

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

Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SVETLANA ALEXANDER and DARIUSH DAVALIAN

Appeal No. 1997-3330
Application 08/271,876

ON BRIEF

Before WINTERS, ROBINSON, 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, 3-6, 8-26 and 28-41, which are all of the claims pending in this application.

We reverse.

DECISION

35 U.S.C. § 103

Claims 1, 3-6, 8-26 and 28-41 stand rejected under 35 U.S.C. § 103 as obvious over Nelson taken with Rose and either of Erlanger or Brinkley.

The claimed invention is directed to:

1. A method for the determination of mycophenolic acid in a sample suspected of containing mycophenolic acid comprising the steps of:

(a) contacting said sample with a monoclonal antibody capable of distinguishing between mycophenolic acid and mycophenolate esters; and

(b) detecting the binding of said antibody to mycophenolic acid, the presence of said binding indicating the presence and/or the amount of mycophenolic acid in said sample.

Nelson describes mycophenolic acid and its derivatives as being well known pharmaceuticals useful as immunosuppressive, anti-inflammatory and anti-tumor agents. The examiner argues that for this reason, the development of bioavailability assays for these compounds would be expected to be routine in the art. Examiner's Answer, page 4. Rose is relied on for the general disclosure of conventional immunoassay formats including the competitive ELISA format which is useful for the assay of haptens. Examiner's Answer, page 5. Each of Erlanger and Brinkley are relied on for the disclosure of conventional methods of preparing immunogenic conjugates and tracers by coupling a hapten with an immunogenic carrier or label. The conjugates are useful in the

preparation of the corresponding antibodies and tracers conventionally used in immunoassays.

It is the examiner's position that (Examiner's Answer, page 5):

[i]n view of the fact that mycophenolic acid is a well known drug (Nelson et al.), it would be obvious to use it as a hapten to prepare immunogens or tracers by the conventional techniques of Brinkley and Erlanger, as claimed, and to further use these immunogens for the preparation of antibodies useful in the conventional assay formats of Rose et al.

It is, further, argued that "the production by conventional means of an antibody or tracer from any well known hapten would be obvious to one of ordinary skill in the art." (*Id.*) In the statements in support of the rejection for obviousness, the examiner has focused on the method claims.

In rejecting the 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). 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). An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one

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

Rejections based on § 103 must rest on a factual basis with these facts being interpreted without hindsight reconstruction of the invention from the prior art. The examiner may not resort to speculation, unfounded assumption or hindsight reconstruction to supply deficiencies in the factual basis for the rejection. See In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Our reviewing court has repeatedly cautioned against employing hindsight by using the appellants' disclosure as a blueprint to reconstruct the claimed invention from the isolated teachings of the prior art. See, e.g., Grain Processing Corp. v. American Maize-Products Co., 840 F.2d 902, 907, 5 USPQ2d 1788, 1792 (Fed. Cir. 1988).

In addition, the Federal Circuit states that "[the] mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." In re Fritch, 972 F.2d 1260, 1266 n.14, 23 USPQ2d 1780, 1783-84 n.14 (Fed. Cir. 1992), citing In re Gordon, 773 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984).

In the present case the examiner has failed to provide a fact based explanation premised on the correct legal standard. It appears that the only reason, suggestion or motivation for preparing the required monoclonal antibodies and using them in a method

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as claimed, comes from appellants' disclosure and not from the cited references. While Nelson would, at best, describe the use of high performance liquid chromatography for determining bioavailability of mycophenolic acid from plasma samples, it does not appear to suggest or enable the preparation and use of monoclonal antibodies for such bioavailability assays, particularly monoclonal antibodies which are capable of distinguishing between mycophenolic acid and mycophenolic esters.

A general incentive does not make obvious a particular result, nor does the existence of isolated techniques by which that particular result can be obtained. See In re Deuel, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1216 (Fed. Cir. 1995). In the present case, the examiner's indication of the existence of and desirability of bioavailability assays and the existence of techniques for the preparation of monoclonal antibodies and assay formats, does not suggest the monoclonal antibodies, which are capable of distinguishing between mycophenolic acid and mycophenolic esters, used in the method claimed. What is lacking here is a suggestion, motivation or reason to be found explicitly or implicitly in the prior art for preparing and using the specific monoclonal antibodies having the indicated properties in the claimed method. In re O'Farrell, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1458 (Fed. Cir. 1998).

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The examiner has not pointed to factual evidence in the cited references as to how one of ordinary skill in the art would prepare or determine which immunogens can be used to prepare monoclonal antibodies capable of distinguishing between mycophenolic acid and mycophenolic esters.

Even if it is assumed, for the sake of argument, that one of ordinary skill in the art could prepare monoclonal antibodies from hapten conjugates based on the general methodologies of Erlanger and Brinkley and use them in conventional assays according to the disclosure of Rose, one of ordinary skill in the art is not provided with sufficient information to prepare and obtain monoclonal antibodies with the capability of distinguishing between mycophenolic acid and mycophenolic ester with a reasonable expectation of success.

Simply put, we find the examiner has not provided the factual support which would have reasonably suggested modifying the teachings of Nelson to obtain a monoclonal antibody capable of distinguishing between mycophenolic acid and mycophenolic ester. The examiner's inclusion of claims to a kit and to modified cells in the rejection is similarly flawed.

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CONCLUSION

The rejection of claims 1, 3-6, 8-26 and 28-41 under 35 U.S.C. § 103 is reversed.

REVERSED

SHERMAN D. WINTERS
Administrative Patent Judge

DOUGLAS W. ROBINSON
Administrative Patent Judge

DEMETRA J. MILLS
Administrative Patent Judge

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