

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* CARLOS M. G. DURAN, DAVID T. CHEUNG  
AND DAVID C. PANG

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Appeal No. 2003-0233  
Application 09/103,874

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ON BRIEF

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Before PAK, OWENS, and KRATZ, *Administrative Patent Judges*.

OWENS, *Administrative Patent Judge*.

*DECISION ON APPEAL*

This appeal is from the final rejection of claims 18-47, which are all of the claims remaining in the application.

*THE INVENTION*

33. A pliable soft tissue specimen which has been prepared in a process comprising the steps of:

(1) treating natural soft tissue obtained from a donor with:

(a) liquid compositions of gradually increasing concentrations of a polar organic solvent or solvents, until the last of said liquid compositions contains at least approximately 25% and at most 75% by volume of said solvent, or mixture of solvents, the balance being water, the solvent being selected from a group consisting of aliphatic alcohols having 1 to 3 carbons and other water miscible polar organic solvents;

(b) thereafter with a second liquid composition of aqueous glycerol or of low molecular weight polyethylene glycol having a molecular weight less than approximately 1000D, containing the glycerol or the low molecular weight polyethylene glycol, or mixtures thereof being in a concentration range of approximately 10 to 50% by volume, said second liquid composition also containing approximately 3 - 20% weight by volume polyethylene glycol of a molecular weight in the range of 6,000 D to 15,000 D and approximately 2 to 75 units per milliliter heparin of a molecular weight greater than approximately 3KD;

(2) thereafter briefly immersing the soft tissue in an aqueous heparin solution, and

(3) thereafter freezing the tissue and lyophilizing the tissue to dryness.

*THE REFERENCES*

Baumgartner	4,300,243	Nov. 17, 1981
Noishiki et al. (Noishiki)	4,704,131	Nov. 3, 1987

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*THE REJECTIONS*

The claims stand rejected under 35 U.S.C. § 103 as follows: claims 18-23, 25-30, 32-38, 40-45 and 47 over Baumgartner in view of Noishiki, and claims 24, 31, 39 and 46 over Baumgartner in view of Noishiki and Brendel.

*OPINION*

We reverse the aforementioned rejections. We need to address only claim 33, which is the broadest independent claim.<sup>1</sup>

The appellants' claims are in product-by-process form. Hence, the patentability of the claimed invention is determined based on the product itself, not on the method of making it. See *In re Thorpe*, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985) ("If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process."). Whether a rejection is under 35 U.S.C. § 102 or § 103, when the appellants' product and that of the prior art appear to be identical or substantially identical, the

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prior art product does not necessarily or inherently possess the relied-upon characteristics of the appellants' claimed product. See *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980); *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

Baumgartner discloses a pliable soft tissue specimen which has been prepared by treating collagenous tissues such as skin, vessels, nerves, sinews, fascies cartilage and dura mater, with a dehydration solvent such as ethanol, propanol, methanol, isopropanol, acetone, methylethylketone or mixtures thereof (col. 2, lines 33-60). Baumgartner teaches (col. 2, lines 37-46):

Due to the optimum freeing of fibers and fibrils the biological material, dura mater for instance, shows in its histological image a morphological structure very similar to the native tissue.

Thus properties are obtained which correspond very well to the properties of the native tissue. Practically, the elasticity is conserved and the extensibility is simultaneously quite negligible. The limit of elasticity amounts, for instance to 1.45 kp.

Noishiki discloses an antithrombotic collagenous medical

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impregnate collagen fibers with protamine, dipping the protamine-impregnated collagenous material in an aqueous glutaraldehyde solution to fix the protamine, and then dipping the collagenous material in an aqueous heparin solution to form a heparinized collagen material having bonds between the positively charged protamine and the negatively charged heparin (col. 1, lines 50-55; col. 2, lines 33-41 and 65-67; col. 3, lines 35-36).

The examiner argues that it would have been obvious to one of ordinary skill in the art to treat Baumgartner's collagenous tissue with heparin to improve the antithrombotic property of the collagenous tissue as taught by Noishiki (answer, pages 4-5).

In order for a *prima facie* case of obviousness to be established, the teachings from the prior art itself must appear to have suggested the claimed subject matter to one of ordinary skill in the art. See *In re Rinehart*, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976). The mere fact that the prior art could be modified as proposed by the examiner is not sufficient to establish a *prima facie* case of obviousness. See *In re*

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*Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992).

The examiner has not explained how the applied references themselves would have led one of ordinary skill in the art to heparinize Baumgartner's collagenous material by Noishiki's method. A desirable characteristic of Baumgartner's collagenous material is that it has properties which correspond very well to those of the native tissue (col. 2, lines 42-46). The examiner has not explained why one of ordinary skill in the art would have reasonably expected Baumgartner's collagenous material, after being treated with Noishiki's protamine, glutaraldehyde and heparin, to have the properties required by Baumgartner.<sup>3</sup>

Nor has the examiner explained how Noishiki would have led one of ordinary skill in the art to heparinize Baumgartner's collagenous material without use of the protamine and glutaraldehyde. Noishiki indicates that the glutaraldehyde is essential to fix the protamine, and that the protamine is essential for bonding to the heparin (col. 2, lines 65-67;

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col. 3, lines 35-36).

The examiner argues that Baumgartner's collagenous material differs from that of the appellants only in that Baumgartner's collagenous material has not been heparinized (answer, page 6). Even if, because Baumgartner's treated collagenous material, like that of the appellants (specification, page 4, lines 19-22), has properties corresponding very well to the native tissue, it could reasonably be considered to appear to be the same or substantially the same as the appellants' collagenous material before being heparinized, the examiner has not established a *prima facie* case of obviousness. The reason is that, as discussed above, the examiner has not established that the applied references themselves would have led one of ordinary skill in the art to heparinize Baumgartner's collagenous material.

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*DECISION*

The rejections under 35 U.S.C. § 103 of claims 18-23, 25-30, 32-38, 40-45 and 47 over Baumgartner in view of Noishiki, and claims 24, 31, 39 and 46 over Baumgartner in view of Noishiki and Brendel, are reversed.

*REVERSED*

CHUNG K. PAK  
Administrative Patent Judge

TERRY J. OWENS  
Administrative Patent Judge

PETER F. KRATZ  
Administrative Patent Judge

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