

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

Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BINIE V. LIPPS

Appeal No. 1997-2639
Application No. 08/237,129

HEARD: January 11, 2001

Before McKELVEY, Senior Administrative Patent Judge, and ADAMS 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 14-24 which are all of the claims pending in this application and the subject of this appeal.

Appeal No. 1997-2639
Application No. 08/237,129

Claims 14, 21 and 23 are illustrative of the claims on appeal and read as follow:

14. A method for treating a wound comprising treating said wound with a composition comprising a cell growth factor, wherein the cell growth factor consists essentially of a peptide, wherein the first 15 amino acids from the N-terminus of said peptide are identified in SEQ ID No: 1.

21. A composition of matter comprising a desalted carrier fluid containing a cell growth factor, wherein the cell growth factor consists essentially of a peptide, wherein the first 15 amino acids from the N-terminus of said peptide are identified in SEQ ID No: 1.

23. An ointment comprising a cell growth factor, wherein the cell growth factor consists essentially of a peptide, wherein the first 15 amino acids from the N-terminus of said peptide are identified in SEQ ID No: 1.

The prior art references relied upon by the examiner are:

Banks et al. (Banks), "The Preparation of Nerve Growth Factors from Snake Venoms," Biochem J., Vol. 106, pp. 157-158 (1968)

Fohlman et al. (Fohlman), "Taipoxin, an Extremely Potent Presynaptic Neurotoxin from the Venom of the Australian Snake Taipan (Oxyuranus s. scutellatus)," Eur. J. Biochem., Vol. 68, pp. 457-469 (1976)

Lind, "Amino-Acid Sequence of the β 1 Isosubunit of Taipoxin, an Extremely Potent Presynaptic Neurotoxin from the Australian Snake Taipan (Oxyuranus s. scutellatus)," Eur. J. Biochem., Vol. 128, pp. 457-469 (1982)

Lawman et al. (Lawman), "Nerve Growth Factor Accelerates the Early Cellular Events Associated with Wound Healing," Experimental and Molecular Pathology, Vol. 43, pp. 274-281 (1985)

Siigur et al. (Siigur), "Isolation and Characterization of Nerve Growth Factor from Vipera Berus Berus (Common Viper) Venom," Comp. Biochem. Physiol., Vol. 83B, No. 3, pp. 621-625 (1986)

Robert K. Scopes (Scopes), Protein Purification Principles and Practice 3rd Ed., 154-158 (Charles Cantor, ed., Springer-Verlag) (1993)

Appeal No. 1997-2639
Application No. 08/237,129

Grounds of Rejection

Claims 14-24 stand rejected under 35 U.S.C. § 103 as unpatentable for obviousness over Lind and Fohlman taken with Siigur and Banks, in further view of Lawman.

We reverse and enter a new ground of rejection of claims 21 and 22 under 35 U.S.C. § 102/103, pursuant to the provisions of 37 CFR § 1.196(b).

DECISION ON APPEAL

In reaching our decision in this appeal, we have given consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the examiner's Answer and Supplemental Answer for the examiner's reasoning in support of the rejection, and to the appellant's Brief and Reply Brief for the appellant's arguments thereagainst. As a consequence of our review, we make the determinations which follow.

Appeal No. 1997-2639
Application No. 08/237,129

35 U.S.C. § 103

Claims 14-24 stand rejected under 35 U.S.C. § 103 as unpatentable for obviousness over Lind and Fohlman taken with Siigur and Banks, in further view of Lawman.

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). It is well-established that before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion, or motivation to lead an inventor to combine those references. Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629, (Fed. Cir. 1996) . 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.

With respect to claims 14-20 and 23-24 the examiner finds that Lind and Fohlman evidence that taipoxin is a potent presynaptic neurotoxin, but that they do not teach the

venom is a growth factor which would be useful in wound healing. Answer, page 5. It is noteworthy that during the oral hearing on January 11, appellant also stipulated that the \$- taipoxin used in the method of appellant and that of Lind are the same.

The examiner finds that Siigur evidences that Vipera berus berus venom is a source for nerve growth factor (NGF) and shows the isolation and purification of this factor. Siigur states that NGF may be isolated from other venoms. Banks also describes the isolation of NGF from snake venoms. Lawman is relied on for the use of NGF to promote wound healing.

The examiner's position is that, based on the disclosure that NGF accelerates wound healing and that NGF is found in snake venoms, "it would have been obvious to one of ordinary skill in the art that the protein isolated from taipoxin can also be reasonably expected to be a growth factor and to accelerate and promote wound healing." Answer, page 6. It would have also been obvious "to incorporate the factor in an ointment since this is a conventional expedient [sic, excipient] in medications for wound healing because of its administration to lesions and wounds." Id.

At best, the examiner has shown that nerve growth factor has been isolated from the venom of other types of snakes and that nerve growth factor has been found to be useful in the treatment of wounds. The examiner has not indicated, and we do not find, evidence of record which shows that any component of the venom from the taipan snake (Oxyuranus s.

Appeal No. 1997-2639
Application No. 08/237,129

scutallatus) or, in particular, \$ taipoxin from such venom, possesses or is capable of acting as a growth factor or nerve growth factor. Importantly, Fohlman indicates that, contrary to the argument of the examiner, not all elapid venoms are the same. In particular, Fohlman states the Taipan snake venom “is strongly neurotoxic and the clinical syndrome resembles severe myasthenia gravis [4]. Tiger snake ... antivenin gives very little protection, which is rather remarkable, since the latter antivenin is effective against most other Australian snakes and in fact against elapid venoms in general [5].” Fohlman, page 457, column 2.

Nor do we find that the cited references disclose an ointment comprising the specifically claimed cell growth factor as set forth in claims 23 and 24. Thus, on the record before us, we do not find the examiner has presented the evidence necessary to establish a prima facie case of obviousness, both suggesting the claimed subject matter and revealing a reasonable expectation of success to one reasonably skilled in the art. The rejection of the claims 14-20, 23 and 24 for obviousness of the claimed invention is reversed. The rejection of claims 21 and 22 is vacated in view of the new grounds of rejection set forth below.

New grounds of rejection - 37 CFR § 1.196(b)

Under the provisions of 37 CFR § 1.196(b), we enter the following new ground of rejection against appellants' claims 21 and 22. Claims 21 and 22 are rejected under 35 U.S.C. § 102/103 over Fohlman in view of Lind.

Claim 21 is directed to a composition of matter comprising a desalted carrier fluid containing a cell growth factor, wherein the cell growth factor consists essentially of a peptide, wherein the first 15 amino acids from the N-terminus of said peptide are identified in SEQ ID No: 1. Claim 22, dependent upon claim 21, further requires that the peptide consists of beta taipoxin obtained from snake venom.

Appellant submits that the "desalted carrier fluid" and cell growth factor of claim 21 is the β -taipoxin protein fraction described in the specification, at page 5, lines 1-3, which has been subjected to a dialysis procedure. The appellant suggests at Paper 26¹, page 2, that, in dialysis, "the membrane enclosing the protein solution is semipermeable, and that water and small solutes, such as glucose or NaCl, pass through the membrane but proteins do not." Lehninger, page 134, 135, Figure 7.6. Apparently, appellant would have us interpret the term "desalted carrier fluid" in claim 21, as a carrier which includes no

¹ During the oral hearing, the Board requested clarification, and an indication of support in the specification for the term "desalted carrier fluid" in claim 21, and indicated that it would accept submission of a paper after the oral hearing indicating such support. Ex parte Cillario, 14 USPQ2d 1079 (Bd. Pat. App. & Int. 1989). Appellant subsequently submitted Paper No 26, providing an indication of support for the term "desalted carrier fluid" in the specification, along with explanatory information relating to dialysis procedures in Lehninger, to aid in the interpretation of the term.

salt (has had the salt removed). Paper No. 26, page 1. In this respect, we remind appellant that it is appellant's burden to precisely define the invention, not the PTO's. In re Morris, 127 F.3d 1048, 1056, 44 USPQ2d 1023, 1029 (Fed. Cir. 1997). In the present case, appellant has failed to make the intended meaning of the term "desalted carrier" in claim 21, explicitly clear in the specification. The legend of Lehninger, Figure 7.6, proffered by appellant, also indicates that in dialysis procedures, the outer aqueous phase must be replaced with distilled water several times before the concentration of small solute particles (NaCl) in the protein solution can be reduced to a vanishingly small amount. Thus, the dialysis procedure, while removing much of the salt present as a result of the protein purification procedure, does not appear to remove all salt content.²

Fohlman evidences the administration of β -taipoxin in physiological saline for the purpose of conducting toxicity studies in mice. Fohlman, page 460, column 2, page 463 and Table 3. β -taipoxin peptide is not described per se in Fohlman. However, one of ordinary skill in the art would understand the reference to β -taipoxin in Fohlman as describing the claimed peptide in view of the disclosure of Lind of the amino acid

² Absent an express definition of the term "desalted carrier" in the specification, the fact that appellants may "be able to point to definitions or usages that conform to their interpretation does not make the PTO's definition unreasonable when the PTO can point to other sources that support its interpretation." In re Morris, 127 F.3d 1048, 1056, 44 USPQ2d 1023, 1029 (Fed. Cir. 1997).

Appeal No. 1997-2639
Application No. 08/237,129

sequence of α -taipoxin (Lind, Fig. 1, page 72). See, In re Samour, 571 F.2d 559, 562, 197 USPQ 1, 4 (CCPA 1978) [holding that in making a rejection under 35 U.S.C. 102(b) on a single prior art reference that discloses every material element of the claimed subject matter the Patent Office can properly rely on additional references to show what was known by or would have been obvious to one of ordinary skill in the art.]

In addition, appellant's counsel has stipulated that the α -taipoxin of Lind, which has been obtained from snake venom, and that used in the claimed composition are the same. In view of the above, we find Fohlman's administration of α -taipoxin in a physiological saline to be administration of the claimed peptide in a desalted carrier fluid.

Nor do we find the language in claim 21 further defining the exact same taipoxin composition as a growth factor, to distinguish the claimed composition from that of Lind. The language in the preamble in a claim, acts as a claim limitation only when such language serves to "give meaning to a claim and properly define the invention," not when the preamble merely states a purpose or intended use of the invention. In re Paulsen, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) (quoting DeGeorge v. Bernier, 768 F.2d 1318, 1322 n.3, 226 USPQ 758, 766 n.3 (Fed. Cir. 1985)).

Thus, claims 21 and 22 stand rejected under 35 U.S.C. § 102/103 over Fohlman in view of Lind.

CONCLUSION

The rejection of claims 14-20, 23 and 24 is reversed. The rejection of claims 21-22 under 35 U.S.C. § 102/103 is vacated and a new ground of rejection of claims 21-24 under § 1.196(b) is made.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides that, "[a] new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

Appeal No. 1997-2639
Application No. 08/237,129

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED - 1.196(b).

FRED E. McKELVEY)	
Senior Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
DONALD E. ADAMS)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
DEMETRA J. MILLS)	
Administrative Patent Judge)	

Appeal No. 1997-2639
Application No. 08/237,129

JOHN R. CASPERSON
P.O. BOX 2174
FRIENDSWOOD, TX 77549

DJM/jlb