UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/709,029	09/19/2017	Pratik SHAH	MAR0001-201-US	3029

94164 7590 08/27/2020

GLOBAL PATENT GROUP - GENERAL
c/o MISSOURI PATENT SERVICES
2275 Cassens Drive
SUITE 118
St. Louis, MO 63026

EXAMINER	
SHOMER, ISAAC	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
08/27/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

admin@globalpatentgroup.com
jstthomas@globalpatentgroup.com
lwilson@globalpatentgroup.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PRATIK SHAH and
JOHN CHRISTOPHER CARTER[1]

Appeal 2020-001498
Application 15/709,029
Technology Center 1600

Before JEFFREY N. FREDMAN, ULRIKE W. JENKS, and
JOHN G. NEW, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

---

[1] We use the term "Appellant" to refer to the "applicant" as defined in 37 C.F.R. § 1.142. Appellant identifies MarlinSpike LLC as the real party-in-interest. App. Br. 2.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1–25. Specifically, claims 1–9, 11–12, 14, 16–18, 21, and 23–25 stand rejected as unpatentable under 35 U.S.C. § 103 as being obvious over Rau et al. (US 2010/0034889 A1, February 11, 2010) ("Rau").[2]

Claims 10 and 13 also stand rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Rau and Ramji et al. (US 2013/0344011 A1, December 26, 2013) ("Ramji").

Claim 15 also stands rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Rau and Simon et al. (US 2015/0196469 A1, July 16, 2015) ("Simon").

Claims 19 and 20 also stand rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Rau and Queiroz et al. (US 2014/0242004 A1, August 28, 2014) ("Queiroz").

Claims 22 stands rejected as unpatentable under 35 U.S.C. § 103(a) as being obvious over the combination of Rau and Katayama et al. (US 5,700,449, December 23, 1997) ("Katayama").

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

We AFFIRM.

---

[2] The Examiner also rejected claim 25 as unpatentable under 35 U.S.C. § 112(a) as failing to meet the written description requirement. *See* Final Act. 2. The Examiner has withdrawn this rejection. Ans. 4.

NATURE OF THE CLAIMED INVENTION

Appellant's claimed invention is directed to a dry mouthwash comprising granules that reconstitute in an aqueous solution, such as water, to produce a solution that tastes and functions as a typical liquid mouthwash. Abstr.

REPRESENTATIVE CLAIM

Claim 1 is representative of the claims on appeal and recites:

> 1. A dry mouthwash granule for reconstitution in an aqueous medium, comprising:
>
> an active component, an organic acid component and a carbonate salt component wherein said granule causes an effervescent reaction to occur upon being combined with said aqueous medium;
>
> wherein said granule has a particle size between 53 microns and 1190 microns, and has a density of from about 0.5–1.2 g/cc; and
>
> wherein said dry mouthwash granule is not a tablet.

App. Br. 18.

ISSUES AND ANALYSES

We adopt the Examiner's findings, reasoning, and conclusion that the claims on appeal are *prima facie* obvious over the combined cited prior art. We address the arguments raised by Appellant below.

Issue 1

Appellant argues that the Examiner erred because the combined citedprior art neither teaches nor suggests the limitation of claim reciting "wherein said granule has a particle size between 53 microns and 1190 microns." App. Br. 6.

Analysis

The Examiner finds that Rau teaches a solid effervescent dosage form. Final Act. 5 (citing Rau Abstr.). The Examiner finds that Rau teaches: (1) sodium benzoate, which is known to have antimicrobial properties, as an active agent; (2) citric and malic acids corresponding to the organic acid recited in the claim; and (3) sodium and potassium bicarbonate, which are carbonate salts. *Id.* (citing Rau ¶ 36 Table). The Examiner acknowledges that, although Rau teaches that the table of paragraph [0036] refers to a formulation in the form of a tablet, Rau also teach that its composition can be in the form of granules. *Id.* at 6 (citing Rau Abstr., ¶ 42).

The Examiner further finds that Rau teaches a composition with a minimum size of approximately 14 mesh, corresponding to a particle size of about 1680 microns, which, the Examiner finds, is slightly larger than the maximum diameter of 1190 microns recited by the claims on appeal. Final Act. 6. However, the Examiner reasons, when the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *Id.* (citing MPEP § 2144.05(11)(A).

With respect to the density requirement recited by claim 1, the Examiner finds that Rau teaches a density of 1.1 to 1.6 g/cc, which overlaps with the density range of 0.5 to 1.2 g/cc recited by the claims. Final Act. 7 (citing Rau ¶ 11, claim 1).

Appellant points out that the minimum granule diameter taught by Rau is 41% larger than the maximum claimed diameter and is, Appellant argues, more than a small difference. App. Br. 6. Appellant notes that the ranges taught by Rau and those recited in the claims do no overlap nor,

Appellant asserts, are they close enough that one skilled in the art would have expected them to have the same properties. *Id.* at 6–7.

Furthermore, contends Appellant, the inventor has shown that a meaningful difference exists between the sizes of the claimed granules and the sizes of granules taught in Rau. App. Br. 7. Appellant asserts that the claimed granule sizes, together with the density, gives rise to several advantages in the claimed compositions, including improved powder dispersion and reduced clumping and segregation of the claimed dry mouthwash granules. *Id.* Appellant contends that simply swirling a suspension of granules in water effectively dispersed and dissolved the mouthwash formulation to form a clear solution in a few seconds. *Id.*

In support of this contention, Appellant argues that, within the claimed ranges, the mouthwash granules had several unexpectedly excellent properties. App. Br. 12. Specifically, Appellant points to the Declaration of Dr. Pratik Shah, the inventor of the claimed composition, filed November 19, 2018 (the "Shah Declaration") as demonstrating unexpected results. *Id.* Appellant asserts that, in contrast to tablet formulation, it was discovered that roller compaction and milling improved powder dispersion, reduced clumping, and reduced segregation of the claimed dry mouthwash granules. *Id.* (citing Shah Decl. ¶ 8). According to Appellant, the Shah Declaration states that simply swirling a suspension of granules in water effectively dispersed and dissolved the mouthwash formulation to form a clear solution in a few seconds. *Id.* Appellant argues that the process stabilized hygroscopic components of the mouthwash formulation with non-hygroscopic components (i.e., mannitol), reducing their hygroscopicity and keeping the dry mouthwash granules from clumping. *Id.* at 12–13. Appellant contends that the process also homogenized the dry mouthwash

formulation into granules that resisted segregation compared to ungranulated powders of various particle sizes and densities. *Id.* at 13. Appellant also argues that the claimed compositions, dissolved rapidly in water, with no clumping or floating material in the solution. *Id.* (citing Shah Decl. ¶ 10, Figs. 1, 2B).

Appellant compares these results to those of SuperSmile™, a fine white powder mixed with encapsulated white and yellow beads containing calcium peroxide. App. Br. 13. Appellant asserts that SuperSmile™ has a density outside the claimed density range and was hygroscopic, which caused it to clump in its package. *Id.* (citing Shah Decl. ¶ 9 Fig. 1). Appellant argues that the hygroscopicity of the powder composition led to clumping, requiring pulverization to reduce the particle size enough for dissolution. *Id.* (citing Smigel et al. (US 4,925,655, May 15, 1990 ("Smigel") cols. 3–4, ll. 66–1). Appellant contends that this clumping likely contributed to its poor dissolution; large lumps of undissolved power floated on the surface of the water, and the SuperSmile™ composition did not fully dissolve. *Id.* (citing Shah Decl. ¶ 9, Fig. 2A).

Appellant reasons that, based upon the teachings of the prior art, a skilled artisan would have expected that optimizing the particle size and density to the claimed range would result in something undesired by the prior art, *viz.*, an undesirable dissolution time. App. Br. 13. Consequently, argues Appellant, there would have been no motivation for a person of skill in the art to attempt to optimize the powder to the requirements recited in the claims. *Id.*

We are not persuaded by Appellant's arguments. We acknowledge that there is a gap between the particle size range recited in the claims (53–1190 μm) and that taught by Rau (14 mesh, which the Examiner stipulates

corresponds to approximately 1680 μm). However, the Examiner concludes that it would have been obvious to a person of ordinary skill in the art to have altered the particle size taught by Rau so as to improve the dissolution properties of the composition. *See* Final Act. 6.

Rau supports this conclusion, teaching that: "The time an effervescent product takes to dissolve is affected by several factors. In addition to the environment in which it is used, key among these factors are: its form (tablet, granule or powder); its size and its density; its hardness and the formulation itself." Rau ¶ 23. Rau further teaches that:

> The needs of the marketplace to provide an effervescent composition that effervesces for a desired amount of time, depending on the temperature of the water in which it is placed, is met by … grinding of tablets prepared to the indicated density, and then selecting for a given size range through a sieving process.

Id. at ¶ 11. Rau also teaches that small granules dissolve more quickly in warm water than do large granules (6–10 mesh) or tablets. *Id.* at ¶ 42, table. Rau thus expressly contemplates experimentation and optimization of its composition's properties to obtain optimal results.

Appellant relies upon the Shah Declaration as demonstrating that the particle size range recited in the claims is critical to the allegedly unexpected properties of the claimed composition. The Shah Declaration states that:

> Contrary to tableting, it was discovered that roller compaction and milling improved dispersion, reduced clumping, and reduced segregation of the claimed dry mouthwash granules. Simply swirling a suspension of granules in water effectively dispersed and substantially dissolved the mouthwash formulation to form a clear solution in less than 30 seconds. The process stabilized hygroscopic components of the mouthwash formulation with non-hygroscopic components (i.e. mannitol), reducing their hygroscopicity and keeping the dry mouthwash granules from

> clumping. No sticking was encountered during the process. Free-flowing mouthwash granules resulted. The process also homogenized the dry mouthwash formulation into granules that resisted segregation compared to ungranulated powders of various particle sizes and densities.

Shah Decl. ¶ 8. The Shah Declaration thus states that granulated forms of its compositions have more desirable properties than tableted forms of the same compositions. However, we fail to see the relevance of this statement, because Rau teaches not only tablets, but granule forms that, as explained *supra*, dissolve more quickly than tablets. *See* Rau ¶ 42.

The Shah Declaration next compares the claimed composition to SuperSmile™, which it describes as "a fine white powder mixed with encapsulated white and yellow beads containing calcium peroxide." Shah Decl. ¶ 9. The Shah Declaration attests that "[SuperSmile™] is a fine power which caused it to clump in its package. This clumping likely contributed to its poor dissolution, where large lumps of undissolved power floated on the surface of the water. Thus, [SuperSmile™] did not fully dissolve." *Id.* (internal reference omitted).

We are not persuaded of the relevance of this argument either. "[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art." *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991). The prior art reference closest in its teachings to the claimed composition is Rau, upon which the Examiner relies. The Examiner finds that Rau teaches compositions similar to that claimed by Appellant, comprising "an active component, an organic acid component and a carbonate salt component," as recited in the claims. *See* Final Act. 5. Moreover, and as we have explained, Rau invites experimentation with granule size as a defining factor

in the dissolution rate of its compositions. *See* Rau ¶¶ 11, 23. The question before us, then, is whether the difference in particle size range between those taught by Rau and those recited in the claims is sufficient to render the properties of the compositions recited in the claims patentably distinct over those taught by Rau.

We conclude that it does not. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955). However, this rule is limited to cases in which the optimized variable is a "result-effective variable." *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (citing *In re Antonie*, 559 F.2d 618, 620 (C.C.P.A. 1977); *see also In re Boesch*, 617 F.2d 272, 276 (C.C.P.A. 1980) (holding that "discovery of an optimum value of a result effective variable ... is ordinarily within the skill of the art").

There is little question, as we have explained, that granule size is a result effective variable: Rau teaches that smaller granules dissolve more quickly than larger granules. *See* Rau ¶ 42. Given the relatively small difference between the upper range of the particles recited in the claims and the lower limit of those taught by Rau (1.2 mm *versus* 1.7 mm, respectively), we conclude that it would be within the ordinary skill of an artisan to optimize the granule size of Rau to within the claimed range.

This conclusion could be overcome by Appellant if the claimed particle size range exhibited properties that would be unexpected or surprising to a skilled artisan. "To be particularly probative, evidence of unexpected results must establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art at the time

of the invention." *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014). However, Appellant fails to adduce any relevant evidence to support their contention that there is a criticality to the claimed particle size range that produces unexpected results. Appellant does not demonstrate any unexpected differences between the properties of its claimed range of particle sizes and those recited by the closest prior art (Rau). Rather, Appellant relies upon the Shah Declaration, which makes comparisons between the claimed composition and: (1) tableted forms of the claimed composition; and (2) SuperSmile™, a "fine white powder mixed with encapsulated white and yellow beads containing calcium peroxide." *See* Shah Decl. ¶¶ 8–9. Neither of these is directly comparable to the compositions taught by Rau, which constitute the closest prior art.

Because Appellant has not met the burden of demonstrating that the claimed particle size range imparts properties that would be unexpected or surprising to a person of ordinary skill in the art, we are not persuaded by Appellant's arguments.

Issue 2

Appellant argued that the Examiner erred in finding that Rau teaches the limitation reciting "wherein said granule … has a density of from about 0.5–1.2 g/cc." App. Br. 7–8.

Analysis

Appellant contends that, although the range of granule densities taught by Rau overlaps with the required density range of 0.5 to 1.2 g/cc recited in the claims, Rau, when taken as a whole, is directed away from the claimed

"low density" granules and is instead directed toward "high density" granules to achieve the desired dissolution time frame. App. Br. 8.

Appellant contends that Rau teaches a different manufacturing process that creates granules that are denser, more compressed granules than those claimed. App. Br. 8. By way of example, Appellant points to dependent claim 25, which further distinguishes density range, requiring 0.5 to 0.8 g/cc. Appellant therefore argues that not all of the claimed ranges overlap and, in those instances in which they do, there would have been no motivation for a person of skill in the art to modify the ranges. *Id.*

Appellant argues further that the granule density alone is not the salient issue in the present appeal. App. Br. 8. Rather, argues Appellant, it is the granule size and density that together give rise to the claimed dissolution time, which differs significantly from that taught by Rau. *Id.*

Appellant contends that Rau teaches compositions that are intended to create long dissolution times. App. Br. 8. According to Appellant, there would have been no motivation for a skilled artisan to modify the particle sizes and densities of Rau, because doing so would render its compositions inoperable for their intended purpose. *Id.* Appellant argues that the granules recited in the claims "substantially dissolve when placed in water of 60–150°F [15–65.5°C] in less than 30 seconds." *Id.* at 8–9 (quoting dependent claim 6). By contrast, Appellant asserts, Rau teaches that "less than half a minute is too little" for dissolution in warm liquids. *Id.* (quoting Rau ¶ 14).

Appellant argues that Rau intentionally designed denser and larger granules to have a longer dissolution time. App. Br. 9 (citing Rau ¶ 5). According to Appellant, Rau teaches "granules of a density of about 1.1–1.6 g/cc, and preferably 1.3–1.6 g/cc, either by direct formation, or by grinding of tablets prepared to the indicated density, and then selecting for a given

size range through a sieving process." *Id.* (quoting Rau ¶ 1). To accomplish this, argues Appellant, Rau teaches a different manufacturing process that creates denser, more compressed particles that are distinct from the claimed particles. *Id.* Appellant asserts that Rau teaches that:

> [A]n optimum dissolution time frame is achieved by providing an effervescent combination of acid and carbonate ... that is then compounded into mini-tablets or high density granules exhibiting a density of about 1.3–1.6 g/cc and exhibit a sustained dissolution time frame within the "consumer interest" window of about 30–120 seconds, give or take 10%.

Id. (quoting Rau ¶ 43). Appellant asserts that the claims on appeal do not recite "mini-tablets" or "high density granules." *Id.*

Appellant argues further that, although Rau teaches the duration of effervescence at paragraph [0005], in this context, effervescence is a function of dissolution. App. Br. 10. Appellant asserts that the acid-base pair in the compositions of Rau (or in the claimed invention) does not effervesce until dissolved and, in both cases, remains storage-stable while dry. *Id.* Appellant asserts that, as the components dissolve, they react with each other to generate carbon dioxide in solution, i.e., to effervesce, and the faster they dissolve, the more quickly they effervesce. *Id.* Conversely, Appellant argues, the slower they dissolve, the more slowly they effervesce. *Id.* Appellant also asserts that dissolution is faster for smaller particles, for lower densities, and at higher temperatures. *Id.*

Therefore, Appellant reasons, a person of ordinary skill in the art would have understood that the time periods for dissolution and effervescence are the same, because effervescence occurs during dissolution and ceases when dissolution completes. App. Br. 10. As such, argues Appellant a skilled artisan would also have understood that Rau's

requirement that effervescence be greater than 30 seconds teaches away from the requirement that the claimed composition dissolve in less than 30 seconds. *Id.* Appellant asserts that the reason that the difference between the claimed range and the prior art range is critical is because the different ranges lead to different dissolution times, which coincide with the duration of effervescence. *Id.*

We are not persuaded by Appellant's arguments. With respect to the limitation reciting the required granule density, independent claim 1 recites that the "granule … has a density of from about 0.5–1.2 g/cc." Dependent claim 25, the only other claim with a density requirement, recites: "The dry mouthwash granule of claim 1, having a density from 0.5 g/cc to 0.8 g/cc." App. Br. 20. Rau teaches:

> The needs of the marketplace to provide an effervescent composition that effervesces for a desired amount of time, depending on the temperature of the water in which it is placed, is met by providing "mini-tablets" or granules of a density of about 1.1-1.6 g/cc, more preferably 1.3–1.6, either by direct formation, or by grinding of tablets prepared to the indicated density, and then selecting for a given size range through a sieving process. Preferably, the products of the invention exhibit effervescence over 30–120 seconds when placed in warm liquids.

Rau ¶ 11. Rau thus teaches a range of granule densities that overlap the ranges of all of the claims except dependent claim 25, to which it is closely adjacent. "In cases involving overlapping ranges, we and our predecessor court have consistently held that even a slight overlap in range establishes a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003). Moreover, "a prima facie case of obviousness exists when the claimed range and the prior art range do not overlap but are close enough

such that one skilled in the art would have expected them to have the same properties." *Id.* Because the density range of the granules taught by Rau substantially overlaps the range recited by claim 1 and its dependent claims except claim 25, the Examiner has established a *prima facie* case of obviousness of the claims over Rau. Furthermore, because Appellant has provided no evidence that there is a critical or unexpected difference in the properties of granule densities between the range of Rau and that of claim 25, we similarly conclude that the Examiner has established a *prima facie* case of obviousness with respect to that claim.

Appellant attempts to rebut the Examiner's *prima facie* case of obviousness by arguing that both particle size and density are critical to the dissolution properties of its claimed invention. However, only dependent claim 6 recites any dissolution properties, and so Appellant's argument is relevant only to dependent claim 6 and not to the remaining claims on appeal.

Dependent claim 6 recites: "The mouthwash granule as recited in claim 1, which substantially dissolves when placed in water of 60–150°F in less than 30 seconds." App. Br. 18. Rau teaches small granules (10–14 mesh) of its compositions that dissolve in 13 seconds in water at 45°C (113°F). Rau ¶ 42. Rau also teaches that:

> *[A]n optimum dissolution time frame* is achieved by providing an effervescent combination of acid and carbonate, and then functional additives (colloidal oatmeal, various extracts oils and fragrances, together with aesthetic additives (fragrance, colorants and the like) to arrive at a final composition that is then compounded into mini-tablets or high density granules exhibiting a density of about 1.3–1.6 g/cc and exhibit a sustained dissolution time frame within the "consumer interest" window of *about 30–120 seconds*, give or take 10%.

Id. at ¶ 43 (emphases added). Rau also teaches that small, high-density granules (10-14) can dissolve in 13 seconds in water at 45ºC (113ºF). *Id.* at ¶ 42. Again, Rau teaches values for dissolution times that substantially overlap those recited in claim 6. Furthermore, although Rau teaches that dissolution times of 30–120 seconds are the "optimum" and "within the 'consumer interest' window," the fact remains that Rau also teaches shorter dissolution times and, in performing our obviousness analysis, "all disclosures of the prior art, including unpreferred embodiments, must be considered." *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989).

Finally, Appellant contends that Rau teaches away from Appellant's claimed invention in preferring longer dissolution times. The evidence we have quoted *supra* do not support that contention. Although Rau expressly teaches "optimum" dilution times, Rao also expressly teaches times that are less than 30 seconds for small granule compositions.

A reference teaches away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed.Cir.1994). Appellant points to no passage of Rau which would expressly discourage or divert a person of ordinary skill in the art from following the path taken by the Appellant. *See also In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (holding that: "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed"). Consequently we are not persuaded by Appellant's arguments.

Issue 3

Finally, Appellants argue that the teachings of Ramji, Simon, Queiroz, and Katayama, alone or in combination, do not cure the alleged deficiencies of Rau. App. Br. 14. We have explained *supra* why we are not persuaded by Appellant's arguments that Rau fails to teach or suggest the limitations disputed by the Appellant. We consequently affirm the Examiner's rejection of the claims.

CONCLUSION

The Examiner's rejection of claims 1–25 under 35 U.S.C. § 103 is reversed.

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

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–9, 11–12, 14, 16–18, 21, 23–25	103	Rau	1–9, 11–12, 14, 16–18, 21, 23–25	
10, 13	103	Rau, Ramji	10, 13	
15	103	Rau, Simon	15	
19, 20	103	Rau, Queiroz	19, 20	
22	103	Rau, Katayama	22	
Overall Outcome			**1–25**	