

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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 D. WADE WALKE, NATHANIEL L. WILGANOWSKI,
and C. ALEXANDER TURNER JR.,

Appeal No. 2006-2131
Application No. 10/309,422

ON BRIEF

Before SCHEINER, GRIMES, and LINCK, 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, 3, and 6-11, all of the claims remaining. Claim 3 is representative and reads as follows:

3. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:16 or SEQ ID NO: 28.

The examiner does not rely on any references.

Claims 1, 3, and 6-11 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, for lack of patentable utility.

We affirm.

Background

The specification discloses polynucleotides encoding human peptides (referred to generically as a “novel human proteins” or NHPs) that “share sequence similarity with mammalian GPI-anchored P137 protein, cerebellin and C1Q proteins.” Page 1. The proteins are also characterized as “shar[ing] structural similarity with mammalian membrane proteins (tumor associated markers) and secreted proteins and peptides such as, but not limited to, cerebellin, C1Q, and collagens” (page 1, line 29 to page 2, line 3) and being “similar to those related to eucaryotic GPI-anchored P137 protein[] (which is thought to facilitate transport of materials across epithelial surfaces), tumor-associated proteins, and precursors of secreted proteins” (page 15, lines 29-32).

The specification does not disclose the biological function of any of the disclosed proteins or their degree of similarity to any known proteins, 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 2, lines 24-30.

The NHP proteins are 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 diseases. Given the similarity information and expression data, the described NHPs can be targeted (by drugs, oligos, antibodies, etc[.]) in order to treat disease, or to therapeutically augment the efficacy of, for example, chemotherapeutic agents used in the treatment of diseases such as, but not limited to, cancer, inflammation, [and] hormonal disorders.” Page 16.

Discussion

Claim 3, the broadest claim on appeal, is directed to nucleic acids encoding the amino acid sequence of SEQ ID NO:16 or SEQ ID NO:28. Page 2, lines 4-9. These two sequences differ only slightly: SEQ ID NO:28 has one amino acid (Ala939) that SEQ ID NO:16 lacks.

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.”).

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 further research. Simply put, to satisfy the ‘substantial’ utility requirement, an

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 Answer, page 6. Therefore, our conclusion with respect to the § 101 issue also applies to the § 112 issue.

asserted use must show that that claimed invention has a significant and presently available benefit to the public.” Id. at 1371, 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 also 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 to be inadequate because “there is no disclosure of biological functions or any physiological significance of the instantly claimed nucleic acid molecules; there is no disclosure of any evidence

indicating the claimed nucleic acid sequences are expressed at altered levels or forms in any specific, diseased tissue, as compared with the healthy control tissue.”

Examiner’s Answer, pages 3-4. The examiner considered the disclosed uses that do not depend on the specific properties of the encoded protein (e.g., for chromosome mapping or as hybridization probes) but concluded that those uses are not substantial or specific. Id., page 4. Finally, the examiner found that the evidence of record does not show that the claimed nucleic acids have a nonasserted, well-established utility. Id., pages 5-6.

The examiner’s reasoning is consistent with the Fisher court’s interpretation of 35 U.S.C. § 101. We agree with the examiner’s reasoning and his conclusion that the instant specification does not disclose a utility for the claimed nucleic acids that meets the requirements of § 101.

Appellants argue that they have provided evidence to support the specification’s statements that the polypeptides encoded by the claimed nucleic acids “are similar to ‘tumor-associated proteins’ (the specification at page 15, line 32), and that diseases associated with the presently claimed sequences include ‘cancer’ (the specification at page 16, line 21).” Appeal Brief, page 12. Appellants rely on comparisons of the amino acid sequence encoded by SEQ ID NO:27 with two sequences from GenBank, and two references that allegedly “confirm[] Appellants’ assertion that the presently claimed sequences are involved in proliferation.” Id., pages 12-13.

We do not agree that the evidence of record shows that those skilled in the art would have recognized a specific and substantial utility for the claimed nucleic acids as

of the filing date of this application. See Brana, 51 F.3d at 1567 n.19, 34 USPQ2d at 1441 n.19 (utility determined as of application's filing date).

Thus, Appellants can rely on the cited GenBank records and post-filing references for the limited purpose of showing the accuracy of the specification's statement that SEQ ID NOs 16 and 28 encode a protein that is "similar to those related to eucaryotic GPI-anchored P137 proteins . . . , tumor-associated proteins, and precursors of secreted proteins." Page 15. The post-filing references cannot be relied on, however, for disclosures that do not reflect the state of the art as of this application's filing date. See In re Hogan, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977) ("[U]se of later publications as evidence of the state of art existing on the filing date of an application" is acceptable.).

The specification states that the disclosed sequences are "similar to those related to eucaryotic GPI-anchored P137 protein[] (which is thought to facilitate transport of materials across epithelial surfaces), tumor-associated proteins, and precursors of secreted proteins." Page 15. Grill² discloses that a cDNA that had been "previously mischaracterized as encoding p137, a 137-kDa GPI-linked membrane protein," was apparently involved in cellular activation or proliferation. Grill proposed renaming the protein as "cytoplasmic activation/proliferation associated protein-1 (caprin-1)."

This post-filing evidence does not provide support for the statements in the specification. It does not support the specification's assertion that the protein encoded

² Grill et al., "Activation/division of lymphocytes results in increased levels of cytoplasmic activation/proliferation-associated protein-1: prototype of a new family of proteins," J. Immunol., Vol. 172, pp. 2389-2400 (2004). Only the abstract of Grill is of record (Exhibit C attached to the Appeal Brief), not the full-text paper, so we have considered only the abstract.

by the claimed nucleic acids is similar to “eucaryotic GPI-anchored P137 proteins,” because Grill does not provide any comparison of caprin-1 with the proteins disclosed in this application. Nor does Grill provide evidence that the proteins encoded by the claimed nucleic acids would have been recognized as “tumor-associated proteins” as of the filing date, because there is no evidence of record that the protein renamed caprin-1 by Grill was recognized as tumor-associated as of this application’s filing date.

Grill’s post-filing disclosure that caprin-1 is apparently involved in cellular activation or proliferation does not support the utility of the instantly claimed nucleic acids, because the instant application does not disclose that the claimed nucleic acids encode caprin-1, and there is no evidence of record that shows that p137 was known to those skilled in the art to be involved in cellular proliferation as of this application’s filing date. The evidence of record does not reveal any specific and substantial utility for proteins similar to “eucaryotic GPI-anchored P137 proteins,” disclosed in either the specification or prior art.

In addition, the specification’s disclosure that the encoded proteins are “similar to . . . tumor-associated proteins, and precursors of secreted proteins” would not allow those skilled in the art to use them in a specific and substantial way. Appellants argue that the specification teaches that “diseases associated with the presently claimed sequences include ‘cancer’ (the specification at page 16, line 21).” Appeal Brief, page 12.

We disagree. The relevant sentence reads as follows: “[T]he described NHPs can be targeted . . . in order to treat disease, or to therapeutically augment the efficacy of, for example, therapeutic agents used in the treatment of . . . cancer.” Thus, the cited passage does not say that the proteins encoded by the claimed nucleic acids are useful

in treating cancer, only that they may be targeted in order to augment the efficacy of other (chemotherapeutic) agents used to treat cancer. Appellants have pointed to no other disclosure in the specification that would indicate that the disclosure that a protein is “similar to . . . tumor-associated proteins, and precursors of secreted proteins” would allow those skilled in the art to use it in a specific and substantial utility.

We conclude that the specification’s characterization of the proteins encoded by the claimed nucleic acids is insufficient to allow those skilled in the art to use the proteins of SEQ ID NO:16 and SEQ ID NO:28 in a specific and substantial way. In addition, the cited references do not show that those skilled in the art, at the time the application was filed, would have recognized any specific and substantial utility for the proteins of SEQ ID NOs 16 and 28.

Appellants also argue that the claimed polynucleotides are useful for “tracking the expression of the gene encoding the described protein, for example using high-throughput DNA chips” (Appeal Brief, page 16); that they are useful in mapping human chromosomes (id., page 18); and that they are “useful for functionally defining exon splice-junctions” (id., page 19).

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 polymorphism in SEQ ID NOs 16 and 28 makes the claimed nucleic acids useful in "forensic analysis." Appeal Brief, pages 4-11.

We do not agree that the difference between SEQ ID NOs 16 and 28, even if accurately characterized as a 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 distinguishing SEQ ID NOs 7 and 8 (page 15, line 33 to page 16, line 6) 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.

Appellants argue that "diagnostic tests, such as forensic analysis, [were] described in the specification as originally filed, at least page 10, line 31." Appeal Brief, page 4.

We do not agree that the cited passage supports Appellants' argument. Line 31 of page 10 of the specification reads as follows: "designing diagnostic tests. For example, sequences derived from". The passage preceding line 31 reads as follows:

Alternatively, suitably labeled NHP nucleotide probes can be used to screen a human genomic library using appropriately stringent conditions or PCR. The identification and characterization of human genomic clones is helpful for identifying polymorphisms (including, but not limited to, nucleotide repeats, microsatellite alleles, single nucleotide polymorphisms,

or coding single nucleotide polymorphisms), determining the genomic structure of a given locus/allele, and designing diagnostic tests.

Page 10, lines 23-31.

Thus, the cited passage states that labeled probes derived from, for example, nucleic acids encoding SEQ ID NO:16 or SEQ ID NO:28 “can be used to screen a human genomic library” and that “characterization of human genomic clones is helpful for . . . designing diagnostic tests.” This disclosure does not reasonably appear to refer to forensic analysis based on the difference between SEQ ID NOs 16 and 28, and Appellants have not adequately explained why a person skilled in the art would have interpreted it that way.

In addition to lacking support in the specification, 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 apart the polymorphism in the claimed nucleic acids from any other polymorphism found in the human genome. See id. at 1374, 76 USPQ2d at 1232.

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, 3, and 6-11.

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)	
Administrative Patent Judge)	
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Administrative Patent Judge)	APPEALS AND
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