

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

Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

---

Ex parte YING JIANG and MARK S. ROBY

---

Appeal No. 2000-0320  
Application No. 08/480,082

---

ON BRIEF

---

Before CALVERT, NASE, and CRAWFORD, Administrative Patent Judges.

NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 to 9 and 18 to 26. Claims 10 to 17 have been withdrawn from consideration under 37 CFR § 1.142(b) as being drawn to a nonelected invention. No claim has been canceled.

We REVERSE.

Appeal No. 2000-0320  
Application No. 08/480,082

Page 2

BACKGROUND

The appellants' invention relates to devices and methods for preventing the formation of post-surgical adhesions between a healing trauma site and adjacent surrounding tissue (specification, p. 1). A copy of the claims under appeal is set forth in the appendix to the appellants' brief.

The two prior art references of record relied upon by the examiner in rejecting the appealed claims are:<sup>1</sup>

Thompson 1996	5,531,735	July 2, (filed Sept. 27, 1994)
Viegas et al. 24, 1996 (Viegas)	5,587,175	Dec. (filed Dec. 28, 1993)

Claims 1 to 9 and 18 to 26 stand rejected under 35 U.S.C. § 103 as being unpatentable over Viegas in view of Thompson.

---

<sup>1</sup> The other five references referred to by the appellants (brief, pp. 7-10, 25-27) and the examiner (answer, p. 3) were not relied upon by the examiner in the rejection under appeal. Accordingly, we will not consider these references in this appeal.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejection, we make reference to the final rejection (Paper No. 17, mailed June 11, 1998) and the answer (Paper No. 22, mailed March 1, 1999) for the examiner's complete reasoning in support of the rejection, and to the brief (Paper No. 21, filed November 16, 1998) for the appellants' arguments thereagainst.

#### OPINION

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. Upon evaluation of all the evidence before us, it is our conclusion that the evidence adduced by the examiner is insufficient to establish a prima facie case of obviousness with respect to the claims under appeal. Accordingly, we will not sustain the examiner's rejection of claims 1 to 9 and 18 to 26 under 35 U.S.C. § 103. Our reasoning for this determination follows.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established by presenting evidence that would have led one of ordinary skill in the art to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988) and In re Lintner, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

We agree with the appellants that the examiner has failed to establish a prima facie case of obviousness since the combined teachings of Viegas and Thompson fail to teach or suggest the claimed subject matter.

The method claims under appeal all require the steps of (1) providing an aqueous solution of chitosan and a complexing agent; (2) providing an aqueous solution of alginate; and (3) combining the chitosan/complexing agent solution with the alginate solution. The apparatus claims under appeal all

require (1) a first sprayer containing an aqueous solution of chitosan and a complexing agent; (2) a second sprayer containing an aqueous solution of alginate; and (3) an actuator which causes the first sprayer and the second sprayer to spray.

Viegas discloses medical uses of in situ formed gels. Specifically, Viegas discloses that balanced pH, hyperosmotic, hypoosmotic, or isoosmotic gels are ideal vehicles for drug delivery since they are especially suited for topical body cavity or injection application of drugs or diagnostic agents; for drug or diagnostic agent delivery to the eye of a mammal; as protective corneal shields; or as ablatable corneal masks useful in laser reprofiling of the cornea. Viegas also discloses that the compositions without the addition of a drug or diagnostic agent are useful as medical devices, for instance, in separating surgically or otherwise injured tissue as a means of preventing adhesions.

Viegas teaches (column 5, lines 23-31) that the compositions of his preferred embodiment comprise aqueous

mixtures of a film forming, water soluble polymer and an ionic polysaccharide,

optionally containing a latent counter-ion to gel the polysaccharide upon release of the counter-ion.

Alternatively, the compositions of the invention can comprise a

two part aqueous system, one of which contains the ionic polysaccharide and film forming polymer and the other part containing an aqueous solution of a counter-ion.

Viegas teaches (column 6, lines 24-39) that a complete listing of useful water soluble, film forming polymers is not possible. Representative useful polymers are the water soluble alkyl celluloses, i.e., methyl and ethyl cellulose; the hydroxyalkyl celluloses, i.e., hydroxypropylmethyl cellulose and hydroxyethyl cellulose; hyaluronic acid and water soluble salts thereof, i.e., sodium hyaluronate; chondroitin sulfate and water soluble salts thereof, i.e., sodium chondroitin sulfate; polymers of acrylamide, acrylic acid, and polycyanoacrylates; polymers of methyl methacrylate and 2-hydroxyethyl methacrylate; polydextrose, cyclodextrin;

polydextrin; maltodextrin, dextran; polydextrose; gelatin, collagen, natural gums, i.e., xanthan, locust bean, acacia, tragacanth, carrageenan, and agar; derivatives of polygalacturonic acid such as pectin; polyvinyl alcohol; polyvinyl pyrrolidone; polyethylene glycol; and polyethylene oxide.

The gel forming ionic polysaccharides found useful in Viegas' invention are hydrophilic colloidal materials and include the natural gums such as gellan gum, alginate gums, i.e., the ammonium and alkali metal salts of alginic acid and mixtures thereof. In addition, chitosan, which is the common name for deacetylated chitin is useful. Generally, the alginates can be any of the water-soluble alginates including the alkali metal alginates, such as sodium, potassium, lithium, rubidium and cesium salts of alginic acid, as well as the ammonium salt, and the soluble alginates of an organic base such as mono-, di-, or tri-ethanolamine alginates, aniline alginates, and the like.

Useful counter-ions in Viegas' invention are cationic gelling agents, preferably, comprising a divalent or trivalent cation. Useful divalent cations include the alkaline earth metals, preferably, selected from the group consisting of calcium and strontium. Useful trivalent cations include aluminum. The most preferred counter-ions are contained in ionic compounds selected from pharmaceutically-acceptable gluconates, fluorides, citrates, phosphates, tartrates, sulfates, acetates, borates, chlorides, and the like having alkaline earth metal cations such as calcium and strontium. Especially preferred counter-ion containing inorganic salts for use as ionic polysaccharide gelling agents include such inorganic salts as the chloride salts, such as strontium chloride, calcium chloride, and mixtures thereof.

Thompson discloses temporary medical devices such as stent implants which can be disintegrated in-vivo upon demand by release of an agent held trapped within the device. The device is fabricated from a matrix polymer material which is essentially insoluble in body fluids and a disintegration agent which acts to initiate decomposition of the matrix

polymer when contacted therewith. The disintegration agent is trapped within and chemically isolated from the matrix polymer such as by

encapsulation, and is releasable within the matrix polymer upon contact of the device with a releasing agent which liberates the encapsulated disintegration agent.

Thompson teaches that the matrix polymer may be fabricated from anionic or cationic crosslinkable polymers and may include but are not limited to carboxylic, sulfate, and amine functionalized polymers such as polyacrylic acid, polymethacrylic acid, polyethylene amine, polysaccharides such as alginic acid, pectinic acid, carboxymethyl cellulose, hyaluronic acid, heparin, chitosan, carboxymethyl chitosan, carboxymethyl starch, carboxymethyl dextran, heparin sulfate, chondroitin sulfate, cationic guar, cationic starch, and their salts. Preferred ionically crosslinkable polymers are alginic acid, pectinic acid, carboxymethyl cellulose, hyaluronic acid, chitosan, and their salts. Most preferred ionically crosslinkable polymers are alginic acid, pectinic acid, and

hyaluronic acid and their salts. Among the ionically crosslinkable cationic polymers that may be employed are chitosan, cationic guar, cationic starch and polyethylene amine.

Thompson further teaches that the polymeric material in which the disintegration agent is encapsulated or associated is an ionically crosslinkable polymer which may be the same as or different from the ionically crosslinkable matrix polymers described above from which the medical device itself is fabricated. Suitable materials include but are not limited to carboxylic, sulfate, and amine functionalized polymers such as polyacrylic acid, polymethacrylic acid, polyethylene amine, polysaccharides such as alginic acid, pectinic acid, carboxymethyl cellulose, hyaluronic acid, chitosan, carboxymethyl chitosan, carboxymethyl starch, carboxymethyl dextran, heparin sulfate, chondroitin sulfate, cationic guar, cationic starch, and their salts. Preferred ionically crosslinked capsule materials are alginic acid, pectinic acid, carboxymethyl cellulose, and chitosan and their salts. Most

preferred ionically crosslinked capsule materials are alginic acid, pectinic acid, chitosan and their salts.

After the scope and content of the prior art are determined, the differences between the prior art and the claims at issue are to be ascertained. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

The examiner ascertained (final rejection, p. 7) that the only difference is that Viegas does not disclose chitosan as the film forming polymer. With regard to this difference, the examiner then determined that as chitosan and cellulose are equivalent biopolymers in the art of matrixed gel polymers useful in the medical art,<sup>2</sup> it would have been obvious to one of ordinary skill in the art to utilized [sic, utilize] chitosan as the film forming polymer in the Viegas composition and method.

---

<sup>2</sup> This finding was apparently based upon the combined teachings of Thompson and Viegas.

Our first reason for not sustaining the examiner's rejection is that even if the teachings of Viegas and Thompson were combined together as set forth by the examiner, the resulting method and apparatus would not be readable on the claimed subject matter. In that regard, the modified method of Viegas would include the steps of (1) providing an aqueous solution of chitosan and alginate; (2) providing an aqueous solution of a complexing agent; and (3) combining the chitosan/alginate solution with the complexing agent solution. Thus, the modified method of Viegas would not include the steps of (1) providing an aqueous solution of chitosan and a complexing agent; (2) providing an aqueous solution of alginate; and (3) combining the chitosan/complexing agent solution with the alginate solution. Likewise, the modified device of Viegas would not include a first sprayer containing an aqueous solution of chitosan and a complexing agent and a second sprayer containing an aqueous solution of alginate.

Our second reason for not sustaining the examiner's rejection is that we find ourselves in agreement with the appellants that the applied prior art would not have suggested

utilizing chitosan as the film forming polymer in the Viegas composition and method. In our view, the only suggestion for modifying Viegas in the manner proposed by the examiner stems from hindsight knowledge derived from the appellants' own disclosure. The use of such hindsight knowledge to support an obviousness rejection under 35 U.S.C. § 103 is, of course, impermissible. See, for example, W. L. Gore and Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

For the reasons set forth above, the decision of the examiner to reject claims 1 to 9 and 18 to 26 under 35 U.S.C. § 103 is reversed.

CONCLUSION

To summarize, the decision of the examiner to reject claims 1 to 9 and 18 to 26 under 35 U.S.C. § 103 is reversed.

REVERSED

IAN A. CALVERT	)	
Administrative Patent Judge	)	
	)	
	)	
	)	
	)	BOARD OF PATENT
JEFFREY V. NASE	)	APPEALS
Administrative Patent Judge	)	AND
	)	INTERFERENCES
	)	
	)	
	)	
MURRIEL E. CRAWFORD	)	
Administrative Patent Judge	)	

Appeal No. 2000-0320  
Application No. 08/480,082

Page 16

MARK FARBER  
UNITED STATES SURGICAL CORPORATION  
150 GLOVER AVENUE  
NORWALK, CT 06856

Appeal No. 2000-0320  
Application No. 08/480,082

Page 17

JVN/ks