance for easy identification by physicians, nurses and patents." *Id.* at 1:13–16. According to the '170 patent:

> Orally Disintegrating Tablets (ODT) dissolve in the oral cavity by contact with saliva, do not require water for ingestion and could permit a buccal absorption of the active ingredient.

> The advantageous properties of ODT over conventional tablets are making them always more and more popular for drug administrations.

Id. at 1:38–43.

The ’170 patent teaches that the use of solid or semisolid forms having a speckled appearance is common in cosmetic and laundry products, such as toothpastes and soaps, with the speckled appearance being achieved by incorporating a colored bead comprised of a different material into the composition. *Id.* at 2:4–8. For ODT, the ’170 patent teaches that the

> colored beads must be soluble and dissolve as fast as the tablets to avoid an unpleasant grinding sensation when the tablet disintegrates in the oral cavity. Moreover, the colored beads must be stable, i.e. they must not release the color during storage, and should give minimal coloration of the oral cavity after disintegration of the tablet.

Id. at 2:9–14.

The ’170 patent teaches that the speckled appearance is achieved by using colored granules of a water-soluble sugar, such as sucrose or sorbitol, which are mixed with a pharmaceutically acceptable carrier in the preparation of the ODT. *Id.* at 2:20–39. The colored granules “have a particle size from about 10 µm to about 1200 µm, preferably from about 200 µm to about 800 µm, most preferably from about 300 µm to about 500 µm.” *Id.* at 2:55–58. According to the ’170 patent, the “particle size of the colored granules is critical,” as “[c]olored granules with too small particle size are not visible,” and will not provide a speckled appearance, whereas “the use of colored granules with too large particle size results in a tablet which appears uniformly colored.” *Id.* at 2:49–54.

C. Illustrative Claim

Petitioner challenges claims 1–9 of the '268 patent. Claim 1 is the only independent claim, is illustrative of the challenged claims, and is reproduced below:

> 1. An orally disintegrating tablets with speckled appearance comprising (a) speckles comprising colored granules of a water-soluble sugar, and (b) a pharmaceutically acceptable carrier.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–9 of the '268 patent on the following grounds (Pet. 11):

References	**Basis**	**Claims Challenged**
Prevacid Label®[1] and Stawski[2]	§ 103(a)	1–9
Prevacid Label and Serpelloni[3]	§ 103(a)	1–3, 5, 6, 8, and 9

Petitioner relies also on the Declaration of Kinam Park, Ph.D. Ex. 1002.

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[1] *PREVACID® (lansoprazole) Delayed-Release Capsules; PREVACID® (lansoprazole) For Delayed-Release Oral Suspension; PREVACID® SoluTab™ (lansoprazole) Delayed-Release Orally Disintegrating Tablets*, Medicine Online (June 2007), http://www.medicineonline.com/drugs/p/3694/PREVACID-lansoprazole-Delayed-Release-CapsulesPREVACID-lansoprazole-For-Delayed-Release-Oral-SuspensionPREVACID-SoluTab-lansoprazole-Delayed-Release-Orally-Disintegrating-Tablets.html (Ex. 1004) ("Prevacid® Label").

[2] Stawski et al., Pub. No. US 2006/0193909 A1, published Aug. 31, 2006 (Ex. 1005) ("Stawski").

[3] Serpelloni, U.S. Patent No. 4,744,991, issued May 17, 1988 (Ex. 1006) ("Serpelloni").

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable constructions in light of the Specification of the patent in which they appear. *See* 37 C.F.R. §42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015) ("Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA," and "the standard was properly adopted by PTO regulation."), *cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 890 (2016) (mem.) (No. 15-446). Under the broadest reasonable construction standard, claim terms are presumed to have their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

i. "Orally Disintegrating Tablets"

Patent Owner contends that "orally disintegrating tablets" should be construed as "one that dissolves in the mouth (without requiring water for ingestion) such that absorption of the active ingredient can occur there." Prelim. Resp. 7. Specifically, Patent Owner points to the following teaching of the '170 patent:

> Orally Disintegrating Tablets (ODT) dissolve in the oral cavity by contact with saliva, do not require water for ingestion and could permit a buccal absorption of the active ingredient.

Id. (quoting Ex. 1001, 1:38–41).

Based on the above quoted language and citing *In re Suitco Surface*, 603 F.3d 1255 (Fed. Cir. 2010), and *In re Buszard*, 504 F.3d 1364 (Fed. Cir. 2007), Patent Owner argues that "orally disintegrating tablets" "must mean

tablets which dissolve in the oral cavity by contact with saliva, break down sufficiently in the oral cavity [such] that water is not required for ingestion, and make the tablet's active ingredient component available for buccal absorption." *Id.* at 8. Such a construction, Patent Owner argues, does not encompass a delayed-release orally disintegrating tablet. *Id.* at 9.

We decline to construe the claims as suggested by Patent Owner. Specifically, Patent Owner does not point us to anything in the claims, or the Specification of the '170 patent, that requires dissolution of the tablet in the mouth such that buccal absorption of the active ingredient occurs. The portion of the Specification relied upon by Patent Owner to read the limitation of buccal absorption into the claims, quoted above, states that the orally disintegrating tablets "*could* permit a buccal absorption of the active ingredient." Ex. 1001, 1:38–41 (emphasis added). "Could" does not mean "must" in this context, but is used to express possibility.[4] The use of "could," therefore, suggests that although buccal absorption may occur, it is not required. Thus, for purposes of this decision, we construe "orally disintegrating tablets" as "tablets that dissolve in the oral cavity by contact with saliva, without the need for water for ingestion."

ii. "Colored Granules"

Petitioner argues that the Specification teaches that the granules have a particle size from about 10 µm to about 1200 µm. Pet. 9. Thus, Petitioner asserts that "colored granules" should be construed as "small particles of a size from about 10 µm to about 1200 µm having or having been given color." *Id.*

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[4] *Could Definition*, Dictionary.com, http://www.dictionary.com/browse/could (last visited May 18, 2016).

Patent Owner responds that the "proper construction of 'colored granules' is *granular particles* (*i.e., larger multi-particle entities which are colored differently from the rest of the ODT*)." Prelim. Resp. 12. Patent Owner asserts that Petitioner's construction of "granule" as a "small particle" is not supported by the Specification. *Id.* at 12–13.

In particular, Patent Owner notes that the Specification requires that the "'colored beads' . . . are 'soluble and dissolve as fast as the tablets to avoid an unpleasant grinding sensation when the tablet disintegrates in the oral cavity.'" *Id.* at 11 (quoting Ex. 1001, 2:9–11). Moreover, Patent Owner asserts that the Specification further specifies "that the 'colored beads' are stable, i.e., they must not release the color during storage, and should give minimal coloration of the oral cavity after disintegration of the tablet." *Id.* (quoting Ex. 1001, 2:12–14). According to Patent Owner, those objectives are achieved by "soluble colored beads [that] are 'soluble colored granules [which] are *granular particles* of a water-soluble sugar.'" *Id.* (second alteration in original) (quoting Ex. 1001, 2:35–36).

Patent Owner asserts further that the term "granule" is not coextensive with the term "particle." *Id.* According to Patent Owner,

> Granules are adhered agglomerates of individual particles. This flows from the specification's clear instructions that "colored granules" are not merely any particles, but more precisely the subset "granular particles". The specification's guidance is that such granular particles can be "prepared by granulation of the water-soluble sugars" (col. 3, line 10 *et seq*.). Granulation is typically understood to mean in general technological parlance to mean "the act or process in which primary powders *particles* are made to adhere to from larger, multiparticles entities called *granules*", as corroborated by the annexed entry from Wikipedia (which source is cited to indicate the ubiquity of the

> understanding, without introducing expert testimony on the subject, an option not available to Alpex at this juncture).

Id. at 11–12.

For purposes of this decision, we construe "colored granules" as "small particles of a size from about 10 μm to about 1200 μm having or having been given color, wherein the granules are colored differently from the remainder of the tablet." We have considered Patent Owner's argument that "granule" should be construed as a "multi-particulate entity," but do not find that construction to be supported by the Specification of the '170 patent.

Patent Owner relies on the disclosure in the '170 patent that the "colored granules are granular particles of a water-soluble sugar such as sucrose or a polyalcohol." Ex. 1001, 2:35–36. That teaching, however, does not unambiguously state that the "granules" are aggregates of smaller particles.

Moreover, other parts of the disclosure appear to equate "granule" and "particle." Specifically, the '170 patent teaches that the colored granules "have a particle size from about 10 μm to about 1200 μm, preferably from about 200 μm to about 800 μm, most preferably from about 300 μm to about 500 μm." *Id.* at 2:55–58. The '170 patent teaches further that the "particle size of the colored granules is critical," as "[c]olored granules with too small particle size are not visible," and will not provide a speckled appearance, whereas "the use of colored granules with too large particle size results in a tablet which appears uniformly colored." *Id.* at 2:49–54.

If the term "granule" were to be construed as an aggregate of particles, as Patent Owner would have us do, it is unclear how the teaching of the size of the particle size would be applicable to the size of the granule. Rather, that portion of the Specification infers that the size of the granule is

the size of the particle, thus equating the term "granule" with "particle." The '170 patent teaches further that the particle size is "critical," because the use of particles that are too small may result in no speckling, whereas the use of too large particles results in a tablet that is uniformly colored. Notably, the '170 patent does not discuss how the particles may be aggregated to obtain the required speckled appearance of the tablet.

iii. Other Claim Terms

We determine that, for purposes of this Decision, none of the remaining terms in the challenged claims require express construction at this time. *See, e.g. Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (noting that only claim terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy).

B. Overview of Art Cited by Petitioner

i. Overview of Prevacid® Label (Ex. 1004)

The Prevacid® Label discusses Prevacid® Delayed-Release Capsules, Delayed-Release Oral Suspension, and Delayed-Release Orally Disintegrating Tablets. Ex. 1004, 1.[5]

As to the delayed-release orally disintegrating tablets, the Prevacid® Label teaches:

> Each delayed-release orally disintegrating tablet contains enteric-coated microgranules consisting of 15 mg or 30 mg of lansoprazole (active ingredient) and the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, magnesium carbonate, hydroxypropyl cellulose, hypromellose, titanium dioxide, talc, mannitol, methacrylic acid, polyacrylate,

[5] The page numbers refer to the page numbers added by Petitioner at the bottom of the pages of the exhibit.

> polyethylene glycol, glyceryl monostearate, polysorbate 80, triethyl citrate, ferric oxide, citric acid, crospovidone, aspartamePhenylketonurics: Contains Phenylalanine 2.5 mg per 15 mg Tablet and 5.1 mg per 30 mg Tablet., artificial strawberry flavor and magnesium stearate.

Id.

According to the Prevacid® Label, the enteric-coated microgranules allow for absorption of lansoprazole to begin after the capsules leave the stomach. *Id.* The tablet is not meant to be chewed, but should be placed on the tongue and allowed to disintegrate, with or without water. *Id.* at 10. The tablets usually dissolve within a minute. *Id.* The tablets are "white to yellowish white uncoated tablets with orange to dark brown speckles." *Id.*

ii. Overview of Stawski (Ex. 1005)

Stawski is drawn to "confectionary products having breath freshening attributes," and in particular, "to pressed tablets having an abrasive surface that is suitable for scrubbing the top surface of the human tongue." Ex. 1005 ¶ 2. As taught by Stawski, "[e]xemplary pressed tablets retain their shape in the mouth and slowly dissolve." *Id.* ¶ 9.

Stawski teaches that the abrasive surface may be provided by abrasive particles, which Stawski also refers to as inclusions. *Id.* ¶ 52. Stawski teaches:

> [T]he inclusions will typically be hard particles of at least 100 microns, preferably at least 200 microns, and most preferably at least 400 microns in size, and which are less soluble than the surrounding matrix. The inclusions may be present on the surface to begin with, or may be exposed as the product is dissolved in the mouth to produce a perceivably rough surface.

Id.

As taught by Stawski, the inclusions may be made from a number of different materials, including crystalline sugars or polyols, and may contain flavors and/or colors. *Id.* ¶ 85.

iii. Overview of Serpelloni (Ex. 1006)

Serpelloni is drawn to "a speckled sugarless chewing-gum." Ex.1006, 1:7–8. Serpelloni teaches that "[t]he speckled appearance is generally obtained by means of solid sweetening particles, colored and possibly flavored." *Id.* at 1:29–31.

According to Serpelloni, when sweetener particles are colored by a water-soluble dye, the dye can diffuse into the mass of the chewing gum. *Id.* at 1:67–2:2. In order to prevent that diffusion, the particles of Serpelloni are encapsulated using a water-insoluble coating, such as a "food grade shellac type." *Id.* at 2:16–19. Specifically, Serpelloni teaches that the "colored particles are constituted essentially of sorbitol," and may be sweetened and/or flavored. *Id.* at 1:36–44. The particles also comprise at least one confining agent, which may be a food grade fatty acid, such as stearate, and in particular, magnesium stearate, and a food grade conventional emulsifier, such as fatty acid esters. *Id.* at 2:36–44. The particles are "generally from 500 to 1500 μm and more particularly from 800 to 1200 μm." *Id.* at 1:45–46.

C. Obviousness over Prevacid® Label (Ex. 1004) and Serpelloni (Ex. 1006)

Petitioner contends that claims 1–3, 5, 6, 8, and 9 are rendered obvious by the combination of the Prevacid® Label and Serpelloni. Pet. 23–31. Patent Owner disagrees. Prelim. Resp. 13–17, 20–24, 29–32.

Petitioner relies on the Prevacid® Label for teaching an orally disintegrating tablet that has a speckled appearance. Pet. 23–24. Petitioner

notes further that the Prevacid® Label teaches the use of a pharmaceutically acceptable carrier. *Id.* at 25–26. According to Petitioner, the Prevacid® Label teaches that the tablets contain mannitol, "but does not specifically disclose speckles comprising colored granules of a water-soluble sugar." *Id.* at 24.

Petitioner relies on Serpelloni for teaching "granules of water-soluble sugar" that are used to obtain a speckled appearance, wherein "the colored particles are constituted essentially of sorbitol." *Id.* (quoting Ex. 1006 1:35–36) (emphasis omitted). Petitioner contends:

> As . . . explained by Dr. Park, "[i]t would have been readily obvious to one of ordinary skill in the art that the speckles disclosed by the *Prevacid Label* could have been comprised of the colored granules of a water-soluble sugar such as taught by *Serpelloni*, as *Serpelloni* specifically teaches colored water-soluble sugars imparting a "speckled appearance" (Ex. 1006 col 1:29-31) to a gum-based composition." (Ex. 1002, ¶ 24). As further explained by Dr. Park, "the *Prevacid Label* also teaches water-soluble sugars as acceptable excipients, the use of a colored water-soluble sugar composition would have been obvious to one of ordinary skill in the art with a reasonable expectation that such would have been successful in producing a speckled appearance in a tablet as claimed." (*Id.*)

Pet. 24–25 (alteration in original).

Petitioner argues further that the ordinary artisan would have expected that the colored granules of Serpelloni, which were used to achieve a speckled appearance in chewing gum, "would have been reasonably expected to achieve the same function of imparting a similar speckled appearance to tablets such as the tablet disclosed in the Prevacid tablets." *Id.* at 28 (quoting Ex. 1002 ¶ 24).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such

that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

We conclude that Petitioner has shown a reasonable likelihood that it would prevail in establishing that independent claim 1 would have been obvious over the Prevacid® Label and Serpelloni. In particular, we conclude that there is a reasonable likelihood Petitioner would prevail in showing that it would have been obvious at the time of invention to use the solid particles of Serpelloni, which Serpelloni specifically teaches may be used to achieve a speckled appearance, to produce the speckles in the speckled orally disintegrating tablets taught by the Prevacid® Label. *See, e.g.*, *KSR*, 550 U.S. at 417 ("[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."). We have carefully considered Patent Owner's arguments to the contrary, but they do not convince us otherwise.

Patent Owner argues that the Prevacid® Label does not teach a tablet that enables buccal absorption of the active ingredient, as required by "'an orally disintegrating tablet' consistent with the claim interpretation required for the '170 Patent." Prelim. Resp. 15. Rather, the tablet taught by

Prevacid® Label contains enteric-coated micro-granules of lansoprazole, which results in absorption of the active ingredient only after the micro-granule leaves the stomach. *Id.* at 16.

As discussed above, for purposes of this Decision, we have construed orally disintegrating tablet as not requiring buccal absorption. Thus, the term "orally disintegrating tablet" as used in challenged claim 1 encompasses the orally disintegrating tablet taught by the Prevacid® Label, wherein absorption of the active ingredient occurs after the micro-granule leaves the stomach.

Patent Owner argues further that the Prevacid® Label fails to describe colored granules as required by the challenged claims. Prelim. Resp. 17. Patent Owner argues also that Serpelloni fails to teach "a large multiparticle body comprising smaller particles adhered together." *Id.* at 23, 30.

Again, as discussed above, we declined to construe "granule" as requiring an aggregate of particles. The '170 patent teaches the use of colored granules that "have a particle size from about 10 μm to about 1200 μm, preferably from about 200 μm to about 800 μm, most preferably from about 300 μm to about 500 μm. Ex. 1001, 2:55–58. Serpelloni teaches that its particles are "generally from 500 to 1500 μm and more particularly from 800 to 1200 μm." Ex. 1006, 1:45–46. The ranges taught by Serpelloni overlap with those taught by the '170 patent, and Serpelloni's preferred range is encompassed by the about 10 μm to about 1200 μm range taught by the '170 patent. Thus, the colored particles taught by Serpelloni appear to be encompassed by the term "colored granules" as set forth in challenged claim 1. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (In cases

involving ranges . . . even a slight overlap in range establishes a *prima facie* case of obviousness.").

Patent Owner argues further as to Serpelloni that its particles are encapsulated by a water-insoluble coating, and are intended to be masticated. Prelim. Resp. 20. According to Patent Owner, "*Serpelloni* is devoid of any discussion relating to whether the sweetener particles ever dissolve, or at what rate," and the presence of the insoluble coating "is tantamount to a 'teaching away' from dissolution properties." *Id.* Specifically Patent Owner contends:

> Combination of the two references as suggested in the Petition would require modification of the *Prevacid Label* product to include *Serpelloni's* particles insoluble in the oral cavity. Thus, the *Prevacid Label* product could not be ingested, especially the particles constituting the active ingredient (the *Prevacid Label* teaches against chewing, so the Serpelloni's particles could never be dissolved and the Prevacid Label product would not be ingested in timely fashion). Thus would render the *Prevacid Label* product unsuitable for its intended purpose.

Id. at 32.

Serpelloni teaches the use of colored particles to obtain a speckled appearance. Ex. 1006, 1:29–31. We are persuaded that Petitioner provides sufficient evidence at this stage to indicate it would have been within the level of skill of the ordinary artisan to adapt the particles of Serpelloni to provide the speckled appearance for the orally disintegrating tablets taught by the Prevacid® Label. *See* Ex. 1002[6] ¶ 24; *see also In re Keller*, 642 F.2d

[6] Patent Owner argues that the Declaration of Dr. Park is unreliable, and should be entitled to no deference. Prelim. Resp. 32–34. The Declarant has not been subjected to cross-examination at this point of the proceeding, and we decline to discount it for purposes of this Decision. Moreover, we

413, 425 (CCPA 1981) ("The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art".). Therefore, based on the record before us at this time, Petitioner reasonably contends that an ordinary artisan would have had reason to use the colored particles disclosed in Serpelloni to create a "speckled appearance" (Ex. 1006, 1:29–31), i.e., to create the "orange to dark brown speckles" described in the Prevacid® Label (Ex. 1004, 10). Pet. 23–25 (citing Ex. 1004, 10; Ex. 1006: 1:29–31; Ex. 1002 ¶ 24).

We acknowledge that Serpelloni does not discuss the dissolution rate of the sweetener particles. However, like our appellate reviewing court, "[w]e will not read into a reference a teaching away from a process where no such language exists." *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co*., 464 F.3d 1356, 1364 (Fed. Cir. 2006). Under the proper legal standard, a reference will teach away when it suggests that the developments flowing from its disclosures are unlikely to produce the objective of the invention. *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005). There is no evidence currently of record demonstrating that the ordinary artisan would not expect that the particles of Serpelloni could be used to produce the speckles in the orally disintegrating tablet of the Prevacid® Label.

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determine that the opinion expressed in paragraph 24 of the Declaration is sufficiently supported by the Prevacid Label® and Serpelloni.

Patent Owner does not present any arguments specific to dependent claims 2, 3, 5, 6, 8, and 9. *See* Prelim. Resp. 34. We have reviewed Petitioner's evidence and claim charts as to the challenge of claims 2, 3, 5, 6, 8, and 9 over the combination of the Prevacid® Label and Serpelloni, and conclude that Petitioner has established a reasonable likelihood that it would prevail in showing that those claims also are rendered obvious by those cited references.

For the reasons set forth above, we conclude that Petitioner has established a reasonable likelihood that it would prevail in showing that claims 1–3, 5, 6, 8, and 9 would have been obvious over the combination of the Prevacid® Label and Serpelloni.

D. Obviousness over the Prevacid® Label (Ex. 1004) and Stawski (Ex. 1005)

Petitioner contends that claims 1–9 are rendered obvious by the combination of the Prevacid® Label and Stawski. Pet. 11–23. Patent Owner disagrees. Prelim. Resp. 13–19, 21–29.

Petitioner relies on the Prevacid® Label for teaching an orally disintegrating tablet that has a speckled appearance. Pet. 13. Petitioner notes that the Prevacid® Label teaches that the granules contain mannitol, "but does not specifically disclose speckles comprising colored granules of a water-soluble sugar." *Id.*

Petitioner relies on Stawski for teaching "granules of a water-soluble sugar in tablets." *Id.* at 14. Petitioner relies on the Declaration of Dr. Park, contending that "the 'blue colored mannitol inclusions' mentioned in Stawski were commercially available at the time of the invention and known to be useful as claimed as indicated." *Id.* at 15 (quoting Ex. 1002 ¶ 16). Petitioner further asserts:

> As further explained by Dr. Park, "as the *Prevacid Label* also teaches water-soluble sugars, including mannitol, as acceptable carriers, as well as various dyes, the use of a colored mannitol composition would have been obvious to one of ordinary skill in the art with a reasonable expectation that such would have been successful in producing a speckled appearance in a tablet as specifically disclosed by *Stawski*."

Id. at 16 (quoting Ex. 1002 ¶ 17).

Patent Owner contends that the inclusions of Stawski are meant to survive disintegration of the tablet. Prelim. Resp. 18. In particular, Patent Owner argues that "the inclusions disclosed in *Stawski* are abrasive, and dissolve less rapidly than the surrounding matrix. This is directly contrary to the requirement in the '170 patent that its 'colored granules' dissolve at least as fast as the rest of the ODT." *Id.* at 19.

A determination of unpatentability on the ground of obviousness must include "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). The obviousness analysis "should be made explicit" and it "can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 550 U.S. at 418. We agree with Patent Owner that Petitioner has not sufficiently articulated reasoning, with adequate rational underpinning, in relation to the ground that challenged claim 1 is rendered obvious by the combination of the Prevacid® Label and Stawski.

As noted above, Stawski teaches that its "inclusions" (i.e., particles) are abrasive, and dissolve more slowly than the remainder of the matrix. Ex. 1005 ¶¶ 52–54. Stawski further teaches that its abrasive particles provide an abrasive surface to the product so that the "abrasive surface is suitable for

scrubbing the top surface of the tongue within the oral cavity." *Id*. at ¶ 53. Petitioner has failed to provide a reason, with adequate rational underpinning, as to why the ordinary artisan would have used those abrasive inclusions as speckles in the orally disintegrating tablet of the Prevacid® Label.

III. CONCLUSION

For the foregoing reasons, we are persuaded that the Petition establishes a reasonable likelihood that Petitioner would prevail in showing claims 1–3, 5, 6, 8, and 9 of the '170 patent are unpatentable under 35 U.S.C. §103(a).

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or any underlying factual and legal issues.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. §314(a), an *inter partes* review is hereby instituted on the following grounds:

Claims 1–3, 5, 6, 8, and 9 as obvious over Prevacid® Label and Serpelloni.

FURTHER ORDERED that no other proposed grounds of unpatentability are authorized; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

PETITIONER:

Gregory J. Gonsalves
gonsalves@gonsalveslawfirm.com

PATENT OWNER:

Silvia Salvadori
silvia@salvadorilaw.com

George B. Snyder
gbs@warefressola.com