

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 21

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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

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Ex parte JOHN F. KEARNEY

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Appeal No. 2002-1366  
Application No. 09/069,628

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ON BRIEF

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Before SCHEINER, MILLS and GRIMES, 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 1-5, which are all of the claims pending in this application.

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

1. An isolated monoclonal antibody specific for the spores of an individual species of *Bacillus*.

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The references are relied upon by the examiner are:

|                         |           |               |
|-------------------------|-----------|---------------|
| DeGreve et al (DeGreve) | 5,254,799 | Oct. 19, 1993 |
| Ladner et al (Ladner)   | 5,223,409 | June 29, 1993 |

Walker et al. (Walker), "Immunology of Spores and Sporeforms," Spores, Vol. 5, pp. 321-337 (1972)

### Grounds of Rejection

Claims 1-5 stand rejected under 35 U.S.C. § 102(b) as anticipated by DeGreve.

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as obvious over Walker in view of Ladner.

We reverse these rejections.

### DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellant's specification and claims, to the applied references, and to the respective positions articulated by the appellant and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the noted rejections, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellant's Brief for the appellant's arguments thereagainst. As a consequence of our review, we make the determinations which follow.

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35 U.S.C. § 102

Claims 1-5 stand rejected under 35 U.S.C. § 102(b) as anticipated by DeGreve.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”

Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is ‘anticipated’ if one of them is in the prior art.” Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985).

Prior to analysis of the prior art before us we interpret claim 1. Claim 1 is directed to an isolated monoclonal antibody specific for the spores of an individual species of *Bacillus*. [Emphasis added.] Upon review of the term “the spores” as used and described in the specification, we interpret the claim term to refer to complete, intact *Bacillus* spores and not to spore components or fragments, such as spore crystals or spore crystal proteins. For example, the specification, pages 1 and 15, indicates that the invention is directed to monoclonal antibody specific for intact *Bacillus* spores. Examples 2 and 3 of the specification describe the inoculation of mice with *Bacillus* spores emulsified in Freund’s adjuvant. Specification, page 10. Hybridomas reactive with specific *Bacillus* spore species were screened and diluted. Monoclonal antibodies were obtained. Specification, page 16. Thus, the specification supports the claim interpretation that the claimed monoclonal antibody is specific for complete *Bacillus*

spores.

It is the examiner's position that DeGreve "teach isolation and preparation of monoclonal antibodies specific for *Bacillus thuringiensis* spore crystal polypeptides."

Answer, pages 3-4. The examiner finds that DeGreve describes the isolation of crystals purified from spore preparations of *Bacillus thuringiensis* (column 15, lines 12-15).

"DeGreve [], produced 17 hybridoma cell lines producing monoclonal antibodies reactive with *Bacillus thuringiensis* spore crystal proteins and 9 out of 17 monoclonal antibodies were found to be reactive and specific for two strains of the *Bacillus thuringiensis* spore proteins (col. 19 lines 10-14)." Answer, page 4. DeGreve "identified *Bacillus thuringiensis* spore crystal protein encoded by the *Bacillus thuringiensis* spore crystal binding gene (col. 17-18) and demonstrated that the cloned peptide bound to *Bacillus thuringiensis* spores (col. 17 lines 12-55)." Id.

In response, appellant argues that DeGreve "was indifferent to the detection of intact *B. thuringiensis* spores." Brief, page 7. Appellant argues that DeGreve's monoclonal antibodies would not detect a *B. thuringiensis* spore that had become separated from the crystal body, an event that occurs easily and frequently. Brief, page 7.

The examiner responds to appellant, arguing that the antibody of DeGreve meets the claim limitations in that 9 monoclonal antibodies were found to be reactive and specific for two strains of the spores of an individual species of *Bacillus*, *B. thuringiensis*. Answer, page 9.

We do not find the examiner has presented sufficient evidence to establish a prima facie case of anticipation. What is missing from the examiner's analysis and evidence is a showing that one of ordinary skill in the art would understand that the monoclonal antibodies of DeGreve which are specific for spore crystal proteins would be also be specific for a complete or intact Bacillus spore. Though the examiner argues that "the claims merely require binding to spores of *Bacillus*" (Answer, page 8), we find that the present claims, when properly interpreted in view of the specification, refer to monoclonal antibodies which bind complete *Bacillus* spores.

The examiner argues that "Appellant has provided no scientific data to support the position that the monoclonal antibody of DeGreve will not bind to spores." Answer, page 8. However, it is the examiner's burden in the first instance to establish that the monoclonal antibodies of DeGreve will bind to *Bacillus* complete spores. This the examiner has not done, and thus the examiner may not shift the burden of proof to appellant to provide scientific data to support the position that the monoclonal antibody of DeGreve will not bind to spores.

The examiner argues that the monoclonal antibodies of DeGreve were selected for crystal protein specificity by enzyme immunoassay using solubilized *Bacillus thuringiensis* protein. Answer, page 10. Thus, the examiner argues the antibodies were elicited by and selected for ability to bind to biologically active protein which indicates that they bind to non-denatured protein. Id. The examiner concludes that the peptide of DeGreve meets the requirement of binding to *Bacillus*. In our view, the

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examiner has misinterpreted what the claim requires. Claim 1 does not require that the monoclonal antibody be specific for a portion of a *Bacillus* spore, namely the spore crystal protein, but that the monoclonal antibody is specific for the complete spore of an individual species of *Bacillus*. The examiner has not indicated where, and we do not find where DeGreve describes a monoclonal antibody to a complete *Bacillus* spore. The rejection of the claims for anticipation in view of DeGreve is reversed.

35 U.S.C. § 103(a)

Claims 1-5 stand rejected under 35 U.S.C. § 103(a) as obvious over Walker in view of Ladner.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). With this as background, we analyze the prior art applied by the examiner in the rejection of the claims on appeal.

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According to the examiner, Walker teaches the immunology of spores and sporeforms and describes that the species *Bacillus thuringiensis* forms a group of aerobic sporeforms which characteristically develop an intracellular crystalline body during sporulation. Answer, page 5; Walker, page 322. Walker describes an association between crystalline inclusion and the exosporium, where it is believed that the crystal is formed and assembled. Further, Walker describes that the crystals and endospore contain one or more common antigens and indicates that serological tests prepared against urea extracts of spores and crystals solubilized in alkali have shown cross-reactions between the crystal and spore. Id.

Walker also indicates that the “specificity of ferritin labeled antibodies to heat stable spore and vegetative antigens of *B. cereus* in staining spores and vegetative cells has been demonstrated [ ] and this work was later extended to the study of several other species of sporeforming bacteria...i.e., *B. cereus*, *B. subtilis*, *C. sporogenes*, *C. bifermentans*, *C. sardellii*...” Answer, page 6; Walker page 327. Walker describes that antisera were prepared against spore suspensions of 12 species of aerobic sporeformers, including *B. cereus*. Page 323. According to the examiner, “Walker teaches a polyclonal sera, however, monoclonal antibodies can be found mixed in format within the polyclonal sera. Walker does not teach a peptide derived from the monoclonal antibody.” Answer, page 6.

The examiner relies on Ladner for the disclosure of the identification of *B. subtilis* spore coat polypeptides. *Id.* Ladner generally describes a method for the directed evolution of novel binding proteins. For example, DNA molecules from a family of similar binding domains and other structural signals which call for the display of the protein on the outer surface of a chosen bacterial cell, bacterial spore or phage are introduced into a genetic package. The cells or viruses bearing the binding domains which recognize a target molecule are isolated and amplified. Successful binding domains are characterized. Abstract. Ladner indicates that several polypeptide components of *B. subtilis* spore coat have been identified, including two complete coat protein sequences and several fragment sequences. Answer, page 6, Ladner, column 65, lines 41-54.

The examiner concludes (Answer, pages 6-7):

it would have been obvious at the time of applicant's invention to have used the known spore coat protein sequences or fragments and the hybridoma technology as taught by Ladner [], with the known antibodies labeled to heat stable spores of *Bacillus cereus* and *subtilis* wherein recent studies have shown that crystals and endospores contain one or more common antigens and there are known antigen-antibody reactions at spore surface of *Bacillus* as taught by Walker [], because Ladner [], teach no more than routine skill would have been required to use bacterial spores to make monoclonal antibodies since it is well known that spores permit the use of a variety of affinity selection conditions; and Ladner [], teach that identification of several polypeptide components derived from the *B. subtilis* spore coat.

Again, we do not find that the examiner has provided sufficient evidence to establish a prima facie case of obviousness. The examiner has not put forth sufficient evidence to establish a nexus between the polyclonal sera to the bacterial spores

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described by Walker and the claimed monoclonal antibodies to complete spores of *Bacillus*. Nor do we find that Ladner overcomes the deficiencies of Walker. The rejection of the claims over Walker in view of Ladner is reversed.

CONCLUSION

The rejection of claims 1-5 under 35 U.S.C. § 102(b) as anticipated by DeGreve is reversed. The rejection of claims 1-5 under 35 U.S.C. § 103(a) as obvious over Walker in view of Ladner is reversed.

REVERSED

TONI R. SCHEINER  
Administrative Patent Judge

DEMETRA J. MILLS  
Administrative Patent Judge

ERIC GRIMES  
Administrative Patent Judge

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