

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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

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### BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Ex parte MARK D. YANDELL

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Appeal No. 2005-2044  
Application No. 09/619,049

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ON BRIEF

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Before SCHEINER, ADAMS and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

#### DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 4, 6, 8 and 22-26, which are all the claims pending in the application.

Claim 4 is illustrative of the subject matter on appeal and is reproduced below:

4. An isolated nucleic acid molecule consisting of a nucleotide sequence selected from the group consisting of:
  - (a) a nucleotide sequence that encodes a protein comprising the amino acid sequence of SEQ ID NO:855;
  - (b) a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID N0:854,
  - (c) a nucleic acid molecule consisting of the nucleic acid sequence of SEQ ID NO:853; and
  - (d) a nucleic acid molecule that is completely complementary to a nucleic acid molecule [o]f (a)-(c).

The examiner does not rely on prior art.

### GROUNDS OF REJECTION

Claims 4, 6, 8 and 22-26 stand rejected under 35 U.S.C. § 101 as lacking a patentable utility.

Claims 4, 6, 8 and 22-26 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 09/618,893.

We reverse.

### DISCUSSION

#### Utility:

The examiner finds (Answer, pages 3), while there are no well-established utilities for the claimed nucleic acids, the specification discloses the use of the claimed “nucleic acids as targets for developing insecticidal agents and to identify vertebrate and invertebrate orthologs.” Although the examiner finds these utilities to be credible (*id.*), the examiner finds (Answer, page 4), the utilities recited in appellant’s specification are neither substantial nor specific to any of SEQ ID NOs. 853-855, to which all claims on appeal are limited.

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 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. In addition, 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.

On this record, appellant’s specification discloses (page 2), “the identification of amino acid sequences for 511 proteins that are produced by Drosophila melanogaster and are essential for survival....” According to appellant’s specification (page 5), “[t]he amino acid sequences of such proteins are provided in SEQ ID NO: 3, 6, 9, ... 1527, 1530 and 1533, encoded by genomic sequences SEQ ID NO: 1, 4, 7, ... 1525, 1528 and 1531, or transcript sequences SEQ ID NO: 2, 5, 8, ... 1526, 1529 and 1532.”<sup>1</sup> In this regard, appellant’s specification discloses (page 3), “the specific subset of genes,

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<sup>1</sup> For clarity, we note that appellant’s disclosure of SEQ ID NOs in the 1500’s may give, at first blush, the impression that the specification has disclosed more than 511 sequences. However, upon closer inspection we note that for each category of amino acid sequence, genomic sequence, and transcript sequence, the SEQ ID NOs increase by a factor of 3. For example, the amino acid sequences are represented by SEQ ID NOs: 3, 6, 9, ... 1527, 1530 and 1533. As we understand appellant’s disclosure SEQ ID NO: 3 would correspond to e.g., the 1<sup>st</sup> protein identified by appellant, while SEQ ID NO: 1533 would correspond to e.g., the 511<sup>th</sup> protein identified by appellant.

transcripts, and proteins of the present invention are essential for [Drosophila melanogaster] survival: when altered by way of P-element insertion, it produces a lethal phenotype.” According to appellant (Brief, page 10), P-element mutation has show that transcripts corresponding to, inter alia, SEQ ID NOs. 853-855 are essential for survival, and thus, the protein encoded by these transcripts “serve as excellent targets for the development of insecticidal agents.” In this regard, we find appellant’s specification discloses (page 25),

Nucleic acid expression assays are useful for insecticide screening to identify compounds that modulate Drosophila nucleic acid expression.

The invention thus provides a method for identifying a compound that can be used to alter (inhibit or enhance) expression of the Drosophila protein gene. The method typically includes assaying the ability of the compound to modulate the expression of the Drosophila nucleic acid and thus identifying a compound that can be used to kill an insect. The assays can be performed in cell-based and cell-free systems. Cell-based assays include cells naturally expressing the Drosophila nucleic acid or recombinant cells genetically engineered to express specific nucleic acid sequences.

While the examiner appreciates (Answer, page 7), that the use of the claimed sequences as targets for the development of insecticidal agents is a credible utility, the examiner finds that this utility is neither specific nor substantial “because the utilities as disclosed in the specification are general (non-specific) utilities to a wide range of drosophila G-protein related genes and none of these utilities are specific to the sequences (SEQ ID N[O]s 853-855) as claimed in the instant claims.” We disagree.

As discussed above, appellant has identified 511 proteins and their corresponding amino acid and nucleotide sequences. Appellant’s specification

discloses that P-element mutation analysis revealed that all 511 proteins are essential for Drosophila melanogaster survival.<sup>2</sup> Accordingly, appellant asserts that these sequences can be used to develop insecticidal agents. Of these 511 sequences, appellant's claims are limited to nucleic acid molecules that encode a protein comprising the amino acid sequence of SEQ ID NO: 853, or a nucleic acid molecule consisting of the nucleic acid sequences SEQ ID NO: 853 or 854, 854, or a complementary sequence. While the examiner asserts (Answer, page 8) that further research would be required to practice the invention, the examiner provides no evidence on this record that further research would be required to use the claimed nucleic acid molecules, or a vector/host cells containing the claimed nucleic acid molecules as targets for the development of insecticidal agents. Stated differently, there is no evidence on this record that appellant's claimed invention is not useful to the public as disclosed in its current form, or that appellant's claimed invention would not provide a well-defined and particular benefit to the public. Accordingly, we find that the examiner did not meet his evidentiary burden<sup>3</sup> of establishing that appellant's asserted utility is not specific and substantial.

For the foregoing reasons, we reverse the rejection of claims 4, 6, 8 and 22-26 under 35 U.S.C. § 101.

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<sup>2</sup> We recognize the examiner's assertion (Answer, page 9) that the claimed nucleic acid molecules encode proteins of unknown function, activity and biological significance. However, as discussed above, the nucleic acid molecules encode proteins that are essential for survival. Therefore, in our opinion, the nucleic acid molecules are biologically significant. There is no evidence on this record to suggest that a person of skill in the art, interested in targeting an insecticidal agent to a nucleic acid molecule, or the protein encoded thereby, that is essential for survival would also need to know the ultimate function and activity of the protein.

Obviousness-type Double Patenting:

According to the examiner (Answer, page 3),

[c]laims 4, 6, 8, [and] 22-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending application No. 09/618,893. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending application comprise SEQ ID Nos. 85-87 which match absolutely with the SEQ ID Nos. 853-855 of the instant claims.

On April 4, 2003, Application No. 09/618,893 was abandoned in favor of continuing Application No. 10/270,333. Accordingly, the obviousness-type double patenting rejection on this record is moot as it applies to now abandoned Application No. 09/618,893.

Nevertheless, we will review the relevance of the obviousness-type double patenting rejection on this record as it would apply to Application No. 10/270,333. On February 4, 2004, claims 3-20 of Application No. 10/270,333 were canceled. See Paper filed February 4, 2004, page 5. Accordingly, the only claims now of record in Application No. 10/270,333 are claims 1 and 2. For clarity, we reproduce claims 1 and 2 below:

1. An isolated protein, wherein the amino acid sequence of said protein consists of SEQ ID NO:108.
2. An isolated protein, wherein the amino acid sequence of said protein comprises SEQ ID NO:108.

There is no evidence on this record to suggest that SEQ ID NO:108 as set forth in claims 1 and 2 of Application No. 10/270,333 is related in any manner to SEQ ID Nos. 853-855 as recited in the instant claims.

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<sup>3</sup> The examiner has the initial burden of challenging appellant's presumptively correct assertion of utility. In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995).

Accordingly we reverse the provisional rejection of claims 4, 6, 8, and 22-26 under the judicially created doctrine of obviousness-type double patenting.

REVERSED

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