



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

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
12/372,328 02/17/2009 Jantzen A. Cole W63747 1120.2 9469

26158 7590 10/28/2016
WOMBLE CARLYLE SANDRIDGE & RICE, LLP
ATTN: IP DOCKETING
P.O. BOX 7037
ATLANTA, GA 30357-0037

Table with 1 column: EXAMINER
NELSON, CHRISTINE L

Table with 2 columns: ART UNIT, PAPER NUMBER
3774

Table with 2 columns: NOTIFICATION DATE, DELIVERY MODE
10/28/2016 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):

IPDocketing@WCSR.COM

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

*Ex parte* JANTZEN A. COLE, MICHAEL E. CARROLL,  
JON P. MOSELEY, and KELLY C. RICHELSON

---

Appeal 2014-009067  
Application 12/372,328  
Technology Center 3700

---

Before LYNNE H. BROWNE, THOMAS F. SMEGAL, and  
GORDON D. KINDER, *Administrative Patent Judges*.

BROWNE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Jantzen A. Cole et al. (Appellants) appeal under 35 U.S.C. § 134 from the rejection of claims 38–41, 43–46, 48, and 49. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

### CLAIMED SUBJECT MATTER

Claim 38, reproduced below, is illustrative of the claimed subject matter:

38. An injectable bone graft material paste composition comprising a mixture of a powder component, a diluent, and an accelerant in an amount of up to 0.2% by weight, the powder component comprising calcium sulfate hemihydrate prepared by immersing calcium sulfate dihydrate in a solution of water and an inorganic salt to form a mixture, and heating the mixture to substantially its boiling point at atmospheric pressure such that the calcium sulfate dihydrate is converted to calcium sulfate hemihydrate, and the diluent being present in an amount sufficient to provide a diluent to powder weight ratio between 0.19:1 and 0.31 :1, wherein the mixture is in the form of an injectable bone graft material paste.

### REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Hoggatt	US 2,616,789	Nov. 4, 1952
Burkard	US 3,870,538	Mar. 11, 1975
Snyders	US 5,425,769	June 20, 1995

### REJECTIONS

- I. Claims 38–41, 44–46, and 49 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Hoggatt and Snyders.
- II. Claims 43 and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hoggatt, Snyders, and Burkard.

## DISCUSSION

### *Rejection I*

Appellants argue claims 38–41, 44–46, and 49 together. Appeal Br. 6–18. We select independent claim 38 as the representative claim, and claims 39–41, 44–46, and 49 stand or fall with claim 38.

The Examiner finds that the combined teachings of Hoggatt and Snyders disclose or suggest all of the limitations of claim 38. *See* Final Act. 2–3. Appellants contend that Hoggatt is non-analogous art. Appeal Br. 6. In support of this contention, Appellants argue that “Hoggatt . . . is an industrial patent and is not directed to the same field of endeavor of bone graft substitute materials” and that “Hoggatt is not reasonably pertinent to the problems addressed by the present invention, of improving working time, injectability, or set time (particularly, with regard to a bone graft substitute material).” Appeal Br. 7–8; *see also* Reply Br. 2–3.

The Examiner responds to this argument by noting that Snyders points out that gypsum plasters having Hoggatt’s composition “have long been known to be not only suitable, but desirable, for use in . . . bone graft materials.” *See* Ans. 4. Hoggatt is directed to a method of producing “calcium sulphate in the form of calcium sulphate hemihydrate ( $\text{CaSO}_4\frac{1}{2}\text{H}_2\text{O}$ ) from calcium sulphate dihydrate ( $\text{CaSO}_4\cdot 2\text{H}_2\text{O}$ ).” Hoggatt 1:2–4. Hoggatt does not specify a use for its gypsum plaster. As noted by the Examiner, Snyder states that “CS [calcium sulphate] alone is still unable to mimic closely enough the mechanical properties of bone. However, I have discovered that CS mixed in certain proportions with reconstituted fibrillar collagen provides the desired properties and requirements of ideal bone substitutes.” Snyders 5: 20–25. Thus, Snyders provides evidence that

gypsum plasters, such as Hoggatt's gypsum plaster are known to be used as bone substitutes. Thus, Hoggatt can fairly be considered to be concerned with this field of endeavor.

Moreover, responding to Appellants' argument that "Hoggatt is not reasonably pertinent to the problems addressed by the present invention, of improving working time, injectability, or set time (particularly, with regard to a bone graft substitute material)," (Appeal Br. 7–8), the Examiner determines that a problem with which Appellants were concerned is the provision a gypsum plaster that in paste form is "'workable' for sufficient time to enable precise placement and shaping of the composition in a desired setting before the composition hardens." *See* Ans. 4. Appellants do not contest the Examiner's determination. *See, generally*, Reply Br. Thus, Hoggatt is analogous art under both tests for analogous art.<sup>1</sup>

Next, Appellants argue that "the Examiner has not established initially what the level of ordinary skill is in the pertinent art." Appeal Br. 9. "While it is always preferable for the factfinder to specify the level of skill it has found to apply to the invention at issue, the absence of specific findings on the level of skill in the art does not give rise to reversible error where the prior art itself reflects an appropriate level and a need for testimony is not

---

<sup>1</sup> "Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *In re Clay*, 966 F.2d 656, 658–59 (Fed. Cir. 1992) (*citing In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986); *In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979)). *Id.*, 966 F.2d at 659.

shown.” *Okajima v. Bourdeau* 261 F.3d 1350, 1355 (Fed. Cir. 2001) (Citing *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed.Cir.1985)). In this case, the prior art reflects an appropriate level of skill in the art. Thus, Appellants do not apprise us of error.

Appellants further argue that the rejection is “based on improper hindsight and not on what one of skill in the art actually would have done . . . the Examiner has relied upon the present application as a roadmap to identify nondescript portions of the cited art to combine without any real rational underpinning.” Appeal Br. 9. However, Appellants do not identify any knowledge relied upon by the Examiner that was gleaned only from Appellants’ disclosure and that was not otherwise within the level of ordinary skill at the time of the invention. *See In re McLaughlin*, 443 F.2d 1392 (CCPA 1971). Accordingly, Appellants do not apprise us of error.

In addition, Appellants contend that “[o]ne of skill in the art would have no motivation to look from the industrial teachings of Hoggatt to a reference directed to medical application to modify the materials disclosed therein.” Appeal Br. 9–10. In support of this contention, Appellants argue that “one of skill in the art, looking to modify a medical material for incorporating within the human body would not look to an industrial reference for guidance in modifying that medical material.” *Id.* at 10; *see also id.* at 12–13 and Reply Br. 3. This argument is foreclosed by *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), in which the Court rejected the rigid requirement of a teaching or suggestion or motivation to combine known elements in order to show obviousness. *KSR*, 550 U.S. at 415. The Court noted that an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for

a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418. Moreover, the Court instructs us that “familiar items may have obvious uses beyond their primary purposes.” *Id.* at 550 U.S. 420. In this instance, Snyder demonstrates that gypsum plaster (a familiar item), such as that disclosed by Hoggatt, has an obvious use as a bone substitute material. *See, e.g.*, Snyder 5:20–25. Thus, Appellants’ argument is unconvincing.

In addition, Appellants argue that “the Examiner has pointed to nothing showing that an amount of accelerant relevant to a bone substitute material would be relevant to an amount of accelerant useful for gypsum plasters for industrial purposes, e.g., as disclosed in Hoggatt.” Appeal Br. 11 (emphasis omitted); *see also* Reply Br. 3. However, as discussed *supra*, Snyder teaches that gypsum plasters, such as those disclosed by Hoggatt, are known to be used as bone substitutes. *See* Snyder 5:20–25. Thus, Hoggatt’s discussion of the use of accelerant in its gypsum plaster is relevant to the use of such gypsum plaster as a bone substitute.

Appellants also contend that “the Examiner is not free to pick and choose selected teachings from a reference, while ignoring others.” Appeal Br. 11. In support of this contention, Appellants cite “*Bausch & Lomb Inc. v. Barnes-Hind Inc.*, 796 F.2d 443, 448 (Fed. Cir. 1986), quoting *In re Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965). *Id.* at 12. However, The Supreme Court, in *KSR*, has provided guidance when addressing a concern about picking and choosing.

For over a half century, the Court has held that a “patent for a combination which only unites old elements with no change in their respective functions ... obviously withdraws what already is known into the field of its monopoly and diminishes the

resources available to skillful men.” *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152–153 (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

*KSR* 550 U.S. at 415-16. Thus, Appellants’ argument is unconvincing.

Noting that the rejection refers to the section of Snyder from column 5, line 67 to column 6, line 7 to teach optimization of an accelerant, Appellants argue that:

the Examiner has alleged that one of ordinary skill in the art would view this single section as suggesting optimization of the amount of an accelerant in a bone graft substitute composition even though: (1) the section does not expressly mention accelerants as a component of such compositions; and (2) the section provides absolutely no guidance as to appropriate weight percentages of an accelerant.

Appeal Br. 12 (emphasis omitted).

Appellants’ argument is not responsive to the rejection as articulated by the Examiner. The rejection relies upon the combination of Hoggatt’s teaching of varying amounts of accelerant as a component in a gypsum plaster (Hoggatt 15:45–47) and the optimization of the components of a gypsum plaster discussed *supra*. See Final Act. 2–3. The Examiner determines that these combined teachings render the limitation at issue obvious. Appellants do not explain why Snyder’s teachings would not apply to Hoggatt’s gypsum plaster components. Thus, Appellants do not apprise us of error.

Next, Appellants argue that “it is not believed that the cited art provides sufficient guidance to enable the Office to argue that it would be mere optimization to arrive at the presently-claimed accelerant amounts,”

because “[w]ithout any weight percentage range taught in the cited art, there is obviously no way to say the claimed amount overlaps or is close to the amounts taught in the cited art.” Appeal Br. 13. Responding to this argument, the Examiner explains that:

While it is acknowledged that no specific range of percentage of accelerant is disclosed by either Hoggatt or Snyders, clearly the lower end of the range is 0%, since neither reference says that an accelerant is a required component in the calcium sulfate hemihydrate composition, which is the same lower end of the range covered by independent claim 38.

Ans. 5. Hoggatt states:

The product produced by the process of the invention may have a setting time generally in the range between 5 to 25 minutes without the addition of retarders or accelerators. This product, however, may have its setting time accelerated or retarded by the addition thereto of accelerators or retarders which are known in the art and which ordinarily are used in connection with gypsum plasters.

Hoggatt 15:41–49. Thus, the Examiner is correct that Hoggatt clearly contemplates a range of zero to a known amount of accelerant.

Further, Hoggatt’s teaching illustrates that the amount of accelerant is a result-effective variable. The lack a specific numerical value assigned to Hoggatt’s known amount of accelerant does not negate Hoggatt’s teachings. “[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 (CCPA 1955). A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618 (CCPA 1977). “The

law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . in such a situation, the applicant must show that the particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range.” *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir.1990). The Examiner has shown that accelerant in a gypsum plaster is a result-effective variable such that optimization of that variable in not inventive. *Aller*, 220 F.2d at 456. Appellants have not shown that the particular range is critical. Thus, Appellants’ argument is unconvincing.

Finally, Appellants contend that “the evidence of unexpected and surprising results should be viewed as overcoming the rejection.” Appeal Br. 14 (referring to the Declaration of Mr. Jon P. Moseley, hereinafter “Declaration,” filed August 30, 2011); *see also* Reply Br. 4–5. In support of this contention, Appellants argue “the specific variables chosen for the claimed materials lead to a composition having surprising results.” *Id.* at 15. However, claim 38 does not recite specific variables. *See* Appeal Br. 21. Rather, claim 38 discloses a range for the percentage by weight of accelerant and a diluent to powder weight ratio. *Id.*

As further evidence of unexpected results, the Declaration provides the results of “[t]ests comparing the injectability of a composition encompassed by the present invention and that of a MIIG<sup>® 115</sup> composition.”<sup>2</sup> Dec. 3. “[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.

---

<sup>2</sup>MIIG<sup>® 115</sup> composition is a one of the brand materials marketed by Wright Medical Technology, Inc. the assignee of the instant invention. *See* Dec. 2.

Cir. 1991). Here, Appellants considers a MIIG<sup>® 115</sup> composition to be the closest prior art. *See* Dec. 2–5. We do not agree that a MIIG<sup>® 115</sup> composition constitutes the closest prior art.

Although we appreciate the difficulty of determining the closest prior art, nonetheless, “[a] comparison of the claimed invention with the disclosure of each cited reference to determine the number of claim limitations in common with each reference, bearing in mind the relative importance of particular limitations, will usually yield the closest single prior art reference.” *In re Merchant*, 575 F.2d 865, 868 (CCPA 1978). In this case Hoggatt, not a MIIG<sup>® 115</sup> composition, is the closest prior art. As noted by the Examiner, “the only difference between the composition of Hoggatt and the composition as claimed is the upper limit of the weight percentage of the optional accelerant recited in the claim, which upper limit is not disclosed by Hoggatt.” (Ans. 7; *see also* Hoggatt 16:14–19). The MIIG<sup>® 115</sup> composition differs from the claimed invention in that it includes 1.76% stearic acid in addition to an increased amount (0.15% rather than 0.0125%) of calcium sulfate accelerator. Dec. 4. Here, Hoggatt and the MIIG<sup>® 115</sup> composition have the same number of features in common with the claimed invention, but the MIIG<sup>® 115</sup> composition has additional features not in common with claimed invention. Thus, Hoggatt constitutes the closest prior art.

Appellants have not adequately explained why the alleged improvements shown in the Declaration are significant and unexpected relative to closest prior art, namely, Hoggatt. Moreover, Appellants have not shown that the allegedly unexpected and surprising results in the comparison of the instant invention and the MIIG<sup>® 115</sup> composition are due to the

increase in the amount of accellerant, rather than the removal of the stearic acid. Accordingly, the Declaration does not provide a comparison of the claimed invention to the closest prior art, and thus, does not support a showing of unexpected or surprising results.

In the Reply Brief Appellants argue that “0% is not the lower end of the range recited in the pending claims, as an accelerant is a required component of the claimed compositions.” Reply Br. 4. Claim 38 recites “an accelerant in an amount of up to 0.2% by weight” which implies a range from 0 to 0.2. The Specification, which describes, “the accelerant forming, by weight, from 0% to 0.2% of the powder” supports this claim construction. Spec. ¶ 16. Thus, Appellants’ argument is unconvincing.

In conclusion, after reviewing all of the evidence before us, including the totality of Appellants’ evidence, it is our conclusion that, on balance, the evidence of obviousness discussed above outweighs the evidence of nonobviousness submitted by Appellants and, accordingly, the subject matter of claim 38 would have been obvious to one of ordinary skill in the art within the meaning of 35 U.S.C. § 103(a) at the time Appellants’ invention was made.

Accordingly, we sustain the Examiner’s decision rejecting claim 38, and claims 39–41, 44–46, and 49, which fall therewith.

#### *Rejection II*

Appellants do not present separate arguments for the patentability of claims 43 and 48, which depend from claim 38. Accordingly, we also sustain the Examiner’s decision rejecting these claims.

Appeal 2014-009067  
Application 12/372,328

DECISION

The Examiner's rejections of claims 38–41, 43–46, 48, and 49 are  
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). *See* 37 C.F.R.  
§ 1.136(a)(1)(iv).

AFFIRMED