

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is not binding precedent of the Board.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. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ESSIEN EYO-OKON ITA and SCOTT HILTON CLARKE

Appeal No. 2001-0645
Application No. 09/055,472

ON BRIEF

Before COHEN, STAAB, and NASE, Administrative Patent Judges.
STAAB, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the examiner's final
rejection of claims 1-9, all the claims pending in the
application.

Appellants' invention pertains to a reconstructive surgical
implant device, and more particularly to a device useful as a

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prosthesis such as a breast implant. Independent claims 1 and 7, reproduced below, are illustrative of the appealed subject matter.

1. A prosthesis for implantation in a mammalian body comprising:

a) a shell made from a flexible, non-absorbable biocompatible material; and

b) a gel filler material contained within said shell wherein said gel filler material comprises glucomannan.

7. A method of making a prosthesis for implantation into a mammalian body which comprises

filling a shell made from flexible, non-absorbable biocompatible material with a filler material comprising glucomannan.

The references cited in the final rejection are:

Perry et al. (Perry)	5,282,857	Feb. 01, 1994
McGinley et al. (McGinley)	5,462,761	Oct. 31, 1995

Claims 1-9 stand rejected under 35 U.S.C. § 103 as being unpatentable over Perry in view of McGinley.

The examiner considers (Office Action dated October 16, 1998, Paper No. 3, page 3) that Perry discloses an implantable prosthesis useful in breast augmentation and/or replacement comprising an outer envelope of medical grade silicon and a gel

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filler material comprising a mixture of water and a cellulose gelling agent. The examiner concedes that Perry does not disclose a glucomannan gel filler material. The examiner turns to McGinley to account for this deficiency.

McGinley pertains to a composition comprising a dry, water-dispersible, particles of microcrystalline cellulose (MCC) coprocessed with a glucomannan. The composition is useful as a bulking agent and as a fat replacement, especially in water-based formulations used as foods (column 2, lines 20-22), and creates a texture and taste similar to that associated with fats (column 3, lines 10-13; column 7, lines 4-5; column 7, lines 52-54). Food products where McGinley's formulation have been found to be useful include smooth-style peanut butter (column 5, line 57), oil-free salad dressing (column 6, line 16), and low fat, low total solids non-sugar sweetened frozen desserts (column 6, lines 39-40). McGinley discloses that an alkali may be added to the MCC/glucomannan mixture to produce a gel (column 2, lines 14-17; column 8, lines 45-47).

According to the examiner, it would have been obvious to have provided the implant device of Perry with an admixture of glucomannan and cellulose as taught by McGinley "in order to

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provide for a prosthesis enjoying enhanced bulk and having a consistency approaching that of fat, thereby further serving to approximate the natural feel of mammary tissue" (Paper No. 3, page 3). Further amplification of the examiner's rationale in rejecting the appealed claims is found on pages 3-4 of the answer, wherein the examiner states:

Perry et al's use of the term "gel" clearly refers to any gelatinous and "jelly-like" materials and further teaches that it is the physical characteristics of the gel material which provide the physical characteristics of the medical implants of their invention (col. 2, lines 12-16). Therefore, Examiner maintains the position that it is prima facie obvious to substitute Perry et al's cellulose gelling agent with any one of well known gelling agents, including the instant glucomannan, in Perry et al's medical implant with a reasonable expectation of success in obtaining a medical implant having similar physical characteristics imparted by the gelling agent based on their equivalent gel forming functions.

The examiner also takes the position (answer, page 4) that the substitution of McGinley's composition of MCC and glucomannan for Perry's gel would have been obvious because appellants have not established the criticality of using the particular gelling agent called for in the claims in an implant.

Reference is made to the first Office action (Paper No. 3) and to the examiner's answer (Paper No. 12) for a complete exposition of the examiner's position.

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Appellants argue, first, that McGinley constitutes nonanalogous art, not being either from appellants' field of endeavor or pertinent to the problem with which appellants are concerned. In the view we take in this case, even if we assume that McGinley is analogous art, the obviousness rejection is not well founded.

In the present case, the reference evidence relied upon by the examiner does not establish which properties are desirable in the design of a prosthesis for implantation in a mammalian body, nor that gel materials comprising glucomannan, admittedly known¹, are recognized to have such desirable properties. In this regard, the examiner's position that Perry's use of the term "gel" in describing the filler material teaches that any material having the physical characteristic of a gel would be suitable for Perry's purpose is not sufficient. In a nutshell, the examiner proposes that it would have been obvious to try each of numerous possible choices of materials having the characteristics of a gel until one possibly arrived at a successful result where the prior art gives no indication of which parameters are critical and no

¹ See, for example, the discussion on pages 3-5 of the specification of the present application.

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direction as to which of many possible choices is likely to be successful. At best, in view of Perry's disclosure one skilled in the art might find it obvious to try various combinations of compounds for fabricating the implantable prosthesis of Perry. However, this not the standard of 35 U.S.C. § 103. See *In re Goodwin*, 576 F.2d 375, 377, 198 USPQ 1, 3 (CCPA 1978); *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977); *In re Tomlinson*, 363 F.2d 928, 931, 150 USPQ 623, 626 (CCPA 1966).

In addition, the examiner's position (answer, page 4) to the effect that the rejection is sound because appellants have not established the criticality of using the particular gelling agent called for in the claims in an implant is noted. The examiner's position in this regard is inappropriate because criticality is not a requirement of patentability. See *W. L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 USPQ 303, 315 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

In the fact situation before us, when we set aside in our minds that which appellants teach us in the present application, we conclude that the applied Perry and McGinley references, by themselves, simply would not have suggested the proposed modification of the implantable prosthesis of Perry to include a

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gel filler material comprising glucomannan. Only appellants teach the use of such a filler material for an implantable prosthesis, and the benefits derived therefrom.² Thus, the rejection is clearly based on the use of impermissible hindsight. Since the evidence of obviousness would not have been suggestive of the claimed invention, the rejection on appeal cannot be sustained.

REVERSED

IRWIN CHARLES COHEN)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
LAWRENCE J. STAAB)	APPEALS AND
Administrative Patent Judge)	INTERFERENCES
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JEFFREY V. NASE)	
Administrative Patent Judge)	

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² See page 2, lines 21-22, of appellants' specification.

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