

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 43

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte JEAN PLOUET, FREDERIC JONICA,
NATALIE ORTEGA and
MARIE-MAGDALEINE RUCHOUX

Appeal No. 2004-0291
Application No. 09/091,561

HEARD: May 18, 2004

Before WINTERS, SCHEINER and 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 25-30 and 32-35. Claims 18-24 and 31, also pending in this application, have been withdrawn from consideration.

Claim 25 is illustrative of the claims on appeal and reads as follows:

25. Anti-idiotypic vascular endothelial growth factor antibody, said antibody being a ligand of the human KDR receptor or of the murine flk-1 and not a ligand of flt.

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Grounds of Rejection

Claims 25-30 and 32-35 stand rejected under 35 U.S.C. 112, first paragraph for lack of enablement.

We reverse this rejection.

DISCUSSION

Background

The claimed invention is directed to anti-idiotypic vascular endothelial growth factor (VEGF) antibodies. “Two different genes code for the transmembrane tyrosine kinases identified as VEGF receptors: KDR in man .. or flk-1 in the mouse...” Specification, page 2. The anti-idiotypic VEGF antibodies recognize the KDR receptor (or the murine flk-1 receptor) but do not recognize the flt receptor. Specification, page 3. The KDR receptor (or flk-1) is the target of pathological angiogenesis. The antibodies would not affect quiescent endothelial cells. Id. According to the specification, VEGF is used to prepare the claimed anti-idiotypic VEGF antibodies which recognize the KDR receptor (or the murine flk-1 receptor) but do not recognize the flt receptor. Specification, page 15.

35 U.S.C. § 112, first paragraph

Claims 25-30 and 32-35 stand rejected under 35 U.S.C. 112, first paragraph for lack of enablement.

It is the examiner's position that (Answer, pages 3-4):

The specification disclosure is insufficient to enable one skilled in the art to practice the invention claimed without undue experimentation because if one of skill in the art performed the method disclosed in the specification said method would not result in the product of the present claims.

The method set forth in the specification would result in a polyclonal antiserum. It is clear however, that only a monoclonal antibody can function in the intended capacity of the antibody of the instant claims. A polyclonal antiserum... would be expected to comprise a mixture of antibodies, some would bind flk-1, some would bind flt, and some would bind both... This concept is demonstrated in Inventor Plouet's declaration filed 9/11/00, which indicates that in one experiment 3 of 4 monoclonal antibodies produced after a polyclonal response were not specific for flk-1...

More specifically, the examiner argues that because "the specification is deficient in disclosing how to make the antibody of the independent claims, it is also deficient in disclosing how to make the Fab fragment of the claims because the Fab fragment is merely an enzymatic cleavage product of the antibody." Answer, page 7. The examiner also appears to be concerned that the methods of purification outlined in the specification would not isolate the selective antibodies claimed.

Appellants respond, arguing (Brief, pages 7-8)

[W]hile the present specification describes the production of the claimed antibodies in a purified polyclonal fraction, the claimed antibody is indisputably present in the polyclonal antiserum described in the present specification.

...[T]he evidence of record further demonstrates that it would be a matter of routine experimentation to further isolate and purify the claimed antibody, as well as to produce monoclonal antibodies using conventional techniques...

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As evidence of enablement, the appellants put forth four declarations.

The first Declaration is that of Jean Plouet dated 9/11/2000, and states that of the four anti-idiotypic monoclonal antibodies of the same isotype isolated, only one, A9, binds to flk-1 but not flt-1. Declaration, page 6.

Another Declaration, that of Dr. Cazenave, stated that the “screening procedure of the application has been established as an assay measuring the inhibition of recombinant human VEGF toward recombinant human VEGFR2 by immunoglobulin.” Cazenave Declaration, page 1.

Dr. Cazenave further states that “an analysis of the specificity of mice antibodies by Radio Receptor Assay would involve only routine experimentation to identify anti-Id immunoglobulin corresponding to the Ig2 J fraction of the present specification.” Id.

The second Declaration of Jean Plouet is dated 3/19/2002. In this Declaration, the inventor Plouet confirms data submitted with the Declaration of Dr. Cazenave, and states that

given the showing in the specification that about 15 to 20% of rabbits produce the anti-idiotypic antibody having the claimed binding specificity, a person skilled in the field of anti-idiotypic science would have at least a “reasonable expectation” that a comparable percentage of mice would produce an anti-idiotypic antibody having that binding specificity...

I also confirm that given the screening methods described in the present specification, an analysis of the specificity of mice antibodies by Radio Receptor Assay would involve only routine experimentation to isolate and identify anti-id immunoglobulin corresponding to the Ig2 J fraction of the present specification. It is only a matter of routine experimentation to produce monoclonal antibodies from the candidate B-lymphocytes and to identify those having the claimed specificity.

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Declaration, page 1.

The Declaration of Pierre Fons, dated 3/25/02, indicates that he was given the task of reproducing the double immunization, of mice, that had been previously performed in rabbits. “I produced several hybridomas, and I used the screening methods described in the present patent application filed by Doctor Jean Plouet, including the Radio Receptor Assay. It took only routine experimentation to isolate and identify anti-id immunoglobulins [sic] from mice corresponding to the Ig2 J fraction of the present application.” Declaration, page 1.

In addition, the appellants argue that the “present specification teaches how to produce and sufficiently purify the claimed antibodies so that one can conduct screening and biological activity studies (present specification, pg. 10, line 1 to pg. 21, line 18).” Reply Brief, page 3. Appellants also argue that a patent need not teach and preferably omits, what is well known in the art, citing Spectra Physics v. Coherent, Inc., 827 F.2d 1524, 3 USPQ2d 1737 at 1743 (Fed. Cir. 1997). Reply Brief, page 4.

Finally, appellants argue that the examiner has failed to “provide any evidence supporting the contrary contention that one of ordinary skill in the art would not be able to produce a monoclonal antibody given the teaching of the polyclonal antiserum.” Brief, page 9.

We agree with appellants that the examiner has failed to provide sufficient evidence to establish a prima facie case of lack of enablement. A patent need not teach and preferably omits, what is well known in the art. Although not explicitly stated in

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section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation." Vaeck, 947 F.2d at 495, 20 USPQ2d at 1444; Wands, 858 F.2d at 736-37, 8 USPQ2d at 1404. Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). An analysis of whether the claims under appeal are supported by an enabling disclosure requires a determination of whether that disclosure contains sufficient information regarding the subject matter of the appealed claims as to enable one skilled in the pertinent art to make and use the claimed invention. Factors to be considered by the examiner in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman, [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404, (Fed. Cir. 1988).

In considering the enablement rejection before us for review, we find the following passage from P.G. Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996) to be instructive.

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[T]he question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation “must not be unduly extensive.” Atlas Powder Co., v. E.I. Dupont De Numbers & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).

The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 USPQ 804, 807 (1982).

In our view, the examiner has not provided sufficient argument or evidence to support his position that the isolation and purification experimentation outlined in the specification, for example the techniques for determining antibody specificity at pages 7 and 17-18, would not amount to routine experimentation or would be undue experimentation in the present case. In our view, the examiner has failed to establish in a meaningful way, that the Wands factors (in particular, the state of the art and the relevant skill of those in the art), have been considered with respect to the enablement issue in this case. The examiner has not established with appropriate evidence that the experimentation required to obtain monoclonal antibodies or Fab fragments in accordance with the claims would have been undue.

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Moreover, even if we assume for the sake of argument that the examiner had established a prima facie case of lack of enablement, we do not find the examiner has sufficiently addressed the Declaration argument and evidence made of record by appellants in support of enablement which would appear to reasonably support appellants position that the experimentation required to isolate the claimed antibodies was routine and used methodologies well known in the art.

After evidence or arguments are submitted by the appellant in response to rejection based on lack of enablement, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of the argument. On balance, we believe that the totality of the evidence presented by the examiner and appellant weighs in favor of finding the claimed invention is enabled by the present specification. The rejection of claims for lack of enablement is reversed.

CONCLUSION

The rejection of claims 25-30 and 32-35 under 35 U.S.C. 112, first paragraph for lack of enablement is reversed.

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No time period for taking any subsequent action in connection with this appeal
may be extended under 37 CFR § 1.136(a).

REVERSED

SHERMAN D. WINTERS
Administrative Patent Judge

TONI R. SCHEINER
Administrative Patent Judge

DEMETRA J. MILLS
Administrative Patent Judge

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