

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte TAKESHI ICHITSUKA,  
TETSURO OGAWA,  
MASAYA SUMITA,  
AKIHIKO YOKOO,  
and  
KATSUMI KAWAMURA

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Appeal No. 1997-3813  
Application No. 08/371,205

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ON BRIEF

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Before GARRIS, PAK, and DELMENDO, Administrative Patent Judges.  
DELMENDO, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claim 62, the only claim pending in the subject application.<sup>1</sup>

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<sup>1</sup> In response to the final Office action of January 11, 1996, the appellants submitted a paper captioned "AMENDMENT UNDER 37 C.F.R. § 1.116" proposing the cancellation of claim 62. (Papers 10 and 11.) The examiner indicated in the

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Claim 62 is reproduced below:

62. A packing for liquid chromatography comprising porous calcium phosphate based granules having open pores with an average pore size of from 0.01 to 20 Fm, said granules being composed of crystalline particles with an average size of from 2 to 10Fm.

The subject matter on appeal relates to a packing for liquid chromatography comprising the recited porous calcium phosphate granules. According to the appellants, the claimed packing provides high resolution and exhibits superior resistance to pressure and dissolution. (Appeal brief, page 4.)

The examiner relies upon the following prior art references as evidence of unpatentability:

Kirkland 1970	3,505,785	Apr. 14,
Takata et al. (Takata) 1986	4,629,464	Dec. 16,

T. Kawasaki, W. Kobayashi, K. Ikeda, S. Takahashi, and H. Monma (Kawasaki), "High-performance liquid chromatography using spherical aggregates of hydroxyapatite micro-crystals as adsorbent," 157 Eur. J. Biochem. 291-95 (1986).

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advisory action of April 18, 1996 that the amendment will be entered upon the filing of an appeal. (Paper 12.)

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Appealed claim 62 stands rejected under 35 U.S.C. § 102(a) and/or (e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Takata. (Examiner's answer, pp. 3-4.) Additionally, appealed claim 62 stands rejected under 35 U.S.C. § 103 as unpatentable over Kawasaki in view of Kirkland. (Id. at pp. 4-5.)

We reverse the aforementioned rejections.

We consider first the examiner's § 102 rejection over Takata. "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." Mehl/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999) (quoting In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997)); accord Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047, 34 USPQ2d 1565, 1567 (Fed. Cir. 1995).

According to the examiner, appealed claim 62 "is considered to read on Takata (U.S. Patent No. 4,629,464)." (Examiner's answer, page 3.) However, the examiner has not adequately explained on this record the basis for the conclusion that each and every element of the claimed

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invention is described, either explicitly or inherently, in Takata. Hence, it is our determination that the examiner has not carried the initial burden of establishing a prima facie case of unpatentability. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Specifically, we find that Takata describes a sintered microporous hydroxyapatite body of an open pore structure having a porosity in the range from 20% to 50%, of which the micropores have a distribution of diameters in the range from 0.01 to 0.1 mm (10 to 100 Fm). (Column 2, lines 34-40.) The sintered microporous hydroxyapatite body is said to be useful as a filling in a bone cavity or as a prosthetic member.

(Column 2, lines 29-33.) Takata further teaches:

The microporous hydroxyapatite body as mentioned above can be prepared, taking the granular form suitable for filling use as a product form, for example, by admixing 100 parts by weight of a powdery hydroxyapatite having a particle size distribution as fine as possible or in the range from 0.1 to 10 Fm with from 25 to 100 parts by weight of a thermally decomposable powdery material having a particle diameter in the range from 0.01 to 0.1 mm [10 to 100 Fm] and granulating the powdery blend into granules having a particle diameter in the range from 0.1 to 3 mm [100 to 3000 Fm] by a known method, optionally, with admixture of a suitable binder such as an aqueous solution of polyvinyl alcohol followed by calcination and

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sintering of the granules at a temperature in the range from 900E to 1400E C. [Col. 3, ll. 13-27.]

As pointed out by the appellants (appeal brief, page 11), Takata does not describe the average particle size of the crystalline particles which compose the calcined and sintered granules. Despite the lack of any teaching in Takata as to the average particle size of the crystalline particles in the calcined and sintered granules, the examiner argues that the appellants' claimed range for the average size of the crystalline particles overlaps with the range for the average size of the powdery hydroxyapatite starting material as described in the applied prior art reference at column 3, line 18. (Examiner's answer, page 6.) But the examiner has not pointed to any evidence that would indicate that this overlap would necessarily entail an identity in, or an overlap between the range of average particle sizes for the crystalline particles in the calcined and sintered product as described in Takata and the appellants' claimed range of average sizes for the crystalline particles that make up the granules. Even if we assume that such is the case, the examiner has not established by way of any evidence that the crystalline

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particle size would necessarily remain unaffected by the calcining and sintering described in Takata.<sup>2</sup> In this regard, it is well settled that inherency may not be established by probabilities or possibilities and that it is insufficient to merely show that a certain thing may result from a given set of circumstances. Mehl/Biophile, 192 F.3d at 1365, 52 USPQ2d at 1305; In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); Hansgirg v. Kemmer, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939).

Moreover, appealed claim 62 recites that the "porous calcium phosphate based granules having open pores with an

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<sup>2</sup> In any event, the appellants have submitted evidence, which was entered into the record (papers 19 and 20), indicating that the sintering of hydroxyapatite increases grain size. T. Kijima and M. Tsutsumi (Kijima), "Preparation and Thermal Properties of Dense Polycrystalline Oxyhydroxyapatite," 62 J. Am. Ceram. Soc., nos. 9-10, 455-460, 457 (1979). The examiner, however, argues (supplemental answer, p. 3) that (i) Kijima is not relevant because it is directed to discs 10 mm in diameter and 1.6 mm thick, (ii) Kijima relates to oxyhydroxyapatite rather than hydroxyapatite, and (iii) the change in particle size in Table I of Kijima is negligible. However, we share the appellants' view (second reply brief, pp. 2-3) that the examiner's arguments are unavailing. Moreover, we observe that Kijima teaches that the calcination of hydroxyapatite particles results in a significant increase in particle size. (Kijima, p. 457.) We find it significant that the formation of the discs described in Kijima is conducted after calcination.

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average pore size of from 0.01 to 20 Fm." (Underscoring added.) As pointed out by the appellants (appeal brief, page 10), Takata teaches that "the micropores have a distribution of diameters in the range from 0.01 to 0.1 mm [10 to 100 Fm]." (Underscoring added; column 2, lines 38-40.) The examiner, however, has not explained how Takata's description with respect to a distribution of diameters for the micropores meets the claim element regarding average pore size.

Under the circumstances recounted above, we cannot agree with the examiner that Takata describes each and every element of the invention recited in appealed claim 62.

Turning to the examiner's § 103 rejection based on Takata, the examiner states: "It would have been obvious to optimize the elements of Takata (U.S. Patent No. 4,629,464) to enhance the physical properties of Takata (U.S. Patent No. 4,629,464)'s apatite." (Examiner's answer, pages 3-4.) However, we share the appellants' concern (appeal brief, page 13) that the examiner has neither identified the "elements" of Takata nor presented any evidence to establish that such optimization would have been obvious to a person having ordinary skill in the art. In particular, the examiner has

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failed to show any reasonable expectation, or some predictability, that Takata's calcined and sintered materials would be effective as a packing for liquid chromatography when the sizes of the crystalline particles are optimized for use as a filling in a bone cavity or as a prosthetic member of bones. In re Shetty, 566 F.2d 81, 86, 191 USPQ 753, 756-57 (CCPA 1977). Nor has the examiner presented any evidence to establish that the optimized range of crystalline particle sizes for the purpose of Takata would at least generically encompass the appellants' range of average crystalline particle sizes. Cf. In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

For these reasons, we hold that the examiner has failed to establish a prima facie case of obviousness against appealed claim 62 over Takata within the meaning of 35 U.S.C. § 103.

Lastly, we consider the examiner's § 103 rejection of appealed claim 62 over Kawasaki in view of Kirkland. The examiner states that "[a]t best, the claim differs from Kawasaki (Eur. J. Biochem. 157, 291-295 (June 2, 1986)) in evidencing the pore size and the new limitation of a particle

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size of 2 to 10 microns." (Examiner's answer, page 4.)

Nevertheless, based on the combined teachings of the prior art references, the examiner concludes as follows:

It would have been obvious that Kawasaki (Eur. J. Biochem. 157, 291-295 (June 2, 1986))'s pore sizes are within the disclosed range of page 5, lines 5-10 of the instant specification because Kirkland (U.S. Patent No. 3,505,785) (column 4, lines 67-68 and column 6, lines 44-45) discloses the pore size is determined by the microparticle size and the pore size is .1 to 1 times the microparticle size. It would have been obvious to use particles of two microns in Kawasaki (Eur. J. Biochem. 157, 291-295 (June 2, 1986)) because Kirkland (U.S. Patent No. 3,505,785) (column 4, lines 67-69) discloses that it is well known to have 1 micron particles and that larger particles are preferred where rapid diffusion is needed. The obviousness is enhanced because page 5, lines 5-10 of the instant specification appears to admit that use of particles of 0.1 to 10 microns are within the same inventive concept. [Id. at pp. 4-5.]

We are in substantial agreement with the appellants' analysis. (Appeal brief, pages 13-18.) In particular, Kawasaki does not teach any micro-crystal particle size other than "diameters of the order of 0.1 Fm." (Column 1, page 291.) To account for this difference, the examiner relies on Kirkland. However, Kirkland teaches:

The particle sizes of the coating microparticles will vary greatly depending on the nature of the particles and their eventual chromatographic

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application. Broadly, particle sizes in the range of from 5 millimicrons to 1 micron may be employed. For convenience of preparing coatings of desired thickness, microparticles in the range of 25-1000 mF are preferred. For many purposes, a relatively large pore size in the coating is desired to permit rapid diffusion of components in chromatographic processes. Since the size of the microparticles determines the size of the pores, 100-1000 mF particles are preferred in cases where rapid diffusion is needed. [Underscoring added; col. 4, ll. 58-69.]

Thus, in its broadest teaching, Kirkland does not describe the use of microparticle sizes any larger than 1 micron. Although Kirkland uses the term "preferred" to describe the 100-1000 mF particle size range for applications where rapid diffusion is needed, this preferred range must be read in context with the broadest workable range of "5 millimicrons to 1 micron."

Accordingly, even if Kawasaki is combined with Kirkland, one of ordinary skill in the art would not have modified Kawasaki's materials to contain crystalline particles having sizes any larger than 1 micron. This, of course, does not result in the invention recited in appealed claim 62.

Therefore, the examiner has not established a prima facie case of obviousness within the meaning of 35 U.S.C. § 103.

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In summary, we reverse the examiner's rejections of appealed claim 62 under 35 U.S.C. § 102 (a) and/or (e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Takata and under 35 U.S.C. § 103 as unpatentable over Kawasaki in view of Kirkland.

The decision of the examiner is reversed.

REVERSED

BRADLEY R. GARRIS	)	
Administrative Patent Judge	)	
	)	
	)	
	)	
	)	BOARD OF PATENT
CHUNG K. PAK	)	APPEALS
Administrative Patent Judge	)	AND

