

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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 TODD HOLMES,  
SHUGUANG ZHANG,  
ALEXANDER RICH,  
C. MICHAEL DIPERSIO, and  
CURTIS LOCKSHIN

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Appeal No. 2001-0636  
Application No. 08/824,513

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ON BRIEF

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Before WILLIAM F. SMITH, ADAMS, and MILLS, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 38 through 53, all the claims in the case. Claim 38 is representative of the subject matter on appeal and reads below:

38. A method for in vitro cell culture comprising:

a) adding a macroscopic membrane which is formed by self-assembly of amphiphilic peptides in an aqueous solution containing monovalent metal cations, wherein the peptides have alternating hydrophobic and hydrophilic amino acids and are complementary and structurally compatible, to a cell culture

medium comprising cells, thereby forming a membrane/culture mixture; and

b) maintaining the mixture under conditions sufficient for cell growth.

Claims 38 through 53 stand rejected under 35 U.S.C. § 112, first paragraph (enablement).

The examiner does not rely upon any evidence in support of this rejection. We reverse.

#### Discussion

Parent Application 08/293,284 has now issued as U.S. Patent No. 5,955,343 ('343 patent). The enablement issue raised by the examiner can be put in perspective in comparing claim 38 of this application reproduced above with claim 1 of the '343 patent which reads as follows:

1. A method for in vitro cell culture comprising:

a) adding a macroscopic membrane which is formed by self-assembly of amphiphilic peptides in an aqueous solution containing monovalent metal cations, wherein the peptides are 12 or more amino acids in length, have alternating hydrophobic and hydrophilic amino acids, and are complementary and structurally compatible, to a cell culture medium comprising cells, thereby forming a membrane/culture mixture;

b) maintaining the mixture under conditions sufficient for cell growth.

As seen, claim 1 of the '343 patent is the same as claim 38 on appeal with one important difference. Claim 1 of the '343 patent further limits the amphiphilic peptides which form the macroscopic membrane to those which have twelve or more amino acids in length. Claim 38 on appeal places no limitation on the length of the amphiphilic peptides. The issue raised by the examiner in the present enablement rejection is whether one skilled in the art would be able to make and use macroscopic membranes from amphiphilic peptides having the three stated requirements of claim 38, i.e.,

alternating hydrophobic and hydrophilic amino acids, complementary and structurally compatible<sup>1</sup>, wherein the peptides are less than 12 amino acids in length.

In stating the rejection on pages 3-4 of the Examiner's Answer, the examiner emphasizes one fact, i.e., the vast majority of the original disclosure of this application describes the present invention in terms of the amphiphilic peptides being of 12 or more amino acids in length. However, that is not to say the original disclosure of this application fails to describes amphiphilic peptides which have the “alternating, complementary and structural” requirements but contain fewer than 12 amino acids in length. For example, original claim 1 of this application was directed to a method for in vitro cell culture as is present claim 38, but placed no length restriction on the amphiphilic peptides which form the macroscopic membranes.

In this regard, we note that the examiner has not rejected the claims on appeal under the written description requirement of 35 U.S.C. § 112, first paragraph. Given that appellants have described an invention broader than claim 1 of the '343 patent, the issue becomes whether one skilled in the art would be able to make and use the claimed invention to the extent it reads upon amphiphilic peptides having the “alternating, complementary, structural” properties but contain fewer than 12 amino acids.

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<sup>1</sup> Hereinafter, these three properties will be referred to as “alternating, complementary and structural.”

Viewed in this light, the issue raised by the examiner is one of undue experimentation. In considering the examiner's concern in this regard, we find the following passage from PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996) instructive:

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

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

The only specific finding made by the examiner which is relevant in considering this legal standard is found at page 8 of the Examiner's Answer where the examiner states "without specific guidance on which 9, 10 and 11 amino acid sequences to use for the peptide membrane forming experiments, a very large amount of peptide sequences

would have to be screened." As seen, the examiner focuses on the amount of experimentation which may be required instead of explaining why that experimentation would be undue and not routine. Absent a fact-based explanation from the examiner as to why the experimentation needed to make and use the claim embodiments where amphiphilic peptides are needed having the "alternating, complementary and structural" properties but contain fewer than 12 amino acids, we hold that the examiner has failed to establish a prima facie case of lack of enablement.

To the extent the examiner is concerned that the claims may embrace possibly inoperative embodiments, we point to Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984), where the court stated:

Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude . . . possible inoperative substances . . ." In re Dinh-Nguyen, 492 F.2d 856, 858-59, 181 USPQ 46, 48 (CCPA 1974) (emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1973). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. See, e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

Again, absent a fact-based explanation from the examiner why the number of possible inoperative embodiments is significant, we do not find that the examiner has established a prima facie case of lack of enablement.

routine, we hold that the examiner has failed to properly establish a prima facie case of non-enablement.

The decision of the examiner is reversed.

REVERSED

William F. Smith	)	
Administrative Patent Judge	)	
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	)	
	)	BOARD OF PATENT
Donald E. Adams	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
Demetra J. Mills	)	
Administrative Patent Judge	)	

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