

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

---

*Ex parte* STEFAN A. BLEDIG, JOSEPH R. BYRUM, and  
JINGDONG LIU

---

Appeal 2008-4080  
Application 10/959,789  
Technology Center 1600

---

Decided: December 22, 2008

---

Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES,  
*Administrative Patent Judges.*

ADAMS, *Administrative Patent Judge.*

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1 and 14, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

## STATEMENT OF THE CASE

The claims are directed to a substantially purified nucleic acid molecule. Claims 1 and 14 are reproduced below:

1. A substantially purified nucleic acid molecule that encodes a maize S-adenosylmethionine decarboxylase fragment wherein said nucleic acid molecule comprises the nucleic acid sequence of SEQ ID NO: 662.
14. A substantially purified nucleic acid molecule comprising the nucleic acid sequence of SEQ ID NO: 662.

The Examiner relies on the following prior art references to show unpatentability:

Lorraine A. Everett et al., *Pendred syndrome is caused by mutations in a putative sulphate transporter gene (PDS)*, 17 NATURE GENETICS 411-422 (1997).

Daryl A. Scott et al., *The Pendred syndrome gene encodes a chloride-iodide transport protein*, 21 NATURE GENETICS 440-443 (1999).

Sequence alignment between SEQ ID NO: 662 and gi 1532072 (see Ans. Appendix).

The rejections as presented by the Examiner are as follows:

Claims 1 and 14 stand rejected under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph based on the finding of lack of utility.

We reverse.

## ISSUE

Did the Examiner meet his initial burden of challenging Appellants' presumptively correct assertion of utility?

## FINDINGS OF FACT

1. Claim 14 is drawn to a substantially purified nucleic acid molecule comprising the nucleic acid sequence of SEQ ID NO: 662 (Claim 14).  
Claim 1 differs from claim 14 only in that the claimed substantially purified nucleic acid molecule encodes a maize S-adenosylmethionine decarboxylase fragment (Claim 1).
2. “Plants contain a pathway for the degradation of L-methionine. This degradation pathway includes . . . S-adenosyl-methionine decarboxylase (EC 4.1.1.50)” (Spec. 10: 11-14). Appellants’ Specification discloses that “[t]he present invention . . . provides a substantially purified maize or soybean S-adenosylmethionine decarboxylase enzyme or fragment thereof encoded by a . . . nucleic acid sequence selected from the group consisting of a complement of SEQ ID NO: 430 through SEQ ID NO: 857” (Spec. 24: 7-9). Table A of Appellants’ Specification discloses that SEQ ID NO: 662 is from Library SATMON008 (Spec. 254: Table A, SEQ ID NO: 662). “The SATMON008 cDNA library is generated from the primary shoot (coleoptile 2-3 cm) of maize . . . seedlings which are approximately 5 days old” (Spec. 166: 4-6). Appellants’ Specification discloses that SEQ ID NO: 662 has 91% identity with adenosylmethionine decarboxylase (EC 4.1.1.50; NCBI gi g1532072) (Spec. 249: 30-40 and 254: 6).
3. Appellants’ Specification discloses

In an aspect of the present invention, one or more of the nucleic molecules of the present invention are used to determine the level (i.e., the concentration of mRNA in a sample, etc.) in a plant (preferably maize or soybean) or pattern (i.e., the kinetics of expression, rate of decomposition, stability profile, etc) of the expression of a protein encoded in part or

whole by one or more of the nucleic acid molecule[s] of the present invention.

(Spec. 90: 3-7.) In addition, Appellants' Specification discloses that “[i]t is understood that one or more of the nucleic acids of the present invention may be introduced into a plant cell and transcribed using an appropriate promoter with transcription resulting in cosuppression of an endogenous Methionine pathway protein” (Spec. 121: 15-17). In this regard, Appellants' Specification discloses that “[a]ntisense approaches are a way of preventing or reducing gene function by targeting the genetic material” (Spec. 121: 18-19).

4. Based on sequence homology comparisons Everett determines that pendrin is a sulfate transporter (Everett 419: col. 2, ll. 32-34; Ans. 7). Scott, however, reports that they “were unable to detect evidence of [pendrin’s] sulfate transport [activity]” (Scott 440: col. 1, ll. 15-16). Scott concludes that despite pendrin’s 45% homology to “the human sulfate transporter ‘downregulated in adenoma’”; “pendrin does not function as a sulfate transporter, as suggested by its close homology to other sulfate transporters, but instead functions as a sodium-independent transporter of chloride and iodide” (Scott 441: col. 1, ll. 33-36; Ans. 7).

#### PRINCIPLES OF LAW

The “utility requirement” originates with the provision of 35 U.S.C. § 101 that a patent may be obtained on “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” An inquiry by the PTO into whether a claimed

invention satisfies the utility requirement typically has two distinct prongs. First, the PTO must determine whether the patent applicant has asserted a specific and substantial utility for the claimed invention. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). Second, the PTO must ascertain whether there is any evidence that one of ordinary skill in the art would reasonably doubt the invention's asserted utility. *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

[T]he PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. . . . Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility. See *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981).

*Brana*, 51 F.3d at 1566.

## ANALYSIS

The Examiner finds that “[t]he claimed nucleic acid is not supported by a specific asserted utility because none of the disclosed uses of the nucleic acid in the specification is specific” (Ans. 4). We disagree.

Appellants’ Specification discloses that SEQ ID NO: 662 has 91% identity with adenosylmethionine decarboxylase (EC 4.1.1.50) and that this enzyme is involved in the degradation of L-methionine (FF 2). Appellants’ Specification further discloses that the inventive nucleic acid molecules can be used, *inter alia*, to determine the concentration of mRNA in a sample, to determine the expression pattern of a protein encoded in part or whole by one or more of the nucleic acid molecules, and to inhibit expression using

antisense approaches (FF 3). There is no evidence on this record that Appellants' claimed nucleic acid molecule would not be useful in determining the mRNA concentration of adenosylmethionine decarboxylase, expression pattern of adenosylmethionine decarboxylase in a sample, or in antisense approaches to prevent or reduce the function of the adenosylmethionine decarboxylase gene. In addition, there is no evidence on this record that a full length sequence or that further research would be required to perform these utilities. Accordingly, we disagree with the Examiner's assertion that "the application does not show that the claimed polynucleotide is useful to the public as disclosed in its current form" (Ans. 5).

The Examiner finds that a person of ordinary skill in this art would "have reasonable doubt that the nucleotide sequence of SEQ ID NO: 662" encodes S-adenosyl methionine decarboxylase (Ans. 6). In this regard, the Examiner finds that "it is only in a small region of gi 1532072 . . . that the best local similarity between the two sequences is 91%" (*id.*). Further, with reference to Everett and Scott the Examiner finds that "[i]n the instant case, the numerous mismatches and the relatively low identity between the two sequences would leave reasonable doubt to one skilled in the art that the sequence of SEQ ID NO:662 would encode[ ] an S-adenosyl methionine decarboxylase activity" (Ans. 7). We are not persuaded.

Claim 14 does not require the claimed nucleic acid molecule to encode an S-adenosyl methionine decarboxylase activity (FF 1). In addition, claim 1 requires only that the claimed substantially purified nucleic acid molecule encode a maize S-adenosylmethionine decarboxylase *fragment* (*id.*). There is no evidence on this record that SEQ ID NO: 662 does not

encode a S-adenosylmethionine decarboxylase fragment. Further, as discussed above, there is no evidence on this record to suggest that the claimed nucleic acid would not be capable of performing the disclosed utilities (FF 3). Accordingly, we are not persuaded by the Examiner's assertion that

without showing the active domain or functional motif for the enzyme S-adenosyl-methionine decarboxylase, if any, is conserved in the sequence of SEQ ID NO:662 and the near 15% difference between the two sequences would not destroy the function of S-adenosyl-methionine decarboxylase, one skilled in the art would have reasonable doubt that SEQ ID NO:662 encodes S-adenosyl-methionine decarboxylase.

(Ans. 11-12). There is no requirement in Appellants' claimed invention that the nucleic acid molecule encode a functional S-adenosyl-methionine decarboxylase protein.

Lastly, we agree with Appellants' contention that Everett and Scott appear to suggest that homology of less than 50% may not provide an accurate functional assignment. However, . . . SEQ ID NO: 662 has at worst an 85.9% identity with a known S-adenosyl-methionine decarboxylase. There is no support for the Examiner's proposition that the claimed invention does not have specific and substantial utility based on the Examiner's citation of Everett *et al.* and Scott *et al.*

(App. Br. 8.)

#### CONCLUSION OF LAW

For the foregoing reasons we find that the Examiner has failed to meet his burden of challenging Appellants' presumptively correct assertion of utility. *Brana*, 51 F.3d at 1566.

Appeal 2008-4080  
Application 10/959,789

Accordingly, the rejection of claims 1 and 14 under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph based on the finding of lack of utility is reversed.

REVERSED

cdc

ARNOLD & PORTER LLP  
555 TWELFTH STREET, N.W.  
ATTN: IP DOCKETING  
WASHINGTON DC 20004