

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 44

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DALE B. SCHENK,
ROBIN M. BARBOUR and KELLY L. JOHNSON

Appeal No. 1995-1989
Application 07/850,142¹

ON BRIEF

Before ELLIS, ROBINSON and LORIN, ***Administrative Patent Judges.***

ELLIS, ***Administrative Patent Judge.***

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 80 through 108, all the claims remaining in the application. Claims 80, 93 and 105 are illustrative of the subject matter on appeal and read as follows:

¹ Application for patent filed March 12, 1992. According to the appellants, this application is a continuation of Application 07/235,055, filed August 19, 1988, now abandoned.

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Sevier, et al. (Sevier), "Monoclonal Antibodies in Clinical Immunology," *Clin. Chem.*, Vol. 27, No. 11, pp. 1797-1806 (1981).

Henry, "Acute Phase Reactants," *Clinical Diagnosis and Management*, 17th Edition, W.B. Saunders Co., p. 213 (1984).

Sigma Chemical Company Catalog, pp. 709-12 (1987).

The claims stand rejected as follows:

I. Claims 80 through 89, 93 through 98 and 105 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a non-enabling disclosure.

II. Claims 80, 81, 87 through 89, 93 and 105 stand rejected under 35 U.S.C. § 103 as being unpatentable over Behan in view of Sevier.

III. Claims 93, 98, 103 through 105 and 108 stand rejected under 35 U.S.C. § 103 as being unpatentable over Cooper in view of Sevier.

IV. Claims 93 through 97, 99 through 102 and 105 through 107 stand rejected under 35 U.S.C. § 103 as being unpatentable over the Sigma catalog in view of Sevier.

We ***reverse***.

Rejection I

In the case before us, the examiner contends that the specification does not provide an enabling disclosure "for any and all monoclonal antibodies" having the claimed properties, or "for a method for aiding in diagnosing AD using such monoclonal antibodies

to acute phase reactants.” Answer, p. 4. The examiner argues, *inter alia*,
that:

[i]t has not been demonstrated that either the method of immunizing using pooled samples from Alzheimer’s patients or the method of immunizing using paired helical filaments (PHF) from Alzheimer’s patients ... as disclosed would reproducibly result in other monoclonal antibodies which would bind to other acute phase reactants as claimed and have the properties required to practice the invention. There is no guidance or information or evidence of record as to what is required to obtain monoclonal antibodies that would work as claimed, or that there is any difference at all between AD patients and normal controls with respect to other monoclonal antibody binding to acute phase reactants in Alzheimer’s disease patients, and should there be a difference, one would not know whether every acute phase reactant-specific monoclonal antibody would be appropriate to use or whether one would have to seek a monoclonal to some particular and as yet undefined epitope on one or more acute phase reactants. . . . Appellants have not identified any other acute phase reactant epitopes that would be useful in the methods as claimed except for those specifically recognized by the particular monoclonals exemplified . . . It would require undue experimentation for one of ordinary skill in the art to produce or to identify other acute phase reactant monoclonal antibodies that would have all the properties required or would bind to the unidentified epitopes in order to practice the invention as claimed since Appellants’ procedure for producing monoclonal antibodies to acute phase reactants has not been demonstrated to be reproducible [Answer, pp. 4-5].

* * *

In the case of alpha haptoglobin, it appears that the epitope bound by Appellants’ monoclonal antibodies may be one that is unique to Alzheimer’s disease [Answer, p. 6].

* * *

[I]t is not evident that, using the instant specification as a guide, one could readily make other antibodies to properdin P like Appellants’ that would work in the claimed method. It would require undue experimentation for one of ordinary skill in the art to identify other epitopes present on alpha-chain haptoglobin or properdin P

against which to make monoclonal antibodies that would have all the properties required or that would bind to the unidentified epitopes in order to practice the invention as claimed [Answer, pp. 6-7].

We find these arguments unpersuasive.

With respect to the examiner's various arguments concerning the identification of other epitopes present on alpha-chain haptoglobin, properdin P, or other wise, we point out that none of the claims requires the identification of an epitope. We acknowledge that the claims require the use of monoclonal antibodies having specific binding properties, but there is no limitation as to the epitope which is recognized by said monoclonals. Thus, we do not find the examiner's arguments that it would require undue experimentation to identify (i) other epitopes present on alpha-chain haptoglobin and properdin P, or (ii) other unidentified epitopes, to be tenable.

As to the examiner's position that it has not been demonstrated that the appellants' method for producing monoclonal antibodies is reproducible, we point out that it is well established that "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented **must** be taken as in compliance with the enabling requirement of the first paragraph of § 112 **unless** there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). The examiner may reject the claims

as being based on a non-enabling disclosure when s/he has reason to conclude that one skilled in the art would be unable to carry out the claimed invention.

In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). Here, we do not find that the examiner has provided any reasons or factual basis as to why one skill in the art would doubt the specification statements. That is, the examiner has not provided any reasons or factual basis to support her conclusion that the method of making monoclonal antibodies having the claimed properties as described on pp. 11-14 of the specification is not reproducible. To the contrary, we find that she is shifting the burden to the appellants to demonstrate, or to provide evidence, that their procedure is reproducible. Accordingly, the rejection is reversed.

The Rejections under 35 U.S.C. § 103

The examiner has premised her various conclusions of obviousness on the teachings of Behan, Sevier, Cooper and the Sigma catalog. However, we agree with the appellants that none of the cited references teaches or suggests the claimed (i) diagnostic method, (ii) monoclonal antibodies having the specified binding characteristics, or (iii) kits for diagnosing AD which employ said monoclonals. In our review of the applied prior art we do not find that any of the references even allude to monoclonal antibodies which bind specifically, and to a statistically greater degree, to acute phase reactant antigens in a sample derived from a subject having AD than to a

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sample derived from a subject who does not have AD. On this record, the only location where such teachings or suggestions appear is in the appellants' specification. Thus, we find that the examiner has relied on impermissible hindsight in making her determination of obviousness. *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992)(“It is impermissible to use the claimed invention as an instruction manual or “template” to piece together the teachings of the prior art so that the claimed invention is rendered obvious.”); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (“To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher”). Accordingly, the prior art rejections are reversed.

The decision of the examiner is reversed.

REVERSED

Joan Ellis)
Administrative Patent Judge)
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Douglas W. Robinson) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
) INTERFERENCES

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