

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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 XUANCHAUAN YU, MARICAR MIRANDA,
and NATHANIEL L. WILGANOWSKI

Appeal No. 2006-0732
Application No. 10/060,974

ON BRIEF

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

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 2, and 4-6, all of the claims remaining. Claim 2 is representative and reads as follows:

2. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:2.

The examiner relies on the following references:

Bork et al., "Sequences and topology: Deriving biological knowledge from genomic sequences," Current Opinion in Structural Biology, Vol. 8, pp. 331-332 (1998)

Skolnick et al., "From genes to protein structure and function: Novel applications of computational approaches in the genomic era," TIBTECH, Vol. 18, pp. 34-38 (2000)

Claims 1, 2, and 4-6 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as lacking patentable utility. We affirm.

Background

The specification discloses a polynucleotide encoding a human polypeptide (referred to generically as a “novel human protein” or NHP) that “shares structural similarity with mammalian transporters, and particularly sodium iodide cotransporters or symporters and multivitamin transporters.” Page 2. The disclosed polynucleotide encodes a polypeptide of 610 amino acids (SEQ ID NO:2). Id.

The specification states that

[t]ransporter proteins are integral membrane proteins that mediate or facilitate the passage of materials across the lipid bilayer. Given that the transport of materials across the membrane often plays an important physiological role, transporter proteins are good drug targets.

Page 1.

The specification does not disclose what material(s) the putative transporter of SEQ ID NO:2 transports across a membrane, or the role the protein of SEQ ID NO:2 plays in any biological process, but contemplates “processes for identifying compounds that modulate, i.e., act as agonists or antagonists of, NHP expression and/or NHP activity Such compounds can be used as therapeutic agents for the treatment of any of a wide variety of symptoms associated with biological disorders or imbalances.”

Page 3. The specification states that the “sequences of the present invention are also useful as additional DNA markers for restriction fragment length polymorphism (RFLP) analysis, and in forensic biology.” Id.

The NHP protein is disclosed to be useful “in assays for screening for compounds that can be used as pharmaceutical reagents useful in the therapeutic treatment of mental, biological, or medical disorders and disease.” Page 19.

Finally, the specification discloses that the nucleotide sequence of SEQ ID NO:1 includes a polymorphic position. See page 17.

Discussion

The examiner rejected all of the claims as lacking a disclosed utility sufficient to satisfy 35 U.S.C. § 101.¹ The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (“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.”).

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005). The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a “de minimis view of utility.” 421 F.3d at 1370, 76 USPQ2d at 1229. The Fisher court held that § 101 requires a utility that is both substantial and specific. Id. at 1371, 76 USPQ2d at 1229. The 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 be useful at some future date after

¹ The examiner also rejected all of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement, but that rejection is merely as a corollary of the finding of lack of utility. See the Examiner’s

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.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because “all of Fisher’s asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world.” Id. at 1373, 76 USPQ2d at 1231. “Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the ‘643 application, we have no choice but to conclude that the claimed ESTs do not have a ‘substantial’ utility under § 101.” Id. at 1374, 76 USPQ2d at 1232.

“Furthermore, Fisher’s seven asserted uses are plainly not ‘specific.’ Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher’s seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the ‘643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101.” Id.

In this case, the examiner found the specification's disclosure to be inadequate because the "claims are drawn to an isolated nucleic acid molecule and the protein encoded thereby of as yet undetermined function or biological significance. . . . In the absence of knowledge of the biological significance of this specific nucleic acid of SEQ ID NO: 1 and encoded protein of SEQ ID NO: 2, there is no immediately obvious patentable use for the polynucleotide or the encoded protein." Examiner's Answer, pages 4-5. With regard to the asserted utility in treating disease, the examiner pointed out that the specification

fails to provide any evidence or sound scientific reasoning that would support a conclusion that the instant nucleic acid or encoded protein is associated with any diseases or disorder. . . . The instant application also fails to demonstrate use of the protein as a marker for any specific disease or condition (which would be a real world use).

Examiner's Answer, page 5.

Appellants argue that "the presently claimed sequence shares greater than 99% identity at the amino acid level . . . with a sequence that is present in the leading scientific repository for biological sequence data (GenBank), which has been annotated by independent third party scientists wholly unaffiliated with Appellants as Homo sapiens sodium solute symporter family 5 member 8 protein (SLC5A8)." Appeal Brief, page 3.² Appellants also cite a scientific article as further evidence that the claimed sequence encodes a sodium transporter. Id., pages 3-4.³ Appellants argue that the evidence supports the specification's assertion that SEQ ID NO:2 is a transporter

² "Appeal Brief" in this opinion refers to the Amended Appeal Brief filed August 8, 2005. The pages in the Appeal Brief are unnumbered but we have inferred the intended numbering from its Table of Contents.

³ Appellants cite Li et al., "SLC5A8, a sodium transporter, is a tumor suppressor gene silenced by methylation in human colon aberrant crypt foci and cancers," Proc. Natl. Acad. Sci. USA, Vol. 100, pp. 8412-8417 (2003).

protein and therefore confirms the patentable utility of the claimed invention. See id., page 4.

We do not agree that the claimed nucleic acids have utility because they encode an apparent sodium transporter protein. While post-filing evidence may be used to show the accuracy of a statement in the specification, it cannot be relied on to “render an insufficient disclosure enabling.” Brana, 51 F.3d at 1567 n.19, 34 USPQ2d at 1441 n.19.

Thus, Appellants can rely on the cited GenBank record and the Li reference for the limited purpose of showing the accuracy of the specification’s statement that SEQ ID NO:2 encodes a protein that “shares structural similarity with mammalian transporters, and particularly sodium iodide cotransporters or symporters and multivitamin transporters.” However, they cannot rely on the substantive disclosures of the post-filing references for the disclosure that, e.g., SLC5A8 is a putative tumor suppressor.

Utility is determined as of the effective filing date of the application. See Brana, 51 F.3d at 1567 n.19, 34 USPQ2d at 1441 n.19. Here, the specification disclosed that the protein encoded by the claimed nucleic acids was likely to be a sodium transporter, and this disclosure was confirmed by post-filing evidence. The relevant question with respect to utility, then, is whether a specific and substantial utility for a sodium transporter was disclosed in the specification or well known in the art as of this application’s effective filing date (February 2, 2001).

The evidence of record does not reveal any specific and substantial utility for sodium transporters, disclosed in either the specification or prior art. The specification does not disclose the role played by the protein of SEQ ID NO:2 in any biological

process, or any association between the protein of SEQ ID NO:2 and any disease or disorder. Thus, the specification's disclosure is inadequate to allow those skilled in the art to use the protein of SEQ ID NO:2 in a specific and substantial way.

Appellants have pointed to no evidence outside of the specification, and publicly available before this application's effective filing date, that would have allowed a person skilled in the art to use the protein of SEQ ID NO:2 in a specific and substantial utility. We therefore conclude that the mere identification of the protein encoded by the claimed nucleic acids as a sodium transporter does not satisfy the utility requirement of 35 U.S.C. § 101.

Appellants also argue that the claimed polynucleotides are useful for "assessing gene expression patterns using high-throughput DNA chips" (Appeal Brief, page 14); that they are useful in mapping human chromosomes (*id.*, page 16); and that they are "useful for functionally defining exon splice-junctions" (*id.*, page 17).

We find that none of these uses meet the requirements of § 101. In this case, as in Fisher, the generic uses asserted by Appellants – assessing gene expression, mapping human chromosomes, and defining exon splice-junctions – are neither substantial nor specific. Like in Fisher, these uses are "merely hypothetical possibilities, objectives which the claimed [cDNAs], or any [cDNA] for that matter, could possibly achieve, but none for which they have been used in the real world." Fisher, 421 F.3d at 1373, 76 USPQ2d at 1231 (emphasis in original). Therefore, they are not substantial utilities.

Nor are they specific utilities, because they could be asserted for any cDNA transcribed from any gene in the human genome. Because nothing about Appellants'

asserted utilities sets the claimed nucleic acids apart from any other human cDNA, Appellants have “only disclosed general uses for [the] claimed [cDNAs], not specific ones that satisfy § 101.” Id. at 1374, 76 USPQ2d at 1232.

Finally, Appellants argue that the identified polymorphism in SEQ ID NO:2 makes the nucleic acids useful in “forensic analysis.” Appeal Brief, pages 7-9.

We do not agree that the disclosed polymorphism establishes the utility of the claimed nucleic acids. First, Appellants’ argument lacks support in the specification or in the evidence of record. The specification discloses the presence of a polymorphism in SEQ ID NO:1 (page 17) but discloses no utilities based on detection of the polymorphism. In particular, the specification does not disclose that the polymorphism is a useful marker for forensic analysis.⁴

In addition, the polymorphism-based utility is neither substantial nor specific. It is not substantial because it is merely a hypothetical possibility, an objective which the disclosed polymorphisms, or any polymorphism for that matter, could achieve, but not one for which the claimed nucleic acids have been used in the real world. See Fisher, 421 F.3d at 1373, 76 USPQ2d at 1231. It is not specific because nothing about the asserted utility sets the polymorphism in SEQ ID NO:1 apart from any other polymorphism found in the human genome. See id. at 1374, 76 USPQ2d at 1232.

⁴ The specification (page 3) states that the “sequences of the present invention are also useful as additional DNA markers for restriction fragment length polymorphism (RFLP) analysis, and in forensic biology.” This passage, however, does not refer to the usefulness of the polymorphism in SEQ ID NO:1 but only generically to the use of the “sequences of the present invention . . . in forensic biology.” Appellants have provided no evidence to show that the cited passage would have been understood by those skilled in the art to mean that the claimed sequences are useful because of the polymorphism found therein.

Summary

The specification does not disclose a specific and substantial utility for the claimed nucleic acids, as required by 35 U.S.C. § 101. We therefore affirm the examiner's rejection of claims 1, 2, and 4-6.

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

AFFIRMED

Toni R. Scheiner)
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