

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DOSUK D. LEE, CHRISTIAN REY,
MARIA AIOLOVA, and ALIASSGHAR TOFIGHI

Appeal No. 2006-0336
Application No. 09/569,081

ON BRIEF

Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 40, 41, 44-51 and 54.¹ Claims 40 and 54 are representative of the subject matter on appeal, and read as follows:

40. A formable paste, suitable for use as a bone substitution material, comprising a mixture of:
 - (a) a powder component, comprising:
 - (i) an amorphous calcium phosphate having a Ca/P molar ratio between 1.1 and 1.55, wherein said amorphous calcium

¹ Claim 52 is also pending, and has been indicated as containing allowable subject matter, but stands objected as being dependent upon a rejected base claim. See Examiner's Answer, page 2.

phosphate is present in an amount greater than 20 wt% of said powder component, and

- (ii) a second, crystalline calcium phosphate;
and
(b) a physiologically acceptable fluid in an amount to provide a paste having a formable or injectable consistency,
wherein the amorphous calcium phosphate and the second calcium phosphate, in combination, have a stoichiometry that permits formation of a calcium-deficient, poorly crystalline apatitic (PCA) calcium phosphate.

54. The paste of claim 40, wherein the paste remains formable for at least one hour at temperatures less than or equal to ambient but hardens at body temperature.

The examiner relies upon the following reference:

Constantz et al. (Constantz) 5,782,971 Jul. 21,1998

Claims 40, 41, 44-51 and 54 stand rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Constantz. After careful review of the record and consideration of the issues before us, we reverse.

DISCUSSION

According to the examiner,

Constantz teaches solid Ca/P of 1-250 micron amorphous particles (col. 2, lines 60-66) meeting the Ca/P instant claim to powder. The ratio of Ca to P is 1.5-1.8; the instant, 1.1-1.55. Both the ACP and the 2nd Ca/P have ratios of 1.5 to 1.8 (col. 3, lines 1-4 and 18-20); the same as that of claims 40 and 44, permitting formation of calcium deficient PCA. The 2nd Ca/P of the instant (claim 45) and Constantz (col. 4, lines 17, 18) can be dicalcium phosphate dehydrate.

Constantz at lines 1-3 of col. 5 use the language “often less than about”. To the artisan in the bone cement substitution field, it would be clear that not often, but sometimes, over 20% of the ACP will be present. Guidance to the amount used is provided; that [is, sic] sufficient to provide for the desired properties of the cement (col. 4, lines 65-67). Instant claim 54 recites one of those desired inherent properties: providing 60 minutes of formable paste.

Examiner's Answer, page 4.

The burden is on the examiner to set forth a prima facie case of unpatentability. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996). With respect to the rejection as made under 35 U.S.C. § 102(e), the prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). With respect to the rejection as made under 35 U.S.C. § 103(a), “[a] rejection based on section 103 clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, all facts must be considered. The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis. To the extent the Patent Office rulings are so supported, there is no basis for resolving doubts against their correctness. Likewise, we may not resolve doubts in favor of the Patent Office determination when there are deficiencies in the record as to the necessary factual bases supporting its legal conclusion of obviousness.” In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. Denied,

389 U.S. 1057 (1968) (emphasis in original). We find that the examiner has met the burden of establishing a prima facie case of unpatentability, and the rejections are reversed.

As noted by appellants, “Constantz makes no mention of any paste containing a dry component having greater than 20 weight percent ACP.” Appeal Brief,² page 10. Moreover, as further noted by appellants, in the experimental section, Constantz does not exemplify compositions wherein the ACP is present in an amount greater than 20 wt% of said powder component. See id. at 10-11.

The examiner’s position appears to be that because Constantz uses the language “often less than about,” and also teaches that amount of ACP present may be varied based on the desired properties, the composition inherently contains greater than 20 wt% of ACP in the powder component. We cannot, however, agree with that reasoning.

Constantz teaches:

The ACP component, when employed as a dry, solid component, will typically be combined with the other dry components prior to combination with the liquid component, described in greater detail below. The amount of solid ACP component will generally be sufficient to provide for the desired properties of the cement, usually being present in at least about 5% by weight, and often less than about 20 weight percent, more often less than about 15 weight percent of the dry ingredients.

Id. at Col. 4, line 62-Col. 5, line 3.

When read in context, the “often less than about 20 weight percent” in view of the language “more often less than about 15 weight percent of the dry

“ingredients” would suggest to the ordinary artisan that the ACP is present less than 20%, and is preferably between 5 and 15%, especially in view of the examples provided in the patent. In addition, the only motivation that the examiner points to for raising the amount of ACP to greater than 20% is that the amount of ACP present may be varied based on the desired properties. The only desired property that the examiner points to that may lead to a composition in which the ACP is present in amounts greater than 20% is instant claim 54, which recites that “the paste remains formable for at least one hour at temperatures less than or equal to ambient but hardens at body temperature.” To use appellants’ own disclosure against them in this manner, however, is impermissible hindsight, and the examiner has not pointed to anything in Constantz that would motivate the ordinary artisan to increase the ACP to greater than 20% by weight.

² All references to the Appeal Brief are to Appellants’ Brief on Appeal (revised), dated February 25, 2004.

CONCLUSION

Because the examiner failed to set forth a prima facie case of unpatentability, the rejections of record are reversed.

REVERSED

Demetra J. Mills)
Administrative Patent Judge)
)
)
)
) BOARD OF PATENT
Eric Grimes)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
Lora M. Green)
Administrative Patent Judge)

LMG/jlb

Clark & Elbing, LLP
101 Federal Street
Boston, MA 02110