

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte CLIVE WALDRON

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Appeal No. 94-2006  
Application 07/586,317<sup>1</sup>

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HEARD: MARCH 11, 1999

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

WILLIAM F. SMITH, Administrative Patent Judge.

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<sup>1</sup> Application for patent filed September 19, 1990. According to appellant, this application is a continuation of Application 07/169,560, filed March 17, 1988, which is a continuation of Application 06/685,824, filed December 24, 1984 (abandoned).

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 49, 51 through 59, 69 through 77, and 79 through 83. Subsequent thereto, claims 74, 76, 78 and 81 through 83 were canceled. The examiner allowed claim 79 at page 1 of the examiner's answer. The examiner also indicated at page 2 of the examiner answer that claim 72 is free of rejection and would be allowed if rewritten in independent form. As a result, claims 49, 51 through 59, 69 through 71, 73, 75, 77, and 80 remain for our consideration on appeal. Claim 49 is illustrative of the subject matter on appeal and reads as follows:

49. A chimeric gene functional in a plant cell, which chimeric gene comprises:

(a) at a position 5' to coding region (c), a plant-expressible promoter sequence;

(b) at a position 3' to coding region (c), a terminator signal sequence; and

(c) a coding region of an aphIV gene, which coding region: (1) encodes a functional hygromycin phosphotransferase enzyme or functional portion thereof; and (ii) is positioned between such plant-expressible promoter sequence (a) and such terminator signal sequence (b) so as to be expressible,

which expression of such coding region in a plant cell confers resistance to hygromycin B on such plant cell and wherein such resistance to hygromycin B is capable of providing a basis for selection of such plant cell.

Claims 49, 51 through 59, 69 through 71, 73, 75, 77 and 80 stand rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled. The examiner does not rely upon any evidence in support of this rejection. We reverse.

### DISCUSSION

The claimed invention involves a chimeric gene functional in a plant cell which comprises three coding regions. Of particular interest in this appeal is the coding region of a aphIV gene set forth in claim 49(c) which encodes either a functional hygromycin phosphotransferase enzyme or a functional portion thereof. It is the examiner's position that one skilled in the art could only make and use that aspect of the claimed subject matter which requires a coding region which encodes a functional portion of hygromycin phosphotransferase enzyme through use of undue experimentation. We disagree.

In setting forth the statement of the rejection in the paragraph bridging pages 3-4 of the examiner's answer, the examiner points to the fact that the specification of this application describes only a single modification of the aphIV gene. The examiner also relies upon the purported lack of guidance in the specification in regard to identifying or evaluating essential or non-essential terminal or internal regions of the aphIV gene. Finally, the examiner relies upon a declaration filed by Dr. Raymond Shillito, filed on December 2, 1992, as evidence of the "unpredictability inherent in the expression of bacterially derived

antibiotic resistance genes in plant cells.” The examiner's position is summarized in the last sentence of the paragraph bridging pages 3-4 of the examiner's answer as “undue experimentation would have been required by one of ordinary skill in the art to evaluate a multitude of non-exemplified terminal or internal deletions to identify and characterize functional portions of the gene product and the corresponding coding regions of the gene.”

As explained in PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996):

In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made based on the disclosure in the specification, without undue experimentation. But the 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 Nemours & 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

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determination of how to practice a desired embodiment of the invention claimed.

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

In considering the rejection, it is important to note that the examiner has not raised any question in regard to the ability of a person skilled in the art to physically make truncated aphIV genes in order to evaluate such products to determine whether they would be functional as required by the claims on appeal. Rather, the examiner has only questioned the ability of a person skilled in the art to “evaluate a multitude on non-exemplified terminal or internal deletions” of the aphIV gene. However, in raising this issue the examiner has not relied upon any evidence which allows one to reasonably conclude that such an evaluation would be considered “undue experimentation.”

As set forth above, the test for “undue experimentation” is not merely quantitative. What the examiner needed to have done in this case is to evaluate the prior art as of the effective filing date of this application in light of the disclosure of this application and determine the ability of workers in this field to identify functional portions of enzymes. It is evidence such as this which the examiner needs to rely upon, not the unsupported generalizations set forth in the statement of the rejection.

We have considered the Shillito declaration, but do not find that it supports the examiner's position. The purpose of the Shillito declaration was to establish that there was a degree of unpredictability in extrapolating successful results in developing

selectable marker systems in animal cells to plant cells. As set forth in paragraph 12 of the Shillito declaration "the results of other antibiotic studies in animal cells would not have led to the expectation of parallel findings in plant cells." This is not the issue raised by the rejection under review herein.

In considering an issue of enablement, the examiner must consider not only the relevant teachings of the prior art but also the disclosure of the supporting specification of the application under review. While the Shillito declaration provides evidence that prior to appellant's invention there was a degree of unpredictability in extrapolating successful selection agents for animal cells to plant cells, that degree of unpredictability was in the context of the prior art. In considering a prior art rejection, the examiner, of course, may not use appellant's description of the present invention in the supporting specification. However, that disclosure must be considered in considering issues of enablement. Here, appellant demonstrated that a coding region which encodes a hygromycin phosphotransferase enzyme will confer resistance to hygromycin B on appropriately transformed plant cells. Thus, it stands to reason that a coding region which encodes a functional portion of hygromycin phosphotransferase enzyme would also work as claimed. The examiner has simply not provided evidence that at the time of the present invention, it would entail undue experimentation for those skilled in the art to determine coding regions which encode a functional portion of hygromycin phosphotransferase enzyme.

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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
	)	
	)	
DOUGLAS W. ROBINSON	)	
Administrative Patent Judge	)	

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