Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JAMES McGREGOR and PAUL W. WATT

Appeal No. 2002-0450
Application No. 09/142,814

ON BRIEF

Before WINTERS, MILLS, and GREEN Administrative Patent Judges,

MILLS, 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 1-8 and 10-11, which are all the claims pending in this application.

Claims 1 and 10 are representative of the claims on appeal and read as follows.

1. A material for use in a wound dressing or a wound implant, the material comprising a plurality of beads, wherein each bead comprises a porous core of a first bioabsorbable material and a substantially non-porous layer of a second bioabsorbable material around said core.

10. A method of making bioabsorbable beads for use in wound dressings or implants, the method comprising:
providing a dispersion of a first bioabsorbable material in a liquid solvent:
generating droplets of said dispersion;
freezing said droplets to form frozen droplets;
freeze drying or solvent drying the frozen droplets to form discrete porous cores of said first bioabsorbable material; and
coating said porous cores with a substantially non-porous layer of a second bioabsorbable material.

The references relied upon by the examiner are:

Berg et al. (Berg)	4,837,285	Jun. 6, 1989
Silver et al. (Silver)	4,970,298	Nov. 13, 1990
United Kingdom Patent Application Arnold	GB 228 1861	Mar. 22, 1995

Grounds of Rejection

Claims 1-8 stand rejected under 35 U.S.C. § 102 as anticipated by Arnold.

Claims 1-8 and 10-11 stand rejected under 35 U.S.C. § 103(a) as obvious over Berg in view of Silver or Arnold.

We reverse these rejections.

DISCUSSION

In reaching our decision in this appeal, we have given careful consideration to the appellants' Specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejection, we make reference to the Examiner's Answer for the examiner's complete reasoning in support of the rejection, and to the appellants' Brief for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

Background

Appellants claim a material for use in a wound dressing or wound implant, the material comprising a plurality of beads, wherein each bead comprises a porous core of a first bioabsorbable material and a substantially non-porous layer of a second bioabsorbable material around said core.

According to appellants' specification, the porous core of the first bioabsorbable material is a bioabsorbable sponge, for example, a product of freeze-drying or solvent drying of a solvent liquid dispersion. This sponge material generally has irregular, interconnected pores. The porous core is enclosed in a substantially non-porous layer

of substantially uniform thickness. This forms a substantially spherical bead. The non-porous layer forms a substantially continuous coating over the core to substantially prevent cellular invasion of the core until the layer has fully degraded in the body. Specification, page 3. In certain embodiments, the material of the invention may be a fluid, gel or paste comprising the coated beads. Specification, page 4.

35 U.S.C. § 102

Claims 1-8 stand rejected under 35 U.S.C. § 102 as anticipated by Arnold.

It is the examiner's position that (Answer, pages 3-4):

> Arnold discloses wound implant material comprising a plurality of one or more bioabsorbable polymers such as polymers or copolymers of lactic acid and/or glycolic acid, collagen, hyaluronic acid or cellulose derivatives bound together by a bioabsorbable matrix .... Arnold's microspheres preferably have a diameter of 50 to 250 microns, are in solid, gel or sponge form. Arnold's microspheres may further comprise a therapeutic agent, such as fibronectin, a growth factor, or an antibiotic.... Arnold specifically teaches the use of a second suitable bioabsorbable polymer such as polylactic/polyglycolic acid or oxidized regenerated cellulose to reinforce the integrity of the matrix.... Arnold discloses microspheres of hyaluronic acid/collagen in a collagen matrix or mesh entity.... Therefore, Arnold meets the limitations set forth in the instant claims.

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Appellants argue the beads of Appellants' invention are not identical to Arnold's matrix of bound together microspheres.

Appellants argue their beads "have a non-porous coating of substantially uniform thickness around said beads." Brief, page 6. According to appellants, "[t]his is in stark contrast Arnold's invention depicted in Fig. 1 of Arnold." Id.

Figure 1 of Arnold depicts microspheres stuck together by a collagen matrix. Arnold, page 7. Figure 1 of Arnold does not reasonably appear to depict a material comprising a plurality of beads, wherein each bead comprises a porous core of a first bioabsorbable material and a substantially non-porous layer of a second bioabsorbable material around said core. Instead, the matrix of Arnold reasonably appears to link or stick together multiple microspheres in a matrix, but does not surround an individual microsphere or bead with a second non-porous layer to form a bead, as required by the claims.

Thus, in our view, Arnold does not anticipate the material for use in a wound dressing or wound implant, the material comprising a plurality of beads.[1] The rejection of the claims for anticipation over Arnold is reversed.

[1] The Appellants also argue "there is clearly no disclosure of unbound beads having a coating of substantially uniform thickness around the beads as claimed by Appellants." Brief, page 7. According to the examiner, the amendment after final rejection filed on January 12, 2001 was not entered. Thus, appellants' argument concerning that the fact that each bead has "a coating of substantially uniform thickness" and "each bead is unbound to each other" does not correspond to a claim limitation now before us.

35 U.S.C. § 103

Claims 1-8 and 10-11 stand rejected under 35 U.S.C. § 103(a) as obvious over Berg in view of Silver or Arnold.

Berg disclose biodegradable collagen based compositions for augmenting soft tissue. According to the examiner, Berg's compositions may be used as wound dressings and implants. Answer, page 4. Berg's compositions comprise resorbable collagen beads, the beads having an average pore size of about 50 to 350 microns. Id.

Berg also teaches methods of preparing the beads comprising dispersing an appropriate biopolymer such as collagen in an appropriate solvent or diluent, forming the dispersion into minute droplets, then freezing the droplets and lyophilizing the droplets to form porous beads. Id. The examiner acknowledges that Berg fails to specifically teach a coating layer on their microspheres. Id.

The examiner relies on Silver to meet the above deficiency of Berg. Silver discloses a biodegradable collagen matrix having a pore size of 50-250 microns and a morphology which enhances the healing of a wound comprising a biopolymer such as collagen, "a therapeutic agent and a diffusion control layer (coating) comprising a biodegradable polymer such as copolymers of polylactic/polyglycolic acid." Answer, page 5. Silver also discloses that at first the collagen may be placed in a suitable solvent such as a solution of HCL to form a mixture or dispersion, then they are frozen in an ethanol or liquid nitrogen bath and finally dried. Id. The examiner finds the

methods of Silver are substantially similar to the instant methods of preparing a wound dressing material. Id.

The examiner summarizes:

> Although Berg does not fully teach the incorporation of second biodegradable polymers such as polylactic acid, polyglycolic acid copolymers in their composition, both Silver and Arnold respectively indicate the use of second polymer in their compositions as means to control releasing rate of the porous beads, or improving the biodegradation of their matrix system; therefore, it would have been obvious to one ordinary skilled in the art at the time of invention to add the second, non-porous biodegradable polymer, as taught by Silver or Arnold, to Berg's composition in the form of a coating to improve the duration of activity, release rate or the biodegradation of such wound dressing material when place in a wound site. Id.

We, again disagree with the examiner's characterization of the diffusion control layer described by Silver and the matrix layer of Arnold. The disclosure of Silver particularly concerns a collagen sponge or sheet material. Column 3, lines 34-43. According to Silver, column 6, lines 45-64, each side of the collagen based matrix may be coated with a diffusion control layer which may be a biodegradable layer of polylactic acid or polyglycolic acid.

Appellants argue that the only form of collagen based matrix described in Silver is in the form of a sheet and not beads. Brief, page 8. Appellants argue that Arnold only discloses microsphere supported in a porous matrix and Silver only discloses sheets of matrix material. Id. The Appellants conclude that the only suggestion to do

what appellants have done, i.e., coat individual beads with a non-porous layer, is found in appellants' own disclosure. Brief, page 9.

In response to Appellants' argument that Silver discloses coating sheets with a diffusion control layer and not coating beads, the examiner argues that Silver is relied upon to show the use of coating on only one form of wound dressings or wound material. Since the teachings of Silver, Berg and Arnold are within the same endeavor, one of ordinary skill in the art would have had a reasonable expectation of success in achieving the same beneficial affects when coating beads according to Silver's methods.

We agree with appellants and do not find that either Silver or Arnold provides evidence of a material comprising a plurality of beads, wherein each bead comprises a porous core of a first bioabsorbable material and a substantially non-porous layer of a second bioabsorbable material around said core.

The examiner argues that the motivation to combine references may come from the references themselves or the knowledge generally available to those of ordinary skill in the art. Answer, page 9. In this case the examiner relies on knowledge generally available to those of ordinary skill in the art. Id. Patent examiners, in relying on what they assert to be general knowledge to negate patentability on the ground of obviousness, must articulate that knowledge and place it of record, since examiners are presumed to act from the viewpoint of a person of ordinary skill in the art in finding

relevant facts, assessing the significance of prior art, and making the ultimate determination of the obviousness issue. Failure to do so is not consistent with either effective administrative procedure or effective judicial review, examiners cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which they rely. See In re Lee, 277 F.3d 1338, 1343-1344, 61 USPQ2d 1430, 1433-1434 (Fed. Cir. 2002). Thus, it is improper to rely on the "common knowledge and common sense" of a person of ordinary skill in art to find an invention obvious over a combination of prior art references, since the factual question of motivation to select and combine references is material to patentability, and cannot be resolved on subjective belief and unknown authority. In re Lee, 277 F.3d 1338, 1343-1344, 61 USPQ2d 1430, 1433-1434 (Fed. Cir. 2002). In the present case, the examiner has not provided sufficient evidence to show knowledge in the art of a material comprising a plurality of beads, wherein each bead comprises a porous core of a first bioabsorbable material and a substantially non-porous layer of a second bioabsorbable material around said core.

While we might agree with the examiner that both Silver and Arnold may support the concept of providing diffusion layer or matrix upon a collagen sheet, we do not find a

suggestion or support for preparing such layer in a manner which completely surrounds a microsphere to form individual beads.

As to the method of making bioabsorbable beads of claim 10, we similarly find that the examiner has not provided sufficient evidence to support a prima facie case of obviousness, as, in our view, the cited references, alone or in combination do not suggest a step of coating porous cores with a substantially non-porous later of a second bioabsorbable material to form a bioabsorbable bead.

After evidence or argument is submitted by the applicants in response to an obviousness rejection, "patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of the argument." In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); see In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787 (Fed. Cir. 1984) ("All evidence on the question of obviousness must be considered, both that supporting and that rebutting the prima facie case."). On balance, we believe that the totality of the evidence and argument presented by the examiner and appellants weighs in favor of finding the claimed invention non-obvious in view of the cited references. The rejection of the claims for obviousness over Berg in view of Silver or Arnold is reversed.

CONCLUSION

The rejection of claims 1-8 under 35 U.S.C. § 102 as anticipated by Arnold is reversed. The rejection of claims 1-8 and 10-11 rejected under 35 U.S.C. § 103(a) as obvious over Berg in view of Silver or Arnold is reversed.

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge	))))) BOARD OF PATENT
DEMETRA J. MILLS Administrative Patent Judge	)) APPEALS AND)) INTERFERENCES
LORA M. GREEN Administrative Patent Judge	))

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