

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 69

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HUBERT J. P. SCHOEMAKER, and RICHARD A. CARRANO

Appeal No. 1999-1434
Application No. 08/307,044

ON BRIEF

Before ADAMS, MILLS, GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

An oral hearing in this case was scheduled for February 5, 2002. Upon reviewing the case, however, we have determined that an oral hearing will not be necessary and we render the following decision based on the record.

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 12-15, 19, 20, 22-24, and 27-34, all of the claims remaining. Claim 12 is representative and reads as follows:

12. A method for treating a gastrointestinal tumor comprising administering to a patient afflicted with a gastrointestinal tumor, a murine monoclonal antibody which specifically binds to an epitope of 17-1A antigen, said antibody being

administered in multiple doses of about 400 milligrams or more per dose.

The examiner relies on no references.

Appellants rely on the following reference:

Fogler et al. (Fogler), "Enhanced cytotoxicity against colon carcinoma by combinations of noncompeting monoclonal antibodies to the 17-1A antigen," Cancer Research, Vol. 48, pp. 6303-6308 (1988)

Claims 12-15, 19, 20, 22-24, and 27-34 stand rejected under 35 U.S.C. § 112, first paragraph, as unsupported by an enabling disclosure.

We reverse.

Background

The specification discloses that

[t]he tumoricidal activity of the murine monoclonal antibody 17-1A has been characterized in the nude mouse and in humans. . . . Several cases have been reported where the administration of Mab 17-1A resulted in a partial or complete regression of metastatic colorectal or pancreatic car[c]inomas. . . . Generally, the antibody has been administered as a single administration of 500 µg or less.

Page 1.

The specification discloses a "method of immunotherapy of gastrointestinal tumors employing multiple, high doses of murine monoclonal antibody against the gastrointestinal tumor-associated antigen 17-1A."¹ Id. The dosages used in the claimed method are orders of magnitude higher than the = 500 µg dosage disclosed to have been known in the art. See the paragraph bridging pages 1 and 2.

¹ The specification refers to both the antigen and a monoclonal antibody as "17-1A."

The specification also states that

[m]urine antibodies against 17-1A can be administered individually or in mixtures (cocktails) of two or more murine anti-17-1A antibodies. Preferably, anti-17-1A antibody having different epitopic specificity for 17-1A is employed in the combination in order to increase anti-tumor activity in an additive or synergistic fashion. Murine antibodies can be selected from the original 17-1A antibody or other murine antibodies which recognize similar or different epitopes of the 17-1A antigen, such as the M72, M74, M77 and M79 antibodies described [in the specification].

Page 4.

Discussion

Claim 12, the broadest claim on appeal, is directed to a “method for treating a gastrointestinal tumor comprising administering to a patient afflicted with a gastrointestinal tumor, a murine monoclonal antibody which specifically binds to an epitope of 17-1A antigen, said antibody being administered in multiple doses of about 400 milligrams or more per dose.” None of the claims are limited to any particular anti-17-1A antibody or antibodies.

The examiner acknowledges that the specification is enabling for the claimed method employing any one of antibodies 17-1A, M72, or M74. Examiner’s Answer, page 3. None of the claims, however, are limited to use of only these antibodies, and so the examiner rejected the claims under 35 U.S.C. § 112, first paragraph, on the basis that the specification “does not reasonably provide enablement for [the claimed method, using] **any** murine monoclonal antibody which specifically binds to **any** epitope of 17-1A antigen.” Id. (emphasis in original).

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The examiner explains her position concisely on page 5 of the Examiner's Answer. She acknowledges that the specification shows that antibody 17-1A is effective for treating gastrointestinal tumors or carcinomas. She also concedes that methods of using antibodies M72 and M74 are enabled, because those antibodies are "disclosed to bind the same or similar epitope identified by monoclonal antibody 17-1A." However, she concludes that the claimed method is not enabled for antibodies M77 and M79 because

[t]he lack of evidence in the specification for these monoclonal antibodies fails to provide a presumption that monoclonal antibodies M77 and M79 will be therapeutically effective, based solely on evidence that they bind the same 37 kD glycoprotein as monoclonal antibodies 17-1A, M72 and M74, but not the same antigenic epitope.

Examiner's Answer, page 5 (emphasis in original).

We will not affirm this rejection. "Section 112 does not require that a specification convince persons skilled in the art that the assertions therein are correct." In re Armbruster, 512 F.2d 676, 678, 185 USPQ 152, 153 (CCPA 1975). Rather, "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 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) (emphasis in original).

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Here, the specification discloses that the claimed method can be practiced with “[m]urine antibody against 17-1A antigen” generally. See page 4, last paragraph. That method is presumed to be enabled by the specification; the burden is on the examiner to show otherwise.

“When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If the PTO meets this burden, the burden then shifts to the applicant to provide suitable proofs indicating that the specification is indeed enabling.” In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). “[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.” Marzocchi, 439 F.2d at 224, 169 USPQ at 370.

In this case, the examiner has pointed to no evidence in support of her position that undue experimentation would be required to practice the claimed

method with murine antibodies recognizing an epitope different from that recognized by antibody 17-1A. Rather, the examiner points only to a purported “lack of evidence in the specification” showing that antibodies other than 17-1A are therapeutically effective. As noted above, however, it is not Appellants’ burden to establish that every embodiment of their generically claimed method is enabled. If the examiner concludes that the claims are too broad, it is her burden to support that conclusion with evidence and/or scientific reasoning. That burden has not been carried here, and we therefore reverse the rejection.

We also disagree with the examiner’s position that the claims are limited to administration of a single antibody. See the Examiner’s Answer, page 7 (“The claimed method . . . is **NOT** drawn to the employment of a **combination of antibodies** for the method of treatment.” (emphasis in original)). The claims use open claim language, and as relevant here require only “administering . . . a murine monoclonal antibody which specifically binds to an epitope of 17-1A antigen.” Thus, the claims are open to administration of any other agents, including other anti-17-1A antibodies, together with the recited monoclonal antibody. During examination, claims are given their broadest reasonable interpretation consistent with the specification. See, e.g., In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). The specification states that anti-17-1A antibodies “can be administered individually or in mixtures (cocktails) of two or more.” Page 4. Since the claims read on administration of two or more anti-17-1A antibodies in the claimed method, and since the

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specification expressly contemplates such an embodiment, the examiner erred in construing the claims not to encompass such an embodiment.

Summary

We reverse the rejection for non-enablement because the specification is presumed to be enabling and the examiner has not presented sufficient evidence or scientific reasoning to support a conclusion to the contrary.

REVERSED

Donald E. Adams)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Demetra J. Mills)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
)	
Eric Grimes)	
Administrative Patent Judge)	

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Hamilton, Brook, Smith & Reynolds P.C.
530 Virginia Road
P.O. Box 9133
Concord Massachusetts 01742-9133