

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte BENJAMIN GRAEME COCKS, JANICE AU-YOUNG
and JEFFREY J. SEILHAMER

Appeal No. 2002-0870
Application No. 09/208,206¹

ON BRIEF

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

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 6 and 23.²

Claim 6 is representative:

6. A purified polypeptide comprising an amino acid sequence selected from the group consisting of

- a) an amino acid sequence of SEQ ID NO:2,
- b) a naturally-occurring amino acid sequence found in humans and having at least 90% sequence identity to the sequence of SEQ ID NO:2, and,
- c) an antigenically-active fragment of the amino acid sequence of SEQ ID NO:2.

DISCUSSION

¹ Application for patent filed December 9, 1998. According to appellants, this application is a divisional of application serial no. 08/602,208, filed February 15, 1996, now U.S. Patent 5,866,332.

² Claims 11, 13, 19, 21 and 22 are also pending; claims 11, 13 and 19 have been withdrawn from consideration, while claims 21 and 22 stand objected to.

Claims 6 and 23 stand rejected under the first paragraph of 35 U.S.C. § 112, “because the specification, while being enabling for polypeptides that contain SEQ ID NO: 2, does not reasonably provide enablement for all naturally occurring polypeptides found in humans that have 90% sequence identity to SEQ ID NO:2.” Answer, page 3. According to the examiner (id.),

[t]he instant application does not provide guidance for one of skill in the art to obtain active or otherwise useful embodiments of the claimed invention commensurate with the scope of the claims without performing undue experimentation. For example, the number of insertion embodiments alone that are 90% identical to SEQ ID NO:2 is 2.95×10^{42} . Additionally, there are approximately 3.38×10^{82} nucleotide sequences that encode the amino acid sequence that is SEQ ID NO:2; thus yielding about 10^{120} nucleotide sequences that would encode amino acid sequences that are at least 90% identical to SEQ ID NO:2. With this vast number of sequence[s], there exist sequences that would not hybridize specifically to any probe sequence disclosed in the instant application and that will not be amplified in a PCR run by any set of primers disclosed in that instant application and yet would encode either SEQ ID NO:2 or a polypeptide sequence at least 90% similar to SEQ ID NO:2.

If we understand the examiner's principal concern, it is that the claims are extremely broad, and it is likely that the amplification and hybridization protocol provided in the specification will fail to identify some polypeptides with naturally-occurring sequences that are at least 90% identical to SEQ ID NO:2.

“The first paragraph of 35 U.S.C. § 112 requires, inter alia, that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without ‘undue experimentation.’ In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). That some experimentation may be required is not fatal; the issue is whether the amount of experimentation is ‘undue.’” In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d

1438, 1444 (Fed. Cir. 1991) (emphasis in original).³ Nevertheless, “[w]hen rejecting a claim under the enablement requirement of section 112,” it is well settled that “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).

Thus, the dispositive issue here is not whether appellants have established that the disclosure is broadly enabling for the scope of the claims, rather, the issue is whether the PTO has met its “initial burden of setting forth a reasonable explanation as to why” it is not.

In the present case, the examiner barely touches on two of the factors to be considered in establishing undue experimentation: the breadth of the claims, and the guidance provided in the specification. While we might agree that the first of these factors, at least, would tend to weigh against a finding of enablement, it is but one of many relevant factors, yet the examiner has not analyzed it in conjunction with other relevant factors.

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Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman [230 USPQ 546, 547 (BdPatAppInt 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 (footnote omitted).

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

With respect to the guidance provided by the specification, the examiner does not appear to question the ability of one skilled in the art to follow the protocol disclosed in the specification. Nor, apparently, does the examiner appear to question whether that protocol would have enabled one skilled in the art to obtain naturally occurring polypeptides found in humans that have a 90% sequence identity to SEQ ID NO:2. We accept, for the sake of argument, that it would be iterative and time consuming to identify naturally occurring polypeptides found in humans that have a 90% sequence identity to SEQ ID NO:2, but undue experimentation has little to do with the quantity of experimentation; it is much more a function of the amount of guidance or direction provided. As explained in PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996):

[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 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).

Further, to the extent the examiner requires the specification to “provide enablement for all naturally occurring polypeptides found in humans that have 90% sequence identity to SEQ ID NO:2” (Answer, page 3, emphasis added), we note that no authority has been cited in support of this requirement. On the contrary, “appellants are

not required to disclose every species encompassed by their claims even in an unpredictable art.” In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976) (emphasis in the original).

Finally, the examiner’s bare assertion that “the instant application does not provide enough guidance for one of skill in the art to make and use antigenically active fragments of SEQ ID NO:2” (Answer, page 3) does not provide a reasonable basis to question the adequacy of the disclosure provided for this aspect of the claimed invention.

In our view, the reasons cited in support of the examiner's rejection are insufficient to support the examiner's conclusion that the claims are not enabled by the specification (Answer, page 3). Accordingly, the rejection of claims 6 and 23 under the first paragraph of 35 U.S.C. § 112 is reversed.

REVERSED

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William F. Smith)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
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Toni R. Scheiner)	APPEALS AND
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