

The opinion in support of the decision being entered today
is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte KEVIN P. BAKER, JIAN CHEN, LUC DESNOYERS, AUDREY GODDARD, PAUL J. GODOWSKI, AUSTIN L. GURNEY, JAMES PAN, VICTORIA SMITH, COLIN K. WATANABE, WILLIAM I. WOOD and ZEMIN ZHANG

Appeal 2007-2953
Application 10/175,749
Technology Center 1600

Decided: August 23, 2007

Before ERIC GRIMES, NANCY J. LINCK, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a polypeptide known as PRO700.¹ The Examiner has rejected the claims as

¹ This application is related to application 10/175,744, which was involved in Appeal 2007-0311 (decided March 26, 2007).

lacking patentable utility. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

The specification discloses 305 DNA sequences and the encoded amino acid sequences. Pages 6-38. Among the disclosed sequences is SEQ ID NO:73, which encodes a polypeptide referred to as “PRO700” having the amino acid sequence shown in SEQ ID NO:74. Page 10 and Figure 74. The encoded amino acid sequence is disclosed to include a signal sequence.

Figure 74.

The present specification does not further characterize the amino acid sequence of SEQ ID NO:74. However, the present application claims priority as follows:

This application is a continuation of . . . a continuation of . . . a continuation-in-part of . . . a continuation-in-part of . . . US Application 09/380138 filed 8/25/1999, now abandoned, which is the National Stage filed under 35 USC §371 of PCT Application PCT/US99/05028 filed 3/18/1999, which claims priority under 35 USC § 119 to US provisional application 60/080333 filed 4/1/1998.

(Preliminary Amendment received Sept. 18, 2002, at 1-2.)

PCT application US99/05028 was published as WO 99/46281 on Sept. 16, 1999. Thus, the contents of that application were known to those of ordinary skill in the art as of that date. WO 99/46281 characterizes PRO700 as follows:

13. PRO700

Protein-disulfide isomerase (PDI) is a catalyst of disulfide formation and isomerization during protein folding. It has two catalytic sites housed in two domains homologous to

thioredoxin, one near the N terminus and the other near the C terminus. . . . PDI is useful for formation of natural type disulfide bonds in a protein which is produced in a[] prokaryotic cell. (See also, U. S. Patent Nos. 5,700,659 and 5,700,678).

Thus, PDI and molecules related thereto are of interest, particularly for ability to catalyze the formation of disulfide bonds. Moreover, these molecules are generally of interest in the study of redox reactions and related processes. PDI and related molecules are further described in Darby, et al., *Biochemistry* 34, 11725-11735 (1995). We herein describe the identification and characterization of novel polypeptides having homology to protein disulfide isomerase, designated herein as PRO700 polypeptides.

(WO 99/46281, at 9.)

DISCUSSION

1. CLAIMS

Claims 25-32 and 35-37 are pending and on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 25 is the only independent claim and reads as follows:

25. An isolated polypeptide having at least 80% amino acid sequence identity to:

- (a) the amino acid sequence of the polypeptide of SEQ ID NO: 74;
- (b) the amino acid sequence of the polypeptide of SEQ ID NO: 74, lacking its associated signal peptide; or
- (c) the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 209721,

wherein said polypeptide has protein disulfide isomerase activity.

2. UTILITY

Claims 25-32 and 35-37 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as lacking patentable utility. The Examiner finds that “[t]he instant specification and the prior art do not teach how the polypeptide of SEQ ID NO:74 functions or a specific and well-established utility for the polypeptide of SEQ ID NO:74” (Answer 4).

The Examiner acknowledges the claim to priority to provisional application 60/080,333 and the disclosure in that application that SEQ ID NO:74 has homology to protein disulfide isomerase (PDI) proteins (*id.* at 4-5). The Examiner finds that “[b]ased on sequence homology to known catalytic sites, *the argument that the polypeptide of SEQ ID NO:74 is a PDI family member and shares some function[al] characteristics with other PDI family members is convincing*” (*id.* at 8).

Nevertheless, the Examiner concludes that the provisional application did not disclose any specific and substantial utility for the polypeptide of SEQ ID NO:74. The Examiner summarizes the disclosed utilities as (1) using the claimed polypeptide to treat “unspecified human disorders,” (2) using the claimed polypeptide to identify molecules that will bind to it, and (3) using the claimed polypeptide to raise antibodies for use in detecting or purifying the polypeptide of SEQ ID NO:74 or as “therapeutics for unspecified disorders” (Answer 8). The Examiner concludes that “[w]ithout identifying a specific disorder, use of the claimed polypeptides . . . as a therapeutic or diagnostic for an unspecified disorder characterized by protein misfolding is not a specific or substantial use” (*id.* at 9).

We agree with the Examiner that Appellants have not disclosed a patentable utility for the claimed polypeptide. Section 101 requires a utility that is both substantial and specific. *See In re Fisher*, 421 F.3d 1365, 1371, 76 USPQ2d 1225, 1229 (Fed. Cir. 2005). The *Fisher* court held that disclosing a substantial utility means “show[ing] that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the ‘substantial’ utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.” *Id.*, 76 USPQ2d at 1230.

The court held that a specific utility is “a use which is not so vague as to be meaningless.” *Id.* In other words, “in addition to providing a ‘substantial’ utility, an asserted use must show that that claimed invention can be used to provide a well-defined and particular benefit to the public.” *Id.*

Appellants argue that “the law does not require that an invention provide an immediate benefit to the public in order to satisfy the utility requirement. Any reasonable use asserted by Applicants that can be viewed as providing a public benefit should be accepted as sufficient with regard to the requirement of ‘substantial’ utility.” (Br. 9.)

Appellants’ asserted definition of “substantial utility” conflicts with the Federal Circuit’s definition. The *Fisher* court squarely held that a substantial utility is one that provides a “significant and *presently available* benefit to the public.” 421 F.3d at 1371, 76 USPQ2d at 1230 (emphasis added). We therefore reject Appellants’ argument that no immediate benefit must be shown to meet the requirements of § 101.

Appellants argue that the identification of SEQ ID NO:74 as a PDI-related protein is sufficient to establish the utility of the claimed antibodies because it has useful therapeutic applications:

In view of the known involvement of other members of the PDI family as regulators of protein folding and cellular viability, the identification of a new member of this family is clearly beneficial to the public, since it allows the development of novel therapies directed to the targeting and/or treatment of diseases involving protein misfolding and cellular viability/proliferation, such as various types of cancer.

. . . In addition, since PDI was known to be involved in the regulation of protein folding and cellular viability/proliferation, that activity would be expected to be useful for a variety of purposes, including the production of therapeutics to treat different types of cancers.

(Br. 9.)

This argument does not persuade us that Appellants have disclosed a utility for the claimed antibodies that meets the requirements of § 101. Appellants have described PDI as “a catalyst of disulfide formation and isomerization during protein folding” and PDI-related proteins as “generally of interest in the study of redox reactions and related processes.”

(WO 99/46281, at 9.)

Appellants have pointed to nothing in the present specification or in any of the priority documents that describes any specific “diseases involving protein misfolding and cellular viability/proliferation, such as various types of cancer,” that would be amenable to treatment with either the polypeptide of SEQ ID NO:74 or an inhibitor of that polypeptide. Nor have Appellants pointed to any other evidence showing that PDI-related proteins were

recognized, as of this application's effective filing date, to be an established or promising treatment for such diseases.

Appellants have not disclosed any specific disorder that could be effectively treated with the claimed polypeptide or an inhibitor of it. Therefore, their argument that the claimed polypeptide "allows the development of novel therapies directed to the targeting and/or treatment of diseases involving protein misfolding and cellular viability/proliferation, such as various types of cancer," does not persuade us that the identification of SEQ ID NO:74 as a PDI-related protein is sufficient, in itself, to establish the patentable utility of the claimed polypeptide.

SUMMARY

Appellants have not disclosed a specific and substantial utility for the claimed polypeptide. We therefore affirm the rejections of claims 25-32 and 35-37 under 35 U.S.C. §§ 101 and 112, first paragraph, for lack of patentable utility.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED

dm

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