THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte ANTHONY J. WALDER

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Appeal No. 95-4669
Application 08/044,674[1]

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ON BRIEF

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Before ABRAMS, JOHN D. SMITH, and STAAB, Administrative Patent Judges.

STAAB, Administrative Patent Judge.

DECISION ON APPEAL

Anthony J. Walder appeals from the final rejection of claims 1-6. Claims 7-10, the only other claims pending in the application, stand withdrawn from consideration pursuant to 37 CFR § 1.142(b).

The subject matter on appeal relates to an anti-infective medical article designed

[1] Application for patent filed April 9, 1993.

to inhibit or reduce bacterial growth during its use in a living body. Claim 1 is illustrative and reads as follows:

1. An anti-infective medical article comprising a hydrophilic polymer having an insoluble silver salt bulk distributed therein, said polymer having a water absorption of 5% or more by weight.

The references of record relied upon by the examiner as evidence of obviousness are:

Pratt et al. (Pratt)	4,849,223	Jul. 18, 1989
Laurin et al. (Laurin)	PCT/US83/01404	Sep. 15, 1983

Allan S. Hoffman, *Synthetic Polymeric Biomaterials, in* Polymeric Materials and Artificial Organs, 13-29 (Charles G. Gebelein, ed., 1983).

The claims on appeal stand rejected under 35 U.S.C. § 103 as follows:

(a) claims 1-5 as being unpatentable over Laurin in view of Hoffman; and

(b) claim 6 as being unpatentable over Laurin in view of Hoffman and further in view of Pratt.

Reference is made to appellant's brief (Paper No. 13) and to the examiner's answer (Paper No. 14) for the respective positions of appellant and the examiner with regard to the merits of these rejections.

Laurin, the examiner's primary reference, pertains to "compositions useful in making medical devices and useful in providing antimicrobial coatings on medical devices" (page 1). As explained on page 3, Laurin's coating

is prepared by mixing a suitable resin and a compound of a physiological,

> antimicrobial metal in an appropriate solvent for the resin. . . . The coating can be applied to a medical device by dipping in the mixture of resin, solvent and physiological, antimicrobial metal compound and thereafter allowing the solvent to evaporate. . . . Alternatively, the medical articles may be sprayed with the mixture and the solvent allowed to evaporate.

In addition, Laurin states that "a quantity of physiological, antimicrobial metal compound may be mixed with a resin for direct molding of an article" (page 4).

On page 4, the Laurin reference lists a number of suitable resins and physiological, antimicrobial metal compounds usable in formulating the mixture. The listed resins include polyurethane, which is one of the polymers indicated by appellant as being suitable for use in the present invention, and the listed metal compounds include silver chloride, which is the silver salt preferred by appellant in making his anti-infective medical article. Laurin is silent as to the water absorption properties of the resin used in making the coating.

Hoffman, the examiner's secondary reference,[2] pertains to applications of synthetic polymers in medicine. Hoffman states that "[w]ater sorption in biomaterials is very important to the functioning of some polymers, such as hydrogels in soft contact lenses" (page 15). On page 17, Hoffman lists the properties of several solid polymers, including soft (rubbery) polymers. Such soft polymers may have "low" water sorption or

[2] In the answer, the examiner refers to Hoffman as Gebelein or Gebelein (Hoffman).

"high" water sorption. Examples of soft polymers having "low" water sorption are SR (silicone rubber(cross linked)), PU (polyurethane rubber), and PVC (poly (vinyl chloride)). Uses of such polymers include tubes, diaphragms, coatings, implants, pacemakers, adhesives, and blood bags. An example of a soft polymer having "high" water sorption is PHEMA (poly (hydroxyethyl methacrylate)). Uses of such polymers include contact lenses, burn dressings, and coatings. On page 18, Hoffman indicates that the water sorption of PU (polyurethane) is in the range of 1-5%.

Independent claim 1 calls for an article comprising a hydrophilic[3] polymer having an insoluble[4] silver bulk distributed[5] therein, with the polymer having a water absorption of 5% or more by weight. Independent claim 2 contains similar limitations.

In rejecting claims 1 and 2, and claims 3-5 that depend from claim 2, as being

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[3] Appellant's specification expressly states on page 2 that, in the present application, the term "hydrophilic" means "having a water absorption of 5% or more by weight."

[4] Read in light of the supporting specification, it is clear that the term "insoluble" as used here does not mean zero solubility, but rather very low solubility such that the active agent (e.g., silver) leaches out slowly during use. See, for example, page 7 of the specification ("The silver chloride in the catheter of the invention is leached slowly because of the very low solubility of the salt. This slow leach rate . . . has the advantage of providing anti-infective activity of long duration.").

[5] Appellant's specification expressly states on page 2 that, in the present application, the term "bulk distributed" means "substantially evenly distributed throughout the polymer."

unpatentable over Laurin in view of Hoffman, the examiner has taken the following positions:

> Laurin et al disclose an anti-infective medical article comprising a hydrophilic polymer which includes an insoluble silver salt bulk. . . . While Laurin et al do not specifically state that the polymers are hydrophilic, such a property is inherent in most of the polymers disclosed. For example, it is well known that polyurethane may be hydrophilic. Laurin et al do not disclose a polymer with a water absorption of 5% or more.
>
> Gebelein (Hoffman) teaches several polymers which are hydrophilic with a water absorption of 5% in the area of biomaterials where water absorption is critical. (See pages 15-18).
>
> It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the polymers with low water absorption (1-5%) disclosed in Gebelein (Hoffman) in the invention disclosed in Laurin et al in order to select a polymer that has a water absorption of 5% or a low water uptake.

We will not sustain this rejection. From our perspective, what is missing from the examiner's evidentiary basis is any teaching of the desirability, and thus the obviousness, of using a resin in Laurin that has a relatively high water absorption, i.e., in the range of 5% or more by weight, as now expressly set forth in claims 1 and 2. Notwithstanding the examiner's theory that some sort of disclosure of significant water absorption for Laurin's resins may be attributed to the primary reference because (1) Laurin merely does not "specifically state" that the polymers are hydrophilic, (2) polyurethane, one of Laurin's resins, *may* be hydrophilic, and/or (3) hydrophilicity is, in the examiner's opinion, an inherent property in *most* of the polymers disclosed in

Laurin, it is our view that the only reasonable conclusion to be drawn from Laurin's silence on the matter of water absorption for the resins used therein is that water absorption is simply of no concern to Laurin. Nothing in Hoffman, and in particular Hoffman's statement that water sorption is important in the functioning of some polymers, such as those used in soft contact lenses, overcomes this fundamental deficiency in the disclosure of Laurin. While we acknowledge that Hoffman teaches that the water sorption of polymers used as biomaterials may vary, and for some uses is a very important consideration, there is nothing in Laurin and Hoffman, taken either individually or collectively, that would have suggested to the artisan that relatively high water sorption like that called for in claims 1 and 2 is important for Laurin's purposes. In this regard, we do not agree with the examiner that Hoffman teaches or suggests that water absorption of 5% is critical in the field of biomaterials.

Therefore, we shall not sustain the standing 35 U.S.C. § 103 rejection of claims 1 and 2, nor claims 3-5 which depend from claim 2.

We also shall not sustain the standing 35 U.S.C. § 103 rejection of claim 6 as being unpatentable over Laurin in view of Hoffman and further in view of Pratt.

Although claim 6 does not expressly call for the water absorption of the second, hydrophilic polyurethane to be 5% or more by weight, the ordinarily skilled artisan would understand this to be the case in light of the requirement of claim 6 that the second polyurethane is "hydrophilic," and the definition of that term as set forth on page

2, lines 21-22 of appellant's specification. The Pratt reference additionally cited against claim 6 does not overcome the deficiencies of Laurin and Hoffman in this regard. In fact, Pratt's teaching at column 3, lines 61-66 that "the polymer . . . may be substantially *hydrophobic* in nature. . . . it is preferred to use *polyurethane*" (emphasis added) tends to support appellant's argument that one of ordinary skill in the art would consider the polyurethane polymers of Laurin and Pratt to be of negligible or low water absorption (i.e., hydrophobic).

The decision of the examiner is reversed.

REVERSED

NEAL E. ABRAMS Administrative Patent Judge	)
JOHN D. SMITH Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
LAWRENCE J. STAAB Administrative Patent Judge	)

Richard J. Rodrick
Becton, Dickinson and Company
One Bection Drive

Franklin Lake, NJ 07417-1880