

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte

MITSUYOSHI OKUDA, TSUYOSHI SATO, KAZUHIRO SAITO,
NOBUYUKI SUMITOMO, YOSHIFUMI IZAWA,
KATSUHISA SAEKI, TOHRU KOBAYASHI,
and MASAFUMI NOMURA

Appeal 2007-1136¹
Application 10/385,662
Technology Center 1600

DECIDED: November 19, 2007

Before TONI R. SCHEINER, NANCY J. LINCK, and RICHARD M.
LEBOVITZ, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134 from a final rejection of claims 1, 9, 10, and 12-14, the only claims remaining in the application. We have jurisdiction under 35 U.S.C. § 6(b).

¹ Heard October 23, 2007.

STATEMENT OF THE CASE

The claims have been rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written descriptive support in the Specification as filed (Answer 4). This is a new matter rejection.

Claim 1 is representative:

1. A polypeptide which has at least 98% homology to SEQ ID NO: 2, and which has alkaline protease activity, wherein the amino acid corresponding to position 65 of SEQ ID NO: 2 is proline (Pro).

THE ISSUE ON APPEAL

The language which gives rise to the Examiner's rejection is the recitation "[a] polypeptide which has at least 98% homology to SEQ ID NO: 2" in claim 1. Specifically, the Examiner finds that "the genus of species having 98-99% homology to SEQ ID NO: 2" is not described in the Specification as filed (Answer 6). The sole issue raised by this appeal is whether the Specification adequately supports the *lower* end of the range implicit in the recitation "[a] polypeptide which has at least 98% homology to SEQ ID NO: 2".

FINDINGS OF FACT²

1. SEQ ID NO: 2³ represents the native sequence of the 434 amino acid alkaline protease, KP43 (Spec. 8: 4-8).

² Abbreviated "FF".

³ SEQ ID NO: 2 was submitted August 4, 2003. SEQ ID NO: 2 represents the sequence of the alkaline protease KP43, which sequence is also shown in original Figure 1, together with the sequences of several other alkaline proteases.

2. Position 65 in SEQ ID NO: 2 is threonine; thus, Claim 1 encompasses polypeptides having at least 98% homology to SEQ ID NO: 2 at the lower endpoint of the range, and polypeptides having 99.77% homology to SEQ ID NO: 2 at the higher endpoint (i.e., wherein proline has been substituted for the threonine at position 65 of the 434 amino acid polypeptide), wherein the polypeptides have alkaline protease activity.
3. According to the Specification, as originally filed, preferred variants “of the parent alkaline protease include . . . proteases having at least 80%, preferably at least 87%, more preferably at least 90%, still more preferably 95% homology with the amino acid sequence represented by the SEQ. ID NO: [2] and having the above-described enzymatic properties” (Spec. 12: 21 to 13: 3).
4. Table 2 lists 30 variants of KP43 that have homologies to SEQ ID NO: 2 between 99.1% (four substitutions) and 99.76% (one substitution), all of which have *enhanced* alkaline protease activity (Spec. 40, Table 2) (*see* Appeal Br. 10).
5. The Specification, on pages 18 and 19, lists several specific examples of proteases with double, triple, and quadruple substitutions, and further states that “[q]uintuple or sextuple substitution can also be employed” (Spec. 19). Quintuple substitution would result in a polypeptide with 98.85% homology to SEQ ID NO: 2, while sextuple substitution would result in 98.62% homology. In addition, the Specification teaches that amino acid residues “may be substituted at two or more of the positions (a) to (i) simultaneously” (Spec. 17: 1-2, and 19-20). Substitution at these nine

positions would result in a polypeptide with 97.93% homology to SEQ ID NO: 2.

DISCUSSION

Again, the sole issue raised by this appeal is whether the Specification adequately supports the lower end of the range implicit in the recitation “[a] polypeptide which has at least 98% homology to SEQ ID NO: 2” (claim 1).

The Examiner contends that “the specification fails to teach any specific polypeptides having 7, 8, or 9 substitutions of (a) to (i) from Table 1 or whether said polypeptides would have the desired activity Therefore, the specification fails to describe the recited invention in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention” (Answer 6).

Appellants contend that the Specification, as originally filed, described a genus of alkaline proteases having 95% to 100% homology to SEQ ID NO: 2. Although the claims were “narrowed . . . during prosecution . . . to avoid the prior art” (Reply Br. 12), Appellants contend that one of skill in the art would have understood that “Appellants also had possession of polypeptides having intermediate homology between 95-100% homology to SEQ ID NO: 2” (*id.* at 11), including those having at least 98% homology to SEQ ID NO: 2 (*id.* at 12), regardless of whether the entire genus was patentable to Appellants.

One purpose of the written description requirement is to ensure that the Specification conveys “with reasonable clarity” that applicant was in possession of whatever is now claimed, as of the filing date sought. *Vas-*

Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Another purpose is to “ensure that the scope of the right to exclude, as set forth in the claims[,] does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.” *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000).

“[A]pplicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable.” *In re Wertheim*, 541 F.2d. 257, 263 (Fed. Cir. 1976). “That what appellants claim as patentable to them is less than what they describe as their invention is not conclusive if their specification also reasonably describes that which they do claim. (*Id.*)

Having reviewed the Specification as originally filed, we find that it reasonably conveys that Appellants had possession of a genus of alkaline proteases having at least 98% homology to SEQ ID NO: 2, given the Specification’s disclosure of the larger genus having 95% to 100% homology to SEQ ID NO: 2 (FF 3); the disclosure of numerous enzymatically active variants having four substitutions (99.1% homology to SEQ ID NO: 2) (FF 4); and the disclosure that variants with five, six, or as many as nine substitutions (from 97.93% to 98.62% homology) were included in the invention (FF 5).

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Accordingly, we reverse the Examiner's rejection of claims 1, 9, 10, and 12-14 under 35 U.S.C. § 112, first paragraph, as lacking adequate written descriptive support in the Specification as filed.

REVERSED

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