

The opinion in support of the decision being entered today was *not* written for publication and 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, et al.

Appeal 2007-0083
Application 10/174,574
Technology Center 1600

ON BRIEF

Before SCHEINER, ADAMS, and GRIMES, *Administrative Patent Judges*.
GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an antibody. The Examiner has rejected the claims as lacking patentable utility and anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm the rejections for lack of utility, and affirm one of the two rejections for anticipation.

BACKGROUND

The specification discloses 305 DNA sequences and the encoded amino acid sequences. Pages 6-38. Among the disclosed sequences is SEQ

ID NO:31, which encodes a polypeptide referred to as “PRO270,” which has the amino acid sequence shown in SEQ ID NO:32. Page 8 and Figure 32. The encoded amino acid sequence is disclosed to include a signal sequence, transmembrane domain, sites for various post-translational modifications, and a “Myb DNA-binding domain repeat signature 1.” Figure 32.

The present specification does not further characterize the amino acid sequence of SEQ ID NO:32. However, the present application claims priority as follows:

This application is a continuation of . . . a continuation of . . . a continuation-in-part of . . . US Application 09/380139 filed 8/25/1999, now abandoned, which is the National Stage filed under 35 USC §371 of PCT Application PCT/US98/19330 filed 9/16/1998, which claims priority under 35 USC § 119 to US provisional application 60/063121 filed 10/24/1997.

Preliminary Amendment filed Sept. 18, 2002, pages 1-2.

PCT application US98/19330 was published as WO 99/14328 on March 25, 1999. Thus, the contents of that application were known to those of ordinary skill in the art as of that date. WO 99/14328 characterizes PRO270 as follows:

Thioredoxins [a]ffect reduction-oxidation (redox) state. Many diseases are potentially related to redox state and reactive oxygen species may play a role in many important biological processes. The transcription factors, NF-kappa-B and AP-1, are regulated by redox state and are known to affect the expression of a large variety of genes thought to be involved in the pathogenesis of AIDS, cancer, atherosclerosis and diabetic complications. Such proteins may also play a role in cellular antioxidant defense, and in pathological conditions involving oxidative stress such as stroke and inflammation in addition to having a role in apoptosis. Therefore, thioredoxins, and

proteins having homology thereto, are of interest to the scientific and medical communities.

We herein describe the identification and characterization of novel polypeptides having homology to thioredoxin, designated herein as PRO270 polypeptides.

Page 25.

DISCUSSION

1. CLAIMS

Claims 25-29 are pending and on appeal. The claims have not been argued separately; therefore, they stand or fall together. 37 CFR § 41.37(c)(1)(vii). Claim 25 is representative and reads as follows:

25. An isolated antibody that binds specifically to the polypeptide of SEQ ID NO:32.

2. UTILITY

Claims 25-29 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as lacking patentable utility. The Examiner argues that claimed antibodies lack utility because PRO270 lacks utility. In particular, the Examiner argues that the disclosed similarity between PRO270 and thioredoxin is not enough, by itself, to establish PRO270's utility:

[T]he mere identification that a protein belongs to a family of proteins, while indicative of evolutionary relatedness, is not indicative of function, nor by extension of utility. . . . [W]ithout any information as to the specific properties of the protein, the mere identification of such as having homology to thioredoxin proteins is not sufficient to impart any particular utility to the polypeptide.

Examiner's Answer, page 4.

We do not necessarily agree with the Examiner's broadly stated position – that sequence similarity is not evidence of function and therefore cannot form the basis of patentable utility. We do, however, agree that the evidence of record shows that PRO270 is unlikely to share the activity of thioredoxin and therefore, in this case, the sequence similarity between PRO270 and thioredoxin is not sufficient to establish the utility of PRO270.

Holmgren¹ states that “[t]hioredoxin and glutaredoxin are small proteins containing an active site with a redox-active disulfide; they function in electron transfer via a simple and elegant mechanism, the reversible oxidation of two vicinal protein-SH groups to a disulfide bridge.” Abstract. Holmgren also states:

Thioredoxin has been isolated and sequenced from a wide variety of prokaryotic and eukaryotic [sic] species. . . . All species have at least one thioredoxin with an M_r around 12,000 and the same active site, Cys-Gly-Pro-Cys. . . . The active site region is highly conserved with the consensus sequence: Val-Asp-Phe-Xaa-Ala-Xaa-Trp-Cys-Gly-Pro-Cys-(Lys)-(Met)-(Ile)-Xaa-Pro.

Page 13964, right-hand column.

Holmgren's disclosure regarding the thioredoxin active site is supported by Meng,² which states that thioredoxin (TRX) “is characterized by two cysteine residues within the conserved active site sequence, CGPC,” which is identical to Holmgren's Cys-Gly-Pro-Cys sequence. Meng, page

¹ Holmgren, “Minireview: Thioredoxin and glutaredoxin,” *J. Biol. Chem.*, Vol. 264, pp. 13963-13966 (1989).

² Meng et al., “Cloning and identification of a novel cDNA coding thioredoxin-related transmembrane protein 2,” *Biochem. Genetics*, Vol. 41, pp. 99-106 (2003).

105. Meng also teaches that “[m]any TRX-like proteins are members of the TRX superfamily and have the CGHC [i.e., Cys-Gly-His-Cys] sequence.” *Id.*

As the Examiner has pointed out, “PRO270 lacks a Cys-Gly-Pro-Cys active site.” Examiner’s Answer, page 8. It also does not contain a Cys-Gly-His-Cys sequence. See SEQ ID NO:32: amino acids 160-166 form the sequence VEFFANW, which roughly matches the first part of the consensus sequence disclosed by Holmgren (VDFXAXW) but the next four amino acids are SNDC, not CGPC or CGHC. See also the Appeal Brief, page 10 (“Meng . . . disclosed a protein ‘thioredoxin-related transmembrane protein 2’ or ‘TMX2’ that is 100% identical to PRO270, excluding a 12 amino acid insert absent in the TMX2 polypeptide”) and Meng, page 105 (“TMX2 protein does not have the CGPC or CGHC sequence”).

The two cysteine (Cys or C) residues in the active site carry the –SH groups that are reversibly oxidized to form a disulfide bridge, the “simple and elegant mechanism” of electron transfer described by Holmgren. Thus, PRO270 lacks the specific amino acids that are known in the art to be the basis of thioredoxin’s activity.

We agree with the Examiner that the evidence shows that, despite the overall similarity of PRO270 and thioredoxin, PRO270 is unlikely to have the same activity as thioredoxin. Therefore, thioredoxin’s activity cannot be relied on as a basis for the patentable utility of PRO270.

Appellants argue that “members of the thioredoxin family (1) have a specific function in mediating the transfer of electrons and (2) that this mediation has been shown to be applicable to a variety of specific

therapeutic purposes.” (Br. 9.) Appellants also cite Sen,³ as teaching that thioredoxin has “specific effects on gene expression, for example, by regulating the transcription factor NF-κB,” and Gallegos⁴ for its teaching that transfection of human breast cancer cells with a dominant-negative mutant of thioredoxin reverses the transformed phenotype. (*Id.*)

The utilities relied on by Appellants are based on thioredoxin’s activity in electron transfer and regulation of the oxidation-reduction (redox) state. Those activities, in turn, rely on the reversible oxidation of the two cysteine residues in thioredoxin’s active site. Since PRO270 lacks those cysteine residues, it is unlikely to share thioredoxin’s electron transfer and redox regulating activities. Therefore, those activities cannot be relied on as a basis for PRO270’s patentable utility.

Appellants have asserted no utility for the claimed antibodies or for PRO270 that is not based on electron transfer and redox regulation. Since the evidence shows that PRO270 is unlikely to have those activities, we agree with the Examiner that the specification does not disclose a patentable utility for the claimed polypeptides. The rejections of claims 25-29 under 35 U.S.C. §§ 101 and 112, first paragraph, for lack of utility are affirmed.

³ Sen et al., “Antioxidant and redox regulation of gene transcription,” *FASEB J.*, Vol. 10, pp. 709-720 (1996).

⁴ Gallegos et al., “Transfection with human thioredoxin increases cell proliferation and a dominant-negative mutant thioredoxin reverses the transformed phenotype of human breast cancer cells,” *Cancer Research*, Vol. 56, pp. 5765-5770 (1996).

3. ANTICIPATION BY TANG

Claims 25-29, and 35 stand rejected under 35 U.S.C. § 102(a) or § 102(e) as anticipated by Tang.⁵

The Examiner argues that

Tang et al. teaches of an antibody [that] binds to [a] protein. The protein of Tang et al., SEQ ID NO:2374 has 100 % identity to the entire full sequence of claimed SEQ ID NO:32. The antibody taught by Tang et al. includes a monoclonal, humanized, antibody fragment, and labeled. Therefore, Tang et al. anticipates the claimed invention.

(Answer 5-6.)

Appellants do not dispute that Tang discloses a polypeptide having the amino acid sequence of SEQ ID NO:32 and antibodies that specifically bind to it. Rather, Appellants argue that Tang was published after the earliest priority date claimed for the instant claims, and is therefore not prior art.

(Br. 12.)

We will affirm the rejection. “It is elementary patent law that a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112.” *In re Chu*, 66 F.3d 292, 297, 36 USPQ2d 1089, 1093 (Fed. Cir. 1995).

For the reasons discussed above, neither the instant application nor any of the earlier-filed applications discloses a utility for the claimed antibody sufficient to satisfy the requirements of § 101. *Ipsso facto*, none of

⁵ Tang et al., WO 01/57188, published August 9, 2001.

the earlier-filed applications provides a disclosure sufficient to satisfy the first paragraph of § 112, and none can be relied on for priority under § 120.

The effective filing date of the present application is its actual filing date: June 18, 2002. Tang qualifies as prior art and Appellants do not dispute that it discloses an antibody that binds to the polypeptide of SEQ ID NO:32. Tang therefore anticipate claim 25. Claims 26-29 fall with claim 25.

4. ANTICIPATION BY RUBEN

Claims 25-29 stand rejected under 35 U.S.C. § 102(b) as anticipated by Ruben. In the Examiner's Answer, the Examiner provided the following citation for Ruben: "Ruben et al. WO 98/04825." Page 3. In the Form PTO-892 that accompanied the Office action mailed Nov. 18, 2004, however, Ruben is cited as "WO 98/40483." In their brief, Appellants direct their arguments to the reference cited in the Examiner's Answer, which does not appear to be in the official Image File Wrapper.

Since it is unclear from the record (1) what reference the Examiner intends to rely on; and (2) whether Appellants had proper notice of the basis of the rejection and an opportunity to respond to it, we will vacate the rejection based on Ruben.

SUMMARY

We affirm the rejections for lack of patentable utility because the evidence of record does not support Appellants' position that PRO270 would be expected to share the activity of thioredoxin. We affirm the anticipation rejection based on Tang and vacate the rejection based on Ruben.

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

AFFIRMED

Toni R. Scheiner)
Administrative Patent Judge)
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) BOARD OF PATENT
Donald E. Adams)
Administrative Patent Judge) APPEALS AND
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) INTERFERENCES
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Eric Grimes)
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