

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WILLIAM M. MITCHELL

Appeal No. 1999-1427
Application 08/372,429

ON BRIEF

Before WILLIAM F. SMITH, SCHEINER, and GRIMES, Administrative Patent Judges.

GRIMES, 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 1-7, all of the claims remaining in the application. Claim 1 is representative and reads as follows:

1. A method of inducing a mucosal immune response to antigen in a mammal, comprising administering to the mucosa of the mammal antigen-encoding DNA complexed to a transfection-facilitating lipospermine or lipospermidine, in an amount effective to induce a mucosal immune response to expressed antigen.

The examiner relies on the following references:

Makela et al., "Animal Models for Vaccines to Prevent Infectious Diseases," Vaccine, Vol. 14, pp. 717-731

Marshall, "Gene Therapy's Growing Pains," Science, Vol. 269, pp. 1050-1055 (1995)

Orkin et al., Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy, National Institutes of Health (1995)

Holmgren et al., "Mucosal Immunity: Implications for Vaccine Development," Immunobiology, Vol. 184, pp. 157-179 (1992)

Claims 1-7 stand rejected under 35 U.S.C. § 112, first paragraph, as unsupported by an enabling disclosure.

We reverse.

Background

"Mucosal surfaces represent the major route of entry for most systemic pathogens with subsequent mucosal immunity usually providing long-term protection against reinfection." Specification, page 1. The specification discloses a "method of inducing a mucosal immune response in a subject, comprising administering to the mucosa of the subject an amount of antigen-encoding DNA effective to induce a mucosal immune response complexed to a transfection-facilitating lipospermine or a lipospermidine." Id.

The specification includes a working example showing that DNA encoding the HIV env protein induces a mucosal immune response in mice when administered, complexed to dioctadecylamidoglycylspermine, via nasal aerosol. See pages 29-34. The specification states that the experiment produced "a clear

anti HIVenv systemic response to mucosal genetic immunization.” Page 34. One of the immunized mice was assayed for secretory IgA response and the specification discloses that both bronchial epithelium and colonic mucosa showed labeling of IgA on mucosal surfaces. Id. The specification concludes that the “visualization of IgA responses following genetic mucosal immunization and the binding of HIV envelope proteins from H9/IIB infected cells represents a specific secretory IgA response to mucosal genetic immunization.” Id.

Discussion

The examiner rejected the claimed method as nonenabled, on the basis that the specification does not enable those skilled in the art “to afford the mammal a long-term protective immune response to a pathogen.” Examiner’s Answer, page 4. The examiner notes that the specification does not include working examples showing that the claimed method provides protective immunity to infection. The examiner also cites prior art which she characterizes as casting doubt on whether mucosal immunity would provide protection from infection, even if the transfected DNA was expressed properly. Id., page 7.

The examiner acknowledges the working example in the specification but concludes that it does not provide the required guidance because “[n]o challenge was performed to test protectivity,” and “[m]ice are not receptive to infection with HIV and are not an art accepted model for HIV infection.” Id., page 10. In addition, the examiner notes that only a single mouse was assayed for secretory IgA response and concludes that “[o]ne cannot extrapolate the results of one

mouse, a model which is not receptive to infection by the pathogen, to protectivity in any mammalian host against any pathogen.” Id.

“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.” In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). “[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.

In this case, the specification contains a working example (pages 29-34) that appears to teach the “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.” Marzocchi, 439 F.2d at 223, 169 USPQ at 369. That is, the working example teaches a method of inducing a mucosal immune response by mucosal administration of antigen-encoding DNA complexed with a

lipospermine. The examiner does not appear to question the objective truth of the statements in the specification.

The examiner nonetheless argues that the example does not adequately support the claims because the specification does not show that the claimed method induces a protective immune response. The claims, however, are not directed to a method of preventing infection, or a method of vaccination, or the equivalent. The claims merely recite a “method of inducing a mucosal immune response.” The examiner has not disputed that the specification’s working example shows induction of a mucosal immune response. Thus, notwithstanding the lack of evidence of protective effect, the working example appears to exemplify and adequately support the claimed method. Practicing the claimed method does not require producing a protective immune response.

The examiner’s concern may be the claims would lack utility under 35 U.S.C. § 101 if the recited method did not induce a protective response. No utility rejection is before us, however, nor does the evidence of record appear to support one. As Appellant points out, even if the claimed method generates an immune response that is less than effectively protective with respect to a given antigen, the method would still have utility as a screening assay. See the Reply Brief, page 2.

Summary

We reverse the rejection under 35 U.S.C § 112, first paragraph, because the examiner has not met his burden of showing that the presumptively enabling specification is inadequate to teach those skilled in the art how to practice the claimed method.

REVERSED

William F. Smith)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Toni R. Scheiner)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Eric Grimes)	
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EG/dm

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