

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte BENJAMIN R. YERXA,
KARLA M. JACOBUS,
WILLIAM PENDERGAST, and
JANET L. RIDEOUT

Appeal No. 2002-1121
Application No. 09/171,169

ON BRIEF

Before WINTERS, MILLS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

An oral hearing in this case was scheduled for January 9, 2003. Upon reviewing the case, however, we have determined that an oral hearing will not be necessary and we render the following decision based on the record. See 37 CFR § 1.194(c).

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 14-22, 24, 25 and 30.¹ The claims are drawn to "[a] method of stimulating tear secretion and mucin production in eyes" comprising administering an effective amount of preparation which includes compounds such as uridine-5'-triphosphate, adenosine-5'-triphosphate or cytidine-5'-triphosphate, and derivatives thereof, as well as a physiologically acceptable vehicle selected from the group consisting of aqueous electrolyte solutions, polyethers, polyvinyls, polymers of acrylic acids, lanolin, and glucosaminoglycans, "whereby said preparation promotes tear secretion and mucin production in the eyes in a subject in need of such treatment." Claim 14.

The examiner relies upon the following reference:

Jacobus et al. (Jacobus)	5,789,391	Aug. 4, 1998
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Claims 14-22, 24, 25 and 30 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by Jacobus.² After careful review of the record and consideration of the issue before us, we reverse.

¹ The statement of the rejection in the Examiner's Answer rejects claims 14-22, 24, 25 and 29. See Examiner's Answer, page 3. In the section entitled "Grouping of Claims," the examiner acknowledges that the Appellants' Brief states that claim 14-22, 24, 25 and 30 stand or fall together. Thus, the reference to claim 29, which claim has been cancelled, is deemed to be a typographical error, and the rejection will be reviewed as it applies to all of the pending claims, i.e., claims 14-22, 24, 25 and 30.

² The panel notes that in the final rejection, and as recognized in the Appeal Brief, claims 14-22, 24, 25 and 30 were also subject to an obviousness-type double patenting rejection over the Jacobus patent. That rejection was apparently dropped by the examiner as the only ground of rejection set forth in the Answer is the obviousness rejection over the Jacobus patent.

DISCUSSION

Claims 14-22, 24, 25 and 30 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the Jacobus patent.

According to the rejection, Jacobus teaches the use of nucleoside phosphates, such as those required by the instantly claimed methods, "to hydrate retained mucous secretions and stimulate ciliary beat frequency which promotes the drainage of sinuses." Examiner's Answer, page 4. The rejection states:

Jacobus [] does not teach a method of treating corneal injury per se; although a further method of treating corneal injury is claimed, the treatment set forth in the instant claims is targeted to lacrimal tissues. As Jacobus [] teach[es] the use of nucleoside phosphates to promote fluid/secretion drainage of the sinuses, and sinus structures such as the sclera venus sinus or canal of Schlemm- a venous channel that encircles the eye in the angle at the sclera-cornea junction, which would be viewed as a part of the cornea, the nexus between the differences in the prior art and the invention as claimed are adequately bridged.

* * * *

A person of ordinary skill in the art would have been motivated to use nucleoside phosphates . . . to treat lacrimal tissues since the prior art has taught the effectiveness of nucleoside phosphates in promoting fluid/secretion drainage in sinus structures present in the eye and nasal cavity. Moreover, as ciliary processes are also present in the eye and are part of the network of drainage associated with structures in the eye such as the cornea, and the prior art teaches that nucleoside phosphates increase the cilial beat frequency and therefore promote drainage, one of skill in the art would have been provided with a reasonable expectation of success in treating lacrimal tissues with nucleoside phosphates.

Examiner's Answer, pages 4-5.

Appellants argue that the claimed method of stimulating tear secretion and mucin production in the eye is not rendered obvious by a method of treating sinusitis. Appellants contend that sinusitis is an inflammation of the paranasal sinuses. The paranasal sinuses, however, appellants assert, are not part of the eye. In fact, according to appellants, the physiology of the sinuses and the eye are very different, thus the ordinary artisan would not expect that a method of treating sinusitis would also have efficacy in treating dry eye disease, i.e., by stimulating tear secretion and mucin production in the eye. See Appeal Brief, pages 6-8. We agree.

The burden is on the examiner to make a prima facie case of obviousness, and the examiner may meet this burden by demonstrating that the prior art would lead the ordinary artisan 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, 1598-99 (Fed. Cir. 1988). The findings of fact underlying the obviousness rejection, as well as the conclusions of law, must be made in accordance with the Administrative Procedure Act, 5 U.S.C. 706 (A), (E) (1994). See Zurko v. Dickinson, 527 U.S. 150, 158, 119 S.Ct. 1816, 1821, 50 USPQ2d 1930, 1934 (1999). Findings of fact underlying the obviousness rejection, upon review by the Court of Appeals for the Federal Circuit, must be supported by substantial evidence within the record. See In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). In addition, in order for meaningful appellate review to occur, the examiner must present a full and reasoned explanation of the rejection. See, e.g., In re Lee, 277 F.3d 1338, 1342, 61

USPQ2d 1430, 1432 (Fed. Cir. 2002). As the obviousness rejection set forth by the examiner does not meet the above criteria, it is reversed.

Jacobus teaches that:

The method of the present invention may be used to hydrate retained mucous secretions and stimulate ciliary beat frequency in the sinuses of a subject in need of such treatment. The present invention increases mucociliary clearance in three ways: (1) by increasing the ciliary beat frequency of cilia on the surface of luminal epithelial cells, (2) by increasing the secretions of mucins by goblet cells, and (3) by increasing the secretion of water into the periciliary liquid layer as a result of increased secretion of Cl⁻ ions by luminal epithelial cells.

Jacobus, column 4, lines 15-23.

The examiner purports to bridge the gap between the teachings of Jacobus and the claimed method of stimulating tear secretion and mucin production in eyes by asserting that “the use of nucleoside phosphates to promote fluid/secretion drainage of the sinuses, and sinus structures such as the sclera venus sinus or canal of Schlemm- a venous channel that encircles the eye in the angle at the sclera-cornea junction, which would be viewed as part of the cornea,” thus apparently asserting that the sclera venus sinus is part of the sinus structure being targeted by the Jacobus patent. The examiner, however, provides no evidence to support that assertion. See In re Lee, 277 F.3d 1338, 1343-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (in reviewing an obviousness rejection, the court noted that “conclusory statements” as to teaching, suggestion or motivation to arrive at the claimed invention “do not adequately address the issue.”). Moreover, as contended by Appellants, the

sclera venus, or the canal of Sclemm, is not part and is unrelated to the paranasal sinuses.

The examiner responds by arguing that “the most common malfunction of the lacrimal drainage system, the system that promotes tears or stimulates tear production, is nasolacrimal duct obstruction,” citing page 3 of the Specification. Examiner’s Answer, page 6. According to the examiner, that recognition “is key” for establishing why one of ordinary skill in the art would have been motivated to use the nucleoside phosphates taught by Jacobus for the treatment of sinusitis for the stimulation of tear and mucin production in eyes.

It appears as if the examiner has misapprehended the claimed invention. The invention is drawn to a method of stimulating tear secretion and mucin production in the eye—not a method of increasing drainage from the eye through the removal of an obstruction of the nasolacrimal duct. The Specification at page 3 states that the lacrimal system has two components—a secretory part, which produces tears, and an excretory part, which drains into the nose. Although the specification acknowledges that the “most common malfunction of the lacrimal drainage system is nasolacrimal duct obstruction, which results in the stasis of tears in the lacrimal sac,” and also teaches that the compounds of the claimed method may also be used to enhance the drainage of the lacrimal system, that is presented as an alternate embodiment to the method of stimulating tear secretion. See, e.g. Specification, page 6.

As explained by appellants, however, it is the surface of the eye, or the conjunctiva, which stimulates tear and mucin production, see Reply Brief,

page 3, see also, Specification, page 8 (UTP is a potent agonist for purigenic receptors found in conjunctival preparations), page 20 (Example 1, stimulation of mucin release from rat conjunctival preparations), and not the nasolacrimal duct as asserted by the examiner, see Examiner's Answer, page 6. Therefore, the motivation to modify the treatment method of Jacobus to arrive at the claimed invention is based on an incorrect factual assumption and a misunderstanding of the claimed invention, and cannot be sustained.

OTHER MATTERS

We note that Appellants have submitted a terminal disclaimer over U.S. Patent No. 5,900,407, which has claims very similar to those that are subject to the instant appeal. On receipt of the application, the examiner should process the terminal disclaimer, as well as address any other issues that may arise regarding the '407 patent.

CONCLUSION

Because the examiner has failed to set forth a prima facie case of obviousness over the Jacobus patent, the rejection is reversed.

REVERSED

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