

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 48

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RONALD M. EVANS, ESTELITA S. ONG
and ANTHONY E. ORO

Appeal No. 1999-1361
Application No. 08/425,716

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ADAMS, 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 26, 31, 35, 36 and 43, which are all the claims pending in the application.

Claim 26 is illustrative of the subject matter on appeal and is reproduced below:

26. An isolated *Drosophila melanogaster* knirps-related receptor polypeptide having the sequence set forth in Figure 2.

Appeal No. 1999-1361
Application No. 08/425,716

The reference relied upon by the examiner is:

Oro et al. (Oro), "The Drosophila gene knirps-related is a member of the steroid-receptor gene superfamily," Nature, Vol. 336, pp. 493-496 (1988)

GROUND OF REJECTION

Claims 26, 31, 35, 36 and 43 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the claimed invention.

We affirm the examiner's rejection.

DISCUSSION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's Answer¹ for the examiner's reasoning in support of the rejections. We further reference appellants' Brief² for the appellants' arguments in favor of patentability.

¹ Paper No. 46, mailed September 16, 1997.

² Paper No. 44, received June 26, 1997.

CLAIM GROUPING:

Appellants state (Brief, page 6) that claims 26, 31, 35, 36 and 43 stand or fall together. Since all claims stand or fall together, we limit our discussion to representative independent claim 26. Claims 31, 35, 36 and 43 will stand or fall together with claim 26. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

It is well settled that the examiner bears the initial burden of providing reasons why a supporting disclosure does not enable a claim. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

The examiner argues (Paper No. 36, mailed February 22, 1996, page 4) that:

The specification further discloses that homology to vertebrate steroid receptors suggests that its function is ligand-dependent, yet the unrelatedness of the Knrl carboxyl terminus makes it “difficult to predict a potential ligand” (pg. 14). In addition, the steroid receptors share between 43-49% sequence identity with Knrl in only the DNA binding domain of this family of receptor molecules; and <15% sequence identity with Knrl elsewhere in the molecule (see pg. 3 of amendment and Fig. 3 of application). Herewithin lies the problem of an enabled use of the applicants’ invention. In Oro et al. (1988), it is taught that relatedness between the carboxyl termini roughly reflects the relatedness of the ligand structures within the steroid receptor superfamily of receptors (pg. 493, 2nd column, 3rd paragraph). Here there is no relatedness in the carboxyl termini and no known ligand, as is discussed above. Therefore, there is no way the skilled artisan can predict how to use the invention without undue experimentation, because putative structures of the Knrl ligand are not related to known steroid receptor ligands.

Appellants' specification follows the Oro text very closely. In fact, most of the Oro text is word for word the same as appellants' specification. However, we note, of interest, the following sections of Oro, not present in the specification.

First, appellants argue (Brief, page 7) that “[a]ppellants clearly disclose that knirps-related (knrl) is an early regulatory gene whose function may be regulated by a ligand ... [t]hus, the claimed DNAs and proteins are useful in assays and methods relating to screening for materials which modulate the claimed receptor.” However, we note the following passage from Oro (page 494, column 2) “[e]xperiments directly addressing the developmental role of the knrl gene must await isolation of loss-of-function alleles. It is formally possible that knrl is not an essential gene, as has been suggested for the z2 transcript of the zerknult locus.” Given that the developmental role of the knrl gene must await loss-of-function alleles, and that it is possible that knrl is not an essential gene it is unclear to this merits panel if assays and methods relating to screening for materials that modulate the claimed receptor could be obtained without undue experimentation.

Next, appellants argue (Brief, page 7) that “[t]hose skilled in the art readily understand, based on [a]ppellants' disclosure, and without any further teaching by [a]ppellants, that the knirps-related receptor, as a member of the steroid/thyroid superfamily of receptors, may be used in those assays and methods already known for other members of the superfamily of receptors.” Appellants then conclude (Brief, page 8) that “[c]ompounds identified thereby

would be useful as insecticides or for other purposes disclosed in [a]ppellants' specification" [emphasis added]. We note the examiner's statement (Answer, page 5) that in contrast to appellants' position, "no 'other purposes' are described in the specification." Furthermore, we note the following text of Oro (page 496, column 1) "[p]erhaps the knr1⁺ product is a constitutive transcriptional regulator and functions without a ligand." If knr1 functions without a ligand, then as explained by the examiner (answer, pages 5-8) that it would require undue experimentation to identify compounds that bind the Knirps-receptor using prior art assays and methods as suggested by appellants.

Finally, Oro (page 493, column 2) teach "lmd2 contains an open reading frame capable of encoding 647 amino acids, beginning with the presumptive initiator methionine at nucleotide 517, and ending with a stop codon beginning at position 2,458." In contrast, the specification (page 12) states "lmd2 contains an open reading frame capable of encoding 647 amino acids, beginning with the presumptive initiator methionine at nucleotide 1499 and ending with a stop codon beginning at position 2460." Since a single amino acid is encoded by a three nucleotide codon the 961 nucleotides contained in the range disclosed by the specification can not contain an open reading frame capable of encoding a 647 amino acids.

On this record, we find that the examiner met his burden of establishing a prima facie case of non-enablement under 35 U.S.C. § 112, first paragraph. The

Appeal No. 1999-1361
Application No. 08/425,716

teachings set forth in the specifications provide no more than a “plan” or “invitation” for those of skill in the art to experiment; they do not provide sufficient guidance or specificity as to how to execute that plan. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1374, 52 USPQ2d 1129, 1138 (Fed. Cir. 1999).

Accordingly, we affirm the examiner’s rejection of claim 26 under 35 U.S.C. § 112, first paragraph. As discussed supra claims 31, 35, 36 and 43 fall together with claim 26.

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

AFFIRMED

SHERMAN D. WINTERS
Administrative Patent Judge

WILLIAM F. SMITH
Administrative Patent Judge

DONALD E. ADAMS
Administrative Patent Judge

)
)
)
)
) BOARD OF PATENT
) APPEALS AND
)
) INTERFERENCES
)
)
)

Appeal No. 1999-1361
Application No. 08/425,716

STEPHEN E. REITER
FOLEY & LARDNER
402 W. BROADWAY, 23RD FLOOR
SAN DIEGO, CA 92101

DEA/jlb