

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

Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MUHARREM GOKCEN and TERRY J. GUY

Appeal No. 1997-0466
Application 08/154,158

ON BRIEF

Before WINTERS, WILLIAM F. SMITH and MILLS, 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 2, 16-22, 49-70 and 72, which are all of the claims pending in this application and the subject of this appeal.

We reverse.

Claims 49 and 53 are illustrative of the claims on appeal:

49. A kit for treating prostatic hypertrophy in living mammals, comprising:

sterile sealed vials containing at least one separate injectable unit-dosage of a composition comprising a therapeutically effective concentration of collagenase and hyaluronidase;

the concentration of the collagenase and hyaluronidase being effective to cause the dissolution and regression of obstructive, hypertrophied, living prostatic tissue; the concentration of the hyaluronidase being about 1,600 to about 160,000 U/ml;

all provided in a pharmaceutically acceptable aqueous carrier suitable for injection into living mammals.

53. A composition for treating prostatic hypertrophy in living mammals, comprising:

a therapeutically effective concentration of collagenase and a therapeutically effective concentration of hyaluronidase, the composition being suitable for administration by direct intraprostatic injection;

the concentration of the collagenase and hyaluronidase being effective to cause the dissolution and regression of obstructive, hypertrophied, living prostatic tissue; the concentration of the hyaluronidase being about 1,600 to about 160,000 U/ml.

The prior art references relied upon by the examiner are:

Pinnell

4,645,668

February 24, 1987

Longo et al. (Longo) "Collagenase as an Adjunct to cryoprostectomy," Gordon & Breach, pp. 113-120 (1972).

Cawston et al. (Cawston) "Methods in Enzymology," Lorand Academic Press," Vol. 80, p. 711-723 (1981)

Baert et al. (Baert) "Treatment of Chronic Bacterial Prostatitis by Local Injection of Antibiotics into Prostate," Urology Vol. 21, pp. 370-375 (1983).

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.

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 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.

Grounds of Rejection¹

1. Claims 2, 53-55 and 72 stand rejected under 35 U.S.C. 103 over Pinnell.
2. Claims 49-52 and 56-60 stand rejected under 35 U.S.C. 103 over Pinnell in view of Cawston.

¹ An additional rejection for obviousness type double patenting in view of U.S. Patent No. 5,116,615 has been withdrawn based on the filing of a terminal disclaimer. Paper No. 27.

3. Claims 16-22 and 61-70 stand rejected under 35 U.S.C. 103 over Pinnell and Longo in view of Baert.

DECISION ON APPEAL

35 U.S.C. 103

Claims 2, 53-55 and 72 stand rejected under 35 U.S.C. 103 over Pinnell.

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 when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). Furthermore, the conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual 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). With this as background, we analyze the prior art applied by the examiner in the rejection of the claims on appeal.

It is the examiner's position that Pinnell clearly discloses compositions comprising collagenase and hyaluronidase. The examiner suggests that the claimed recitations of

effective amount are within the skill of the practitioner. Answer, page 4. The examiner finds that Pinnell evidences that suitable amounts of enzymes required for dilution of mammalian cicatrices will be varied and can be determined based on the nature of the cicatrix being treated, the concentration of enzymes in the solution, the types of enzymes being used, the amount, location and nature of the fibers to be dissolved, as well as the nature of the tissue adjacent to the cicatrix being treated. Pinnell, column 4, lines 46-56. Based on this disclosure in Pinnell, the examiner concludes it is well within the skill of one of ordinary skill in the art to optimize the amounts of enzyme components for the particular and individual area to be treated. Answer, page 10.

The examiner properly recognizes that the recitation of a new intended use for an old product does not make a claim to that old product patentable. "The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, can not impart patentability to claims to the known composition." In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). Intended use of an old composition does not render composition claims patentable. In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974). However, due to differences in claimed hyaluronidase enzyme concentrations, we do not find the claimed composition to be a new use of an old product, the product disclosed in Pinnell.

During prosecution appellants amended the claims of the application to recite a therapeutically effective concentration of collagenase and hyaluronidase, the concentration of collagenase and hyaluronidase being effective to cause the dissolution and regression of obstructive, hypertrophied, living prostatic tissue and to limit the concentration of hyaluronidase to about 1600 to about 160,000 U/ml.²

Pinnell describes the administration of 150 units of hyaluronidase in a total volume of 0.2/ml³ along with various amounts of collagenase for the purpose of dissolution of mammalian cicatrices. Pinnell further suggests that suitable amounts of enzymes required for dilution of mammalian cicatrices will be varied and can be determined based on the nature of the cicatrix being treated, etc.⁴

What is missing from the examiner's analysis is why one of ordinary skill in the art would be led to a composition including concentrations of hyaluronidase of about 1600 to about 160,000 U/ml. (about 10 to 1000 times higher than that disclosed in Pinnell) combined with collagenase for any reason, upon knowledge of the disclosure of Pinnell.

We do not find that one of ordinary skill in the art reading the disclosure of Pinnell regarding suitable amounts and concentrations of enzymes would be led to a composition

² Paper No. 18, November 17, 1994.

³ Pinnell, columns 3-4, Examples II, III and V.

⁴ Pinnell, column 4, lines 46-56.

including concentrations of hyaluronidase which are about 10 to 1000 times greater than those described in Pinnell. In addition, appellant argues that the disclosure of Pinnell pertains to hypertrophied scar tissue which consists primarily of collagen connective tissue. In contrast, the prostate tissue treated with the claimed composition is different from the collagen tissue treated by the composition of Pinnell, as prostate tissue is composed of smooth muscle tissue and fibrous connective tissue. Brief, page 6. Thus, appellants argue there is no motivation provided to one of ordinary skill in the art in Pinnell to increase the amount and concentration of enzymes to the levels claimed in appellants composition to a level appropriate to dissolve smooth muscle tissue as well as connective tissue. Brief, pages 7-8.

On this basis we do not find the examiner has provided sufficient evidence or support for the claimed hyaluronidase concentrations to establish a prima facie case of obviousness. The rejection of claims 2, 53-55 and 72 under 35 U.S.C. 103 over Pinnell is reversed.

35 U.S.C. 103

Claims 49-52 and 56-60 stand rejected under 35 U.S.C. 103 over Pinnell in view of Cawston.

The disclosure of Pinnell is discussed herein. The examiner recognizes that Pinnell does not disclose the addition of a non-ionic surfactant to its composition for the treatment of cicatrix. The examiner relies on Cawston for establishing evidence that the stability of collagenase is enhanced by detergents such as Brij 35 and Triton X-100 which may be employed in the purification of collagenase. From this disclosure, the examiner concludes that the addition of a detergent for the purpose of enhancing the stability of collagenase would have been obvious to one of ordinary skill in the art at the time the invention was made, and the incorporation of the composition into a kit would have been obvious as it is conventional in the pharmaceutical industry to package individual pharmaceutical compositions usable in the treatment of given conditions together. Answer, page 5.

However, Cawston fails to overcome the deficiencies of Pinnell and its failure to disclose the claimed concentration of hyaluronidase. A prima facie case of obviousness has not been established by the examiner. The rejection is reversed.

35 U.S.C. 103

Claims 16-22 and 61-70 stand rejected under 35 U.S.C. 103 over Pinnell and Longo in view of Baert.

The examiner relies on Pinnell as evidence that hyaluronidase is known in the art for use in human medicine to increase the effect of local anesthetics and to permit wider

infiltration of subcutaneously administered fluids. The examiner suggests that it is well known that connective tissue contains hyaluronic acid, the substance on which hyaluronidase acts.

Longo discloses a composition of collagenase for injection into frozen prostate tissue for the purpose of degrading or decomposing cryo-slough. Baert is indicated to establish the conventional use of antibiotics for injection into and for the treatment of the prostate.

The examiner suggests that Longo motivates one to treat benign prostatic hypertrophy with collagenase, and that one of ordinary skill in the art would be motivated to include hyaluronidase for the purpose of increasing the infiltration of the collagenase into the prostate and would have been further motivated to include the antibiotics as such as claimed for the prophylaxis of bacterial prostatitis. Answer, page 6. However, Longo and Baert fail to overcome the deficiencies of Pinnell and its failure to disclose the claimed concentration of hyaluronidase. A prima facie case of obviousness has not been established by the examiner. The rejection is reversed.

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CONCLUSION

The rejection of claims 2, 16-22, 49-70 and 72 under 35 U.S.C. § 103 is reversed.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
William F. Smith)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
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Demetra J. Mills)	
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