

The opinion in support of the decision being entered
is not binding precedent of the Board.

Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARGRET B. BASINSKI
and BRIGITTE E. SCHONER

Appeal No. 1999-1676
Application No. 08/452,228

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 1-8, which are all the claims pending in the application.

Claims 1 and 3 are illustrative of the subject matter on appeal and are reproduced below:

1. An isolated protein nucleic acid molecule consisting of a nucleotide sequence that encodes a protein having the following amino acid sequence:

NH₂-Val Pro Ile Gln Lys Val Gln Ser Asp Thr Lys Thr Leu Ile
Lys Thr Ile Val Thr Arg Ile Asn Asp Ile Ser His Thr Gln Ser
Val Ser Ser Lys Gln Arg Val Thr Gly Leu Asp Phe Ile Pro Gly
Leu His Pro Val Leu Thr Leu Ser Gln Met Asp Gln Thr Leu Ala
Ile Tyr Gln Gln Ile Leu Ile Asn Leu Pro Ser Arg Asn Val Ile
Gln Ile Ser Asn Asp Leu Glu Asn Leu Arg Asp Leu Leu His Leu
Leu Ala Phe Ser Lys Ser Cys His Leu Pro Leu Ala Ser Gly Leu
Glu Thr Leu Glu Ser Leu Gly Asp Val Leu Glu Ala Ser Leu Tyr
Ser Thr Glu Val Val Ala Leu Ser Arg Leu Gln Gly Ser Leu Gln
Asp Met Leu Trp Gln Leu Asp Leu Ser Pro Gly Cys-COOH
(SEQ ID NO: 2).

3. A recombinant DNA vector comprising a nucleic acid molecule of [c]aim 1.

The references relied upon by the examiner are:

Martial et al. (Martial), "Human Growth Hormone: Complementary DNA Cloning and Expression in Bacteria," Science, Vol. 205, pp. 602-607 (1979)

Zhang et al. (Zhang), "Positional cloning of the mouse obese gene and its human homologue," Nature, Vol. 372, pp. 425-429 (1994)

GROUND OF REJECTION

Claims 1 and 2 stand rejected under 35 U.S.C. § 103, as being unpatentable over Zhang.

Claims 3-8 stand rejected under 35 U.S.C. § 103, as being unpatentable over Zhang in view of Martial.

We reverse.

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 rejection. We further reference appellants' Brief² for the appellants' arguments in favor of patentability.

BACKGROUND

The present invention is based on the discovery of an obesity gene cloned from Rhesus monkey adipose tissue. Specification, page 2. According to the specification (page 3) "[t]he invention is drawn to isolated nucleic acid molecules consisting of a nucleotide sequence that encodes a protein having the amino acid sequence of SEQ ID NO:2."

According to the specification (Example 1) the obesity gene from Rhesus monkey was obtained by polymerase chain reaction amplification methods using degenerate primers "designed based on the published amino acid sequence of [the] region flanking the human ob gene."

While we note appellants' statement (Brief, page 2) that there are no related appeals and interferences, we make reference to Appeal No. 1999-1702 (Application No. 08/445,305). Claim 1 at issue in Appeal No. 1999-1702 is drawn to an isolated protein of the formula: SEQ ID NO:1 or a pharmaceutically acceptable

¹ Paper No. 15, mailed October 14, 1998.

² Paper No. 13, received December 22, 1997.

salt thereof. The protein of SEQ ID NO: 1 is generic to both the bovine and the porcine obesity protein. Eli Lilly and Company, the real party in interest, is common to both of these appeals. In addition, Zhang is implicated in each appeal, and the issues presented for review are similar.

THE REJECTION UNDER 35 U.S.C. § 103:

Claims 1 and 2:

According to the examiner (Answer, pages 3-4) Zhang:

teach mouse obese gene (Fig. 4) and [the] use [of] this DNA to acquire the human homologue of this gene (page 429, col. 2, para. 2 and Fig. 6a) via Southern blot hybridization of the mouse obese gene to a human adipose tissue cDNA library (page 429, col. 2, para. 2). The mouse and human obese genes were found to be highly homologous and encoded proteins that were 84% identical (page 431, col. 1 top and Fig. 6b). Additionally, Southern blot hybridization of genomic DNA of rat, human, rabbit, vole, cat, cow, sheep, pig, chicken, eel, and Drosophila with the mouse obese gene resulted in detectable hybridization signals in each animal genomic DNA, demonstrating the evolutionary conservation of the gene across species (Fig. 6a and legend).

The examiner reasons (Answer, page 4) that given the teachings of Zhang:

one would reasonably expect that Rhesus would also have this obese gene and that it could be readily isolated on gel via southern blot hybridization of mouse obese gene to Rhesus genomic DNA. This genomic DNA would encode the protein sequence set forth in [c]laim 1... and be the cDNA set forth in [c]laim 2.

According to the examiner (Answer, pages 4-5) “[b]ecause one skilled in the art knows from the teachings of Zhang et al. what the mouse obese gene looks like and that it is conserved across many species, one skilled in the art can envision or extrapolate to what the Rhesus obese gene cDNA would look like.”

In response appellants argue (Brief, bridging paragraph, pages 4-5) with reference to In re Bell, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993) that “[t]he fact that methods exist which might allow one to clone a rhesus ob cDNA, however, is irrelevant as to whether that particular cDNA is obvious. . . . Similarly, [a]pplicants do not claim a method of isolating an ob cDNA, but rather claim the ob cDNA itself.” Appellants appear to argue that Bell, see also In re Deuel, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995), stands for the proposition that it is per se error to rely upon so-called methodology in determining the patentability of claims directed to a product. In this regard, we note that since the decisions in Bell and Deuel, our appellate reviewing court has made it clear that there are no per se rules of obviousness or nonobviousness. In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995)(“reliance on per se rules of obviousness is legally incorrect”). Accord, In re Brouwer, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996).

Further, such a per se approach would be in conflict with long standing precedent as to the relevance of the method of making a product to the obviousness of the product. Note In re Payne, 606 F.2d 303, 314, 203 USPQ 245, 255 (CCPA 1979), citing In re Hoeksema, 399 F.2d 269, 274, 158 USPQ 596, 601 (CPA 1968)(“[a]n invention is not ‘possessed’ absent some known or obvious way to make it”). In a similar manner, the court in In re O’Farrell, 853 F.2d 894, 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988), in considering the Polisky reference relative to the rejected claims stated “Polisky contained detailed enabling methodology for

Appeal No. 1999-1676
Application No. 08/452,228

practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful.”

Since there are no per se rules of obviousness or nonobviousness, each case must be decided upon the facts in evidence in that case. See In re Cofer, 354 F.2d 664, 667, 148 USPQ 268, 271 (CCPA 1966)(“[n]ecessarily it is facts appearing in the record, rather than prior decisions in and of themselves, which must support the legal conclusion of obviousness under 35 U.S.C. § 103”); and Ex parte Goldgaber, 41 USPQ2d 1172, 1176 (Bd. Pat. App. & Int. 1995) (“each case under 35 U.S.C § 103 is decided on its own particular facts”).

Considering the facts on this record, appellants argue (Brief, bridging paragraph, pages 5-6) that “[t]he studies in Zhang do not indicate that an OB homolog exists in rhesus monkeys because genomic DNA from monkeys is not included in the blot.” Appellants further argue (Brief, page 7) that Zhang provides “no information regarding probe content or specific hybridization conditions that would enable one to clone the rhesus ob cDNA and identify the corresponding protein. It is often quite difficult to predict whether a particular probe will work, under a certain set of hybridization conditions, to clone a particular gene.”

In response, the examiner argues (Answer, pages 7-8) that:

it is not the method that renders the Rhesus ob gene obvious per se, but the fact that the ob gene of twelve species are disclosed by Zhang et al. Therefore, one skilled in the art can predictably acquire the DNA encoding the Rhesus ob gene using the method of Zhang et al., and, for the most part, will know what this gene looks like because Zhang et al. teach this gene across twelve different species.

We recognize that claim 1 on appeal is drawn broadly to any nucleic acid molecule that encodes a protein having the amino acid sequence of SEQ ID NO:2. Given the degeneracy of the genetic code a large number of distinct nucleic acid molecules are included within the scope of claim 1. Nevertheless, based on the facts presented on this record we can not agree with the examiner's position.

Conclusions of obviousness must be based upon facts, not generalities. In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968); In re Freed, 425 F.2d 785, 788, 165 USPQ 570, 571 (CCPA 1970). On this record, there are no facts supporting the examiner's generalization that a person of ordinary skill in the art would have been able to isolate a rhesus ob nucleic acid using the mouse ob gene. We are not persuaded by the examiner's argument that since the mouse ob gene was capable of hybridizing on a Southern blot to mouse, rat, rabbit, vole, cat, cow, sheep, pig, human, chicken, eel, and Drosophila, that it would also be useful in isolating a rhesus ob gene. There is no evidence on this record that a rhesus ob gene exists. Furthermore, appellants point out there is no evidence on this record that the mouse ob gene would be capable of hybridizing to a rhesus ob nucleic acid or under what conditions said hybridization would occur. In our opinion,

Appeal No. 1999-1676
Application No. 08/452,228

given the lack of evidence relating to the claimed rhesus nucleic acid a person of ordinary skill in the art would not have had a reasonable expectation of success in obtaining the claimed nucleic acid. In the absence of a reasonable expectation of success of isolating and identifying the specific DNA sequence of the claim, one is left with only an “obvious to try” situation which is not the standard of obviousness under 35 U.S.C. § 103. See In re O’Farrell, 853 F.2d at 903, 7 USPQ2d at 1680.

The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). On this record the examiner has failed to provide the evidence necessary to support a prima facie case of obviousness. Where the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Accordingly, we reverse the rejection of claims 1 and 2 under 35 U.S.C. § 103, as being unpatentable over Zhang.

Claims 3-8:

According to the examiner (Answer, page 5):

Zhang et al. do not teach to place the cDNA encoding the obese gene into a vector, transfect host cells with the vector, and produce the encoded obese gene protein. However, it is art-recognized to use recombinant methods to produce large quantities of proteins for pharmaceutical purposes, for example.

Martial et al. is an exemplary teaching for using recombinant techniques to make large quantities of protein.

Martial, however, fails to make up for the deficiencies in Zhang as discussed, supra. Accordingly, we reverse the rejection of claims 3-8 under 35 U.S.C. § 103, as being unpatentable over Zhang in view of Martial.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
)	
)	BOARD OF PATENT
William F. Smith)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Donald E. Adams)	
Administrative Patent Judge)	

Appeal No. 1999-1676
Application No. 08/452,228

Eli Lilly and Company
Patent Div./AEH
Lilly Corporate Center
Indianapolis, IN 46285