

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHI-HUEY WONG, YOSHITKA ICHIKAWA,
GWO-JENN SHEN, and KUN-CHIN LIU

Appeal No. 1998-0529
Application No. 07/961,076

HEARD: January 23, 2001

Before ROBINSON, ADAMS, and GRIMES, Administrative Patent Judges.
ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 - 20, which are all of the claims pending in the case.

Claim 1 is illustrative of the subject matter on appeal and reads as follows:

1.¹ A method of producing a fucosylated carbohydrate in a single reaction mixture comprising the steps of:

¹ An amendment was filed on October 29, 1993 which sought to cancel the phrase "with fucose" from part "(b)" of claim 1. The record does not reflect that this amendment has been considered by the examiner or properly entered in this record. Therefore, the claim remains as filed and as reproduced above.

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obviousness, the examiner relies upon Gokhale, Wong, Ichikawa (I) and Ichikawa (II).

We reverse.

Background

The applicants describe the presently claimed invention at pages 1-2 of the specification as providing a method of producing a fucosylated carbohydrate in a single reaction mixture comprising the steps of using a fucosyltransferase to form an O-glycosidic bond between a nucleoside 5'-diphospho-fucose and an available hydroxyl group of a carbohydrate acceptor molecule to yield a fucosylated carbohydrate and a nucleoside 5'-diphosphate wherein the nucleoside 5'-diphosphate is recycled in situ with fucose to form the corresponding nucleoside 5'-diphospho-fucose.

Discussion

The rejection under 35 U.S.C. § 103

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) (citation omitted). Moreover, the prior art must also establish that one would have had a reasonable expectation of achieving the present invention, i.e., a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

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Both the suggestion and the reasonable expectation of success must be found in the prior art, not in appellants' disclosure. In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

The examiner relies on Gokhale as disclosing a process of transferring a fucose from nucleoside 5'-diphospho-fucose to the hydroxyl group of a carbohydrate in the presence of a transferase. (Office Action of February 9, 1995 (Paper No. 15), pages 2-3). The examiner relies on Wong, Ichikawa (I), and Ichikawa (II) as disclosing the synthesis of sialyl carbohydrate by transferring the sialyl group to the carbohydrate from a nucleoside sialic acid in the presence of a sialyl transferase. In addition, these secondary references describe the regeneration in situ of the nucleoside sialic acid in the presence of sialic acid and a synthetase. (Paper No. 15, page 3).

The examiner concludes that (Paper No. 15, page 3):

it would have been obvious to regenerate the neucleoside [sic] fucose in the process of Gokhale et al. by supplying fucose and a synthetase as suggested by the secondary references disclosing an analogous regeneration. It would have been expected that in situ regeneration of neucleoside [sic] 5'-diphosphate fucose in the process of Gokhale et al. would have been advantageous for the same reason that in situ regeneration of neucleoisde [sic] sialic acid is advantageous in the processes of the secondary references.

Thus, the examiner's position can be summarized by stating that Gokhale discloses a process which reasonably corresponds to step "(a)" of claim 1. The secondary

references, Wong, Ichikawa (I), and Ichikawa (II), disclose an analogous process wherein sialyl carbohydrate is produced by transferring a sialyl group to a carbohydrate from a donor molecule, e.g. cytidine monophosphate-sialic acid (CMP-sialic acid), in the presence of a sialyl transferase and wherein the donor molecule CMP-sialic acid is regenerated in situ using sialic acid, a CMP-sialic acid synthetase and the CMP from which the sialyl has been removed. (E.g., Wong, col. 5, line 66 - col. 6, line 37, and Figure 1).

In order to establish a prima facie case of obviousness on the facts before us, the examiner must have provided evidence which would have led one of ordinary skill in this art, at the time of the invention, to the claimed method of producing a fucosylated carbohydrate. Even if we assume for purposes of argument that one of ordinary skill in this art would have been motivated by Wong, Ichikawa (I), and/or Ichikawa (II) to try modifying the process disclosed in Gokhale in order to regenerate the donor molecule in situ, it remains that we have not yet reached the presently claimed method. Claim 1 requires "recycling in situ the nucleoside 5'-phosphate with fucose to form the corresponding nucleoside 5'-diphospho-fucose." (Claim 1). On this record, the examiner has provided no facts or evidence which would suggest how this is to be accomplished. To the extent that the examiner would urge the substitution of fucose for the sialic acid in the secondary references, it has not been demonstrated that one of ordinary skill in this art led to this

substitution would have had a reasonable expectation of success. The recycling step of the secondary references require the presence of a synthetase which serves as a catalyst for the reaction between sialic acid and CMP. The examiner has provided no evidence which would demonstrate that the synthetase useful for generating CMP-sialic acid in situ in the processes described by Wong, Ichikawa (I) and Ichikawa (II) would function in a similar manner to produce the required nucleoside 5'-diphospho-fucose in situ in the process of Gokhale. The prior art, relied on by the examiner, does not establish, or even suggest, that nucleoside 5'-diphospho-fucose can be generated in this manner. We note that Gokhale uses a chemical synthesis to produce the necessary nucleoside 5'-phospho-fucose (Gokhale, page 1068, col. 2, second paragraph through page 1069, col. 1). Thus, we find nothing in the references relied on by the examiner which would have directed one of ordinary skill in this art, at the time of the invention, to those conditions and ingredients which would have permitted the in situ regeneration of nucleoside 5'-phospho-fucose in the process described by Gokhale.

The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). On these circumstances, we are constrained to conclude that the examiner has failed to provide the evidence necessary to support a prima facie case of obviousness as to a method of producing fucosylated carbohydrates in a single reaction mixture as presently

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claimed. Where the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). Therefore, the rejection of claims 1 - 20 under 35 U.S.C. § 103, as unpatentable over Gokhale, Wong, Ichikawa (I) and Ichikawa (II) is reversed.

Summary

To summarize, the examiner's rejection of claims 1 - 20 under 35 U.S.C. § 103 is reversed.

REVERSED

Douglas W. Robinson)	
Administrative Patent Judge)	
)	
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)	BOARD OF PATENT
Donald E. Adams)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
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Eric Grimes)	
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