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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BRIAN M. HATCHER, ANTHONY BRENNAN,
BRIAN CUEVAS, and CHARLES SEEGER¹

Appeal 2015-05296
Application 13/690,538
Technology Center 1600

Before DONALD E. ADAMS, TIMOTHY G. MAJORS, and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

NEWMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims to a bioactive sol-gel solution. The Examiner entered final rejections for obviousness.

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

STATEMENT OF THE CASE

The Specification discloses: “[t]he invention concerns a bioactive sol solution, a bioactive gel, and bioactive glass (BG), each combined with a biocompatible polymer to form a composite, and methods for producing the

¹ Appellants identify the Real Party in Interest as the University of Florida. App. Br. 2.

same. The BG composite can be provided in a variety of forms, including fibers, particulates, spheres, coatings, and foamed scaffolds.” Spec. ¶ 11. “A bioactive sol-gel solution comprises a biocompatible polymer, a gelable inorganic base material, and at least one calcium and phosphorous molecular species.” *Id.* at ¶ 15.

The following rejection is before us to review (Ans. 2–3):

Claims 1 and 4–10 stand rejected under 35 U.S.C. § 103(a) as obvious over Dunn ’552,² Orefice,³ and Dunn ’334.⁴ Claim 1 illustrates the appealed subject matter and reads as follows:

1. A bioactive sol-gel solution, comprising:
a biocompatible polymer, a gelable inorganic base material, wherein the gelable base material is selected from the group consisting of alkoxysilanes, aluminates, titanates and borates; and
at least one calcium and phosphorous molecular species;
where the calcium molecular species is calcium oxide and
where the phosphorus molecular species is phosphorus pentoxide.

App. Br. 7, Claims App’x.

ISSUE

Does a preponderance of the evidence relied upon by the Examiner support a conclusion of obviousness?

² Dunn et al., US 5,599,552, issued Feb. 4, 1997 (“Dunn ’552”).

³ Orefice et al., *Novel sol-gel bioactive fibers*, October 2000, Jon Wiley & Sons (“Orefice”).

⁴ Dunn et al., US 5,200,334, issued Apr. 6, 1993 (“Dunn ’334”).

FACTUAL FINDINGS (FF)

FF 1. Dunn '552 discloses:

The invention is directed to a composition composed of a thermoplastic or thermosetting polymer which is capable of forming a biodegradable and/or bioerodible microporous, solid or gelatinous polymer matrix. The matrix is useful as an implant in animals for enhancing regeneration of cells and tissue, such as bone and nerve cells, or for delivery of biologically-active substances to tissue or organs. The composition is administered to an implant site as a liquid. The invention also includes a method of preventing and treating disorders and diseases, such as bone or nerve growth disorders

Dunn '552, Abstract.

FF 2. Dunn '552 discloses:

[T]he composition is a liquid formulation of a thermoplastic polymer and a pharmaceutically acceptable organic solvent. The composition is administered as a liquid to an implant site, whereupon the solvent diffuses or dissipates into the surrounding aqueous tissue fluids. The thermoplastic polymer is not soluble in these aqueous fluids so that it coagulates or solidifies to form a microporous solid or gelatinous matrix. The matrix preferably has a two-layered pore structure composed of a core portion and an outer surface layer or skin. The polymer matrix is suitable for use as an in situ formed implant in an animal, including humans and other mammals. The composition may be administered to tissue, to a surgical incision, or to a void space.

Id. at 2:35–48.

FF 3. Dunn '552 discloses:

[t]he composition is a liquid formulation of a thermoset prepolymer or copolymer, preferably an acrylic ester-terminated biodegradable prepolymer, which is capable of cross-linking in situ to form a polymeric or copolymeric solid or gelatinous matrix. The composition preferably is a neat liquid but may include a pharmaceutically acceptable organic solvent that is miscible with water and body fluids.

Id. at 2:51–58.

FF 4. Dunn '552 discloses “[t]he composition may further contain at least one biologically-active agent which is capable of providing a biological, physiological or therapeutic effect in an animal.” *Id.* at 3:50–52.

FF 5. Dunn '552 discloses:

[a]crylic pre-polymers for use in the compositions may be synthesized according to a variety of methods including, but not limited to, reaction of a carboxylic acid, such as acrylic or methacrylic acid, with an alcohol; reaction of a carboxylic acid ester, such as methyl acrylate or methyl methacrylate, with an alcohol by transesterification; and reaction of an isocyanatoalkyl acrylate, such as isocyanatoethyl methacrylate, with an alcohol.

Id. at 5:21–28.

FF 6. Dunn '552 discloses “the agent may be a bone growth promoting substance such as hydroxyapatite, tricalcium phosphate, a di- or polyphosphonic acid, an anti-estrogen, a sodium fluoride preparation, a substance having a phosphate to calcium ratio similar to natural bone, and the like.” *Id.* at 10:61–65.

FF 7. Orefice discloses sol-gel bioactive fibers with in vivo bioactivity. Orefice Abstract, Fig. 11.

FF 8. Orefice discloses that sol-gel compositions containing the bioactive fibers may be made from “a mixture of TEOS, phosphorous alkoxide and calcium nitrate, or calcium chloride in a water ethanol solution.” *Id.* at Abstract.

FF 9. Orefice discloses:

[s]ol-gel ceramic materials usually are porous before the densification step. The evolution of pore texture during heat treatment is used frequently to follow the densification of the material. The densification of sol-gel discontinuous bioactive fibers was investigated in this work by studying the pore texture of fibers heat treated at different temperatures.

Id. at p. 464, 2nd col.

FF 10. Orefice discloses fiber compositions of calcium oxide and phosphorous pentoxide in Table 1:

TABLE I
Fiber Compositions

Fiber Designation	SiO ₂ (mol %)	CaO (mol %)	P ₂ O ₅ (mol %)
585	60	36	4
775	80	16	4

Id. at p. 461, 2nd col.

FF 11. Orefice discloses “[t]he *in vitro* bioactivity of the fibers in [simulated body fluid] was demonstrated. Hence, the fibers described in this publication have potential applications in both soft and hard tissue repair and regeneration.” *Id.* at p. 467, 2nd col.

FF 12. The Specification discloses “[a] bioactive sol-gel solution comprises a biocompatible polymer, a gelable inorganic base material, and at least one calcium and phosphorous molecular species. The base material can be an alkoxy silane alkoxide, such as TEOS.” Spec. at 4.

Principle of Law

An invention is not patentable under 35 U.S.C. § 103 if it is obvious. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007). Under § 103: the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). A central question in analyzing obviousness is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *KSR*, 550 U.S. at 417.

OBVIOUSNESS

Based on the combination of Dunn ’552 and Orefice, the Examiner concludes that, at the time Appellants’ invention was made, it would have been “obvious to combine the prior art with an expected result of a stable sol-gel solution capable of forming a composite material for implantation” and to “follow the suggestions of the ’552 patent to include tissue augmentation materials including metal oxides and include the materials described in the Orefice study, as they would be useful in achieving the

same goal of improving tissue growth upon in situ implantation.” (Ans. 4. FF 1–11).

Initially, we note that, for the foregoing reasons, we find the subject matter of Appellants’ claimed invention *prima facie* obvious in view of Dunn ’552 and Orefice alone.⁵ The Board may rely upon less than all the references cited by the Examiner. *See In re May*, 574 F.2d 1082, 1090 (CCPA 1978). We adopt and incorporate by reference the Examiner’s findings and conclusions with respect to these references as presented in the Final Action mailed March 3, 2014, and Answer. We address the arguments raised by Appellants on appeal below.

Appellants argue “[t]here is [] no motivation to combine Dunn ’552 with Orefice since the sol-gel material of Orefice would not a) produce pores and b) is not soluble with water or body fluids” and that doing so would “destroy[] the intent of the references.” App. Br. 4–5. According to Appellants:

If the Examiner intended to replace the pore formers of Dunn ’552 with the sol-gel fibers of Orefice, then it follows that the sol-gel fibers would not be able to perform the function of the pore formers. In addition, sol-gel materials manufactured from alkoxy silanes are not soluble in water or body fluids, because silica (which is obtained from alkoxy silanes as disclosed by Orefice) is not water soluble or soluble in body fluids.

Combining the sol-gel fibers of Orefice with the composition of

⁵ We recognize that the Examiner relied on Dunn ’334 to address elements pertaining to Appellants’ dependent claims; however, as Appellants have not separately argued those claims, we do not address them here. 37 C.F.R. § 41.37(c)(1)(iv).

Dunn '552 would therefore destroy the principle of operation of Dunn '552 since the sol-gel fibers would not facilitate the formation of pores that is required by Dunn '552.

Id. at 4.

The Examiner responds that the sol-gel fibers of Orefice, which are “porous upon formation” “would not be combined with Dunn ['552] as a substitute for the pore forming agents, but as an agent for promoting bone growth.” Ans. 5–6. The Examiner finds it would have been obvious to include the fibers “due to their *in vitro* bioactivity and compositional similarity to compounds suggested by Dunn ['552] such as hydroxyapatite and calcium compounds.” *Id.* at 6. The Examiner notes that the porosity of the fibers of Orefice would promote solubility and the existing “pore-forming agents of Dunn '55[2] would remain.” *Id.*

Absent evidence from Appellants to the contrary, we are not persuaded that the sol-gel fibers of Orefice, which are porous at formation (FF 9), would need to supplant the existing pore-forming agents of Dunn '552 (FF 2) in the proposed combination. Appellants provide no evidence why the proposed combination would fail in the instance where the Orefice fibers are additions to — not substitutions for — the pore-forming agents of Dunn '552. Specifically, Appellants have not provided any evidence in support of their argument that the Examiner’s combination of Dunn '552 and Orefice “has destroyed the intent of the references.” App. Br. 5–6. Without evidence, this attorney argument is unpersuasive. *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) (“Attorney’s argument in a brief cannot take the place of evidence.”).

In their Reply Brief, Appellants argue for the first time that the combination suggested by the Examiner “would not teach all elements of the independent claim 1” because it “does not teach the presence of an alkoxy silane after the glass fibers are produced.” Reply Br. 3–4. Although this argument pertains to the rejection dated March 3, 2014, Appellants did not raise it until the Reply Brief. The Board will not consider a new argument that is “not raised in the appeal brief, or is not responsive to an argument raised in the examiner’s answer . . . unless good cause is shown.” 37 CFR 41.41(b)(2). Appellants did not explain why they waited until after the Appeal Brief to raise this argument. Consequently, the Examiner has not had the opportunity to address this argument nor do we have the benefit of the Examiner’s response. Consequently, we do not consider this new argument.

Finally, Appellants acknowledge that “if Dunn ’5[5]2 were to be combined with Orefice prior to the production of glass fibers, one would obtain the polymer (an acrylate), an alkoxy silane (TEOS), a pore former, a calcium compound and a phosphate compound and a solvent” (*i.e.*, a composition meeting the limitations of claim 1) but argue that “the Examiner has not spelled [out] any motivation as to why one of ordinary skill in the art would combine Dunn ’5[5]2 with Orefice prior to the production of the sol gel fibers. TEOS present in the solution would be harmful to the human body and its presence would destroy the intent of Dunn ’5[5]2.” App. Br. 4.

Initially, we note that Appellants’ argument that “TEOS present in the solution would be harmful to the human body” is not persuasive in light of Appellants’ Specification, which discloses use of TEOS as a gelable

inorganic base material used in a composition for insertion in the human body. *See* FF 12 and Appellants' Specification at ¶ 23: “[i]n another embodiment of the invention, the composition is disposed on a surface of or integrated within a medical device adapted for implantation into a patient.” Further, Appellants provide no evidence supporting this new argument or an explanation of “good cause” for why it was raised for the first time in their Reply Brief. We decline to consider the argument. The rejection is affirmed.

Conclusion of Law

A preponderance of the evidence relied upon by the Examiner supports a conclusion of obviousness. The rejection of claim 1 under 35 U.S.C. § 103(a) as unpatentable over Dunn '552 and Orefice is affirmed. Claims 4–10 are not argued separately and fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

SUMMARY

We affirm the rejection of obviousness of claims 1 and 4–10 under 35 U.S.C. § 103(a) as unpatentable over Dunn '552 and Orefice.

TIME PERIOD FOR RESPONSE

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

AFFIRMED