

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte THOMAS L. STEINEMANN, IVORY A. REIS,
LOUS M. FINK, HARRY H. BROWN and RICHARD A. MARLAR

Appeal No. 2001-1685
Application No. 08/596,698

ON BRIEF

Before WILLIAM F. SMITH, SCHEINER 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 1-21 which are the claims on appeal in this application.

Claims 1 and 9 are representative of the claims on appeal and read as follows:

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1. A method of reducing amounts of intraocular fibrin comprising the administration of a pharmacologically effective dose of Protein C so as to reduce the amount of intraocular fibrin in an individual having elevated levels of intraocular fibrin.

9. A method of inhibiting intraocular fibrin formation comprising the administration of a pharmacologically effective dose of Protein C so as to reduce the amount of intraocular fibrin in an individual at risk for development of elevated levels of intraocular fibrin.

The references relied upon by the examiner are:

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| Bang et al. (Bang) | 5,151,268 | Sept. 29, 1992 |
| Stocker et al. (Stocker) | 4,849,403 | July 18, 1989 |

Iverson et al. (Iverson), "Inhibition of Intraocular Fibrin Formation Following Infusion of Low-Molecular Weight Heparin During Vitrectomy," Arch. Ophthalmol., Vol. 109. pp. 405-409 (1991)

The references relied upon by the appellants are:

Howard et al. (Howard), "Intraocular Tissue Plasminogen Activator in a Rabbit Model of Traumatic Hyphema," Arch. Ophthalmol., Vol. 109, pp. 272-274 (1991)

Snyder et al. (Snyder), "Intraocular Fibrinolysis With Recombinant Human Tissue Plasminogen Activator," Arch. Ophthalmol., Vol. 105, pp. 1277-1280 (1987)

Grounds of Rejection

Claims 1-21 stand rejected under 35 U.S.C. § 103(a) as obvious over Iverson in view of Bang.

Claims 7-8 and 20-21 stand rejected under 35 U.S.C. § 103(a) as obvious over Iverson in view of Bang in further view of Stocker.

We reverse.

DISCUSSION

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 complete 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.

35 U.S.C. § 103

Claims 1-21 stand rejected under 35 U.S.C. § 103(a) as obvious over Iverson in view of Bang. Claims 7-8 and 20-21 stand rejected under 35 U.S.C. § 103(a) as obvious over Iverson in view of Bang in further view of Stocker.

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). An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveals a reasonable

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expectation of success to one reasonably skilled in the art. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Iverson addresses the same problem as that of the claimed invention, the treatment and prevention of fibrin formation in the eye, such as after surgery, by administration of heparin, an anticoagulant. Bang teaches the general administration of protein C systemically to reduce vascular fibrin formation, but does not teach administration of protein C systemically or otherwise to treat the eye.

It is the examiner's position that (Answer, page 4):

Iverson teaches that the intraocular fibrin formation during Vitrectomy is inhibited by heparin (note the abstract and page 405). Iverson does not specifically teach the use of protein C.

The use of protein C to reduce the fibrin formation or the treatment of a disease resulting from such fibrin formation, instead of heparin taught by Iverson would have been obvious to an artisan since Bang teaches its superiority over heparin taught by Bang.

Put in another way: Iverson teaches that intraocular fibrin is the result of blood coagulation and can be reduced in an individual by administering heparin as the anticoagulant.

Bang teaches that protein C is a better anticoagulant than heparin. Therefore, it would be prima facie obvious to substitute protein C for the heparin of Iverson as an anticoagulant with a reasonable expectation of success that it too would reduce intraocular fibrin formation.

Appellants argue that "a person of ordinary skill in the art would not have had a reasonable expectation that protein C would have a pharmacological effect in the eye." Brief, page 6. In support of this position appellants argue that "delivery of therapeutic pharmaceuticals to the eye is not a trivial matter. In many instances, systemically administered drugs do not reach the eye in therapeutic levels; and ... [m]any drugs, if

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systemically administered in large concentrations to achieve a desired result in the eye, would result in serious systemic dysfunction, side effects and possibly death.” Brief, page 7.

The examiner “completely agrees” with appellants' statement that in many instances systemically administered drugs do not reach the eye in therapeutic levels. Answer, page 5. Evidence of record also appears to support appellants' arguments as to the difficulties associated with systemic delivery of drugs to treat the eyes. In particular, Synder and Howard, submitted by appellants in an information disclosure statement filed October 11, 1994, indicate that upon evaluation of various fibrinolytic agents including urokinase, streptokinase, fibrinolysin and tissue plasminogen activator (tPA), that all of these substances, except tPA were associated with corneal toxicity and a marked inflammatory response. Howard, page 272, column 1. Snyder indicates that “... fibrin degradation products have been shown to be toxic to rabbit corneal epithelium and chemotactic for leukocytes. Rapid fibrinolysis may cause clinically significant corneal damage” Snyder, page 1280, column 2.

In spite of the examiner's agreement with appellants' arguments concerning the lack of expectation of success when administering fibrinolytic agents to the eye, the examiner continues to argue, “[o]ne would reasonably expect protein C which has a wider therapeutic index than available anti-coagulants according to Bang, to be more effective than heparin taught by Iverson upon similar intraocular administration.” Answer, page 5.

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In our view, the examiner's evidence does not provide a clear suggestion or expectation of success of the reduction of fibrin formation in the eye upon systemic administration of protein C. The rebuttal argument of the examiner does not come to grips with, or provide sufficient rebuttal to appellants' evidence and argument of record as to the lack of expectation of success upon substituting protein C for heparin to reduce fibrin formation in the eye. To summarize, the examiner essentially argues that it would have been obvious to try the substitution of the protein C anticoagulant of Bang for the heparin anticoagulant of Iverson, even though Bang does not disclose the effective systemic use of protein C to reduce fibrin formation in the eye. "Obvious to try" has long been held not to constitute obviousness. In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988). A general incentive, as indicated by the examiner, does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out. In re Deuel, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215-16 (Fed. Cir. 1995). Stocker is relied on by the examiner for the disclosure that protein S potentiates the action of protein C. Answer, page 6. We do not find that Stocker overcomes the deficiencies of the primary combination of references.

A conclusion as to obviousness is arrived at by reviewing the evidence as a whole. When considered anew, we find, on balance, that the evidence and arguments presented by the appellants, taken as a whole, are sufficient to outweigh the evidence of obviousness provided by the examiner. Newell Cos. v. Kenney Mfg. Co., 864 F.2d

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757, 768, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988), cert. denied, 493 U.S. 814 (1989);
and In re Beattie, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1043 (Fed. Cir. 1992).

These rejections are reversed.

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CONCLUSION

The rejections of claims 1-21 under 35 U.S.C. § 103(a) as obvious over Iverson in view of Bang, and claims 7-8 and 20-21 under 35 U.S.C. § 103(a) as obvious over Iverson in view of Bang in further view of Stocker are reversed.

REVERSED

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| WILLIAM F. SMITH |) | |
| Administrative Patent Judge |) | |
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| |) | BOARD OF PATENT |
| TONI R. SCHEINER |) | |
| Administrative Patent Judge |) | APPEALS AND |
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| DEMETRA J. MILLS |) | |
| Administrative Patent Judge |) | |

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