

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PATRICK G. JOHNSTON,
CARMEN J. ALLEGRA,
BRUCE A. CHABNER
and
CHI-MING LIANG

Appeal No. 1996-1815
Application 07/690,841¹

HEARD: December 6, 1999

Before WINTERS, WILLIAM F. SMITH, and ROBINSON, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 through 8, 10, 11 and 14 through 23, all the claims pending in the application.

¹ Application for patent filed April 24, 1991.

Claims 1, 6 and 14 are representative of the subject matter on appeal and read as follows:

1. A hybridoma that produces a monoclonal antibody specific for an antigenic determinant of thymidylate synthase, said antibody with sufficient binding affinity to detect thymidylate synthase in a Western blot assay.

6. A monoclonal antibody, or binding fragment thereof, specific for an antigenic determinant of thymidylate synthase, said antibody with sufficient binding affinity to detect thymidylate synthase in a Western blot assay.

14. A method of determining the presence of thymidylate synthase in a biological sample, comprising:

i) contacting said sample with at least one monoclonal antibody specific for an antigenic determinant of thymidylate synthase, under conditions such that binding of said monoclonal antibody to said antigenic determinant occurs, and

ii) detecting the presence or absence of complex formed between said monoclonal antibody and said antigenic determinant, said antibody with sufficient binding affinity to detect thymidylate synthase in Western blot assay.

The references relied upon by the examiner are:²

Navalgund et al. (Navalgund), "Cell Cycle Regulation of Thymidylate Synthetase Gene Expression in Cultured Mouse Fibroblasts," The Journal of Biological Chemistry, Vol. 255, No. 15, (Aug. 1980), pp. 7386-90.

Jastreboff et al. (Jastreboff), "Isolation and Functional Effects of Monoclonal Antibodies Binding to Thymidylate Synthase," Biochemistry, Vol. 24, (1985), pp. 587-92.

² We note that the examiner cited a reference to Harlow at page 4 of the Supplemental Examiner's Answer mailed September 8, 1994. However, the examiner did not incorporate that reference into the statement of rejection. Furthermore, we can not find a copy of the reference of record. Nor did the examiner list this reference on a PTO form-892. Accordingly, we have not considered this reference in reaching our decision on appeal.

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Brown et al. (Brown), "Murine Monoclonal Antibodies," Antibodies: A Practical Approach, Vol. 1, (1988), pp. 81-104.

DISCUSSION

All of the claims stand rejected under 35 U.S.C. § 103. In regard to claims 1 through 8, 10, 11, 14 and 18 through 23, the examiner relies upon Jastreboff and Brown as evidence of obviousness. In regard to claims 15 through 17, the examiner relies upon those two references and Navalgund. We reverse.

By now it is well settled that the initial burden of establishing unpatentability rests on the examiner. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). Here, all the claims require the presence or use of a monoclonal antibody specific for an antigenic determinant of thymidylate synthase wherein the monoclonal antibody has sufficient binding affinity to detect thymidylate synthase in a Western blot assay.

Jastreboff describes the isolation of monoclonal antibodies which bind to thymidylate synthase. However, the examiner agrees with appellants that the monoclonal antibodies isolated in Jastreboff do not have sufficient binding affinity to detect thymidylate synthase in a Western blot assay. Rather, we understand the examiner's position to be that it would have been obvious to one of ordinary skill in the art to make other monoclonal antibodies using the procedures set forth in Jastreboff with the reasonable expectation that subsequent runs would produce monoclonal antibodies as required by the claims on appeal. As set forth at page 9 of the Examiner's Answer, "the binding characteristics required for use in Western blots are not unusual or rare, as evidenced by the large

number of such antibodies in the prior art. Therefore, one would have a reasonable expectation of selecting such an antibody when conventional antibody production and screening methods are used.”

It has also been long held that a conclusion of obviousness must be based upon facts, not generalities. In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968); In re Freed, 425 F.2d 785, 788, 165 USPQ 570, 571 (CCPA 1970). Here, the examiner has asserted that the prior art contains disclosure of a “large number” of antibodies which are useful in Western blots. However, the examiner has not relied upon any such prior art in support of her rejection under 35 U.S.C. § 103. This Board functions as a Board of review, not a de novo examination tribunal. 35 U.S.C. § 7(b)(“[t]he [Board] ... shall review adverse decisions of examiners upon applications for patents”). We cannot review conclusions of obviousness based upon phantom prior art. Rather than asserting what the prior art teaches, it is incumbent upon the examiner to introduce evidence in the record which establishes what the prior art does teach. The examiner did not do so here.

Absent a fact-based explanation by the examiner why one of ordinary skill in the art would have had a reasonable expectation of success in making monoclonal antibodies specific for an antigenic determinant of thymidylate synthase which would be useful in a Western blot assay, we do not find the examiner has satisfied her initial burden of establishing reasons of unpatentability.

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The decision of the examiner is reversed.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
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William F. Smith)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
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)	
Douglas W. Robinson)	
Administrative Patent Judge)	

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