

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is not binding precedent of the Board.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. 33

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARK ANDREW MARCHIONNI and CARL D. JOHNSON

Appeal No. 1996-3330
Application 07/861,458

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ROBINSON, Administrative Patent Judges.
ROBINSON, 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 1-92. Claims 27-29, 33-37, 55-57, 61-65, 82-84 and 88-92 have been canceled by amendment subsequent to the final rejection. In the Examiner's Answer (Answer) mailed January 5, 1996 (Paper No. 32), the examiner entered a new ground of rejection as to claims 1-26 and 30-32 under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the invention. The record in the application

indicates that appellants failed to file a reply brief addressing the new ground of rejection within the time period permitted.¹ (37 CFR 1.93(b) 1995). Therefore, the appeal as to claims 1-26 and 30-32 is dismissed. Id. We have considered the issues raised by this appeal as they relate to the remaining claims 38-54, 58-60, 66-81, and 85-87.

Claim 38 is illustrative of the subject matter on appeal and reads as follows:

38. A method for identifying a structural homologue in a first organism which is structurally homologous with a gene first identified in a second organism of a non-vertebrate phylum, said method comprising the steps of:

(a) detecting, with two or more probes corresponding to nucleotide sequences of said gene, hybridization signals in the genome of a third organism which is positioned phylogenetically between said first organism and said second organism;

(b) cloning said hybridization signals that are detected by at least two of said two or more probes, determining arrangement or strandedness of probe-binding regions in said cloned hybridization signals, and selecting candidate homologues from said hybridization signals based on sameness in arrangement or strandedness of said probe-binding regions;

(c) sequencing said probe-binding regions in said candidate homologues and selecting putative homologues from said candidate homologues based on presence of an open reading frame in said sequence probe-binding regions;

(d) sequencing said putative homologues and selecting structural homologues from said putative homologues based on multiple resemblance in structural characteristics;

¹ Several attempts were made during the period of August 28, 2000 through September 7, 2000, by Paralegal Specialist Dianne Maggard, to contact appellants' designated representative in an effort to verify that a reply brief in response to the Examiner's Answer had not been filed. Ms. Maggard was unable to ascertain that a reply brief had been timely filed.

directed to a method of isolating a structural homologue of a higher organism which is structurally homologous with a gene of a second lower organism.

Discussion

The rejection under 35 U.S.C. § 112, second paragraph

Claims 38-54, 58-60, 66-81, and 85-87 stand rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the invention. The examiner urges that the language "structural homolog", "positioned phylogenetically between", and "multiple resemblance in structural characteristics" render the claims in which they appear confusing. (Answer, paragraph bridging pages 3-4). The examiner acknowledges that "structural homolog" is defined at page 16 of the specification and that several examples of what is encompassed by such structural characteristics are provided, but urges that (Answer, page 4):

the skilled artisan would nevertheless be unable to determine the entire universe of such "characteristics", and therefore would not know what the metes and bounds of the claims is (sic, are). The same discussion applies with regard to the language "multiple resemblance in structural characteristics".

The examiner has the initial burden of demonstrating indefiniteness of the claims. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). It is well established that "definiteness of the language employed must be analyzed -- not in a vacuum, but always in light of the teachings of the prior art and of the particular application

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disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). We note that the purpose of the second paragraph of 35 U.S.C. § 112 is to basically insure, with a reasonable degree of particularity, an adequate notification of the metes and bounds of what is being claimed. See In re Hammack, 427 F.2d 1378, 1382, 166 USPO 204, 208 (CCPA 1970). Further, the applicants may be their own lexicographer as long as the meaning assigned to the terms is not repugnant to the term's well known usage. In re Hill, 161 F.2d 367, 73 USPQ 482, 484 (CCPA 1947). Where an explicit definition is provided by the applicants for a term, that definition will control interpretation of the term as it is used in the claim. Toro Co. v. White Consolidated Industries, Inc., 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999). Here, one reading the claims in light of the specification would readily appreciate that the terminology "structural homologue" and "multiple resemblance in structural characteristics" have the meanings set forth at page 16 of the specification. The examiner's questioning of the ability of one skilled in this art to "determine the entire universe of such characteristics" would appear to reflect a concern as to whether the present disclosure would have enabled the practice of the invention throughout the scope of subject matter encompassed by the claim. However, this is an issue properly raised under 35 U.S.C. § 112, first paragraph, and has not been presented as an issue in this appeal. Similarly, the examiner's rejection

of the claims based on the phrase "positioned phylogenetically between" (Answer, page 4) focuses on whether one skilled in this art could make the selection of an organism which would be "positioned phylogenetically between" two divergent organisms, i.e., a giraffe and elephant or a cat and dog. However, the examiner offers no evidence which would support the propositions that these determinations are necessary in order to determine the metes and bounds of the present claims or that one skilled in this art could not readily make such a determination. Additionally, we noted that independent claims 38 and 66 require that the second or lower organism be a "non-vertebrate phylum." Thus, the examples offered by the examiner fall outside the scope of the claims. When viewed in light of the above authority, we do not agree with the examiner that the metes and bounds of the rejected claims would not be capable of being determined when read in light of the specification and as one skilled in this art would interpret them. We, therefore, reverse the rejection of claims 38-54, 58-60, 66-81, and 85-87 under 35 U.S.C. § 112, second paragraph.

The rejection under 35 U.S.C. § 103

In rejecting claims 38-54, 58-60, 66-81, and 85-87 under 35 U.S.C. § 103, the examiner urges that Chalfie teaches (Answer, page 5):

several *C.elegans* genes, including *deg-1*, *mec-4*, *mec-6*, which are involved in neuronal degeneration . . . Chalfie et al. suggest in said Abstract and on page 415, second-to-last paragraph, that study of such genes would be desirable because of a possible correlation with several human diseases.

However, in our opinion, Chalfie stops short of suggesting that the corresponding gene might be found in or should be isolated from the human genome. At page 410, column 1, first full paragraph, Chalfie states that "[i]nsights into how genetic lesions can lead to neuronal degeneration could be obtained by studying animal models with similar defects." Thus, we read Chalfie as suggesting the use of *C. elegans* as a model for studying disease conditions in humans which might share a genetic cause. We find no suggestion in Chalfie that one should try to isolate or identify homologues, in humans, of those genes identified in *C. elegans*.

Goddard is relied upon, by the examiner, as teaching that *C. elegans* has DNA sequences related to a human gene and the use of nucleic acid probes based on a first organism to obtain and sequence hybridization signals from a second organism. (Answer, page 5). The examiner, also, notes that Goddard teaches the desirability of studying an organism of intermediate complexity between the other two organism. (Answer, page 6). However, as pointed out by appellants, both Chalfie and Goddard are "silent as to the subject matter of this invention, namely, how to clone an unknown gene in a higher organism which is homologous to an identified gene in a lower organism." (Brief, page

15). Similarly, Webster and Libert do not supply the suggestion or direction which would have reasonably led one of ordinary skill in this art to arrive at a method of isolating, in other animals, unknown structural homologues of genes previously identified in a second animal. While Webster and Libert describe methodology which one could use in isolating structural homologues from a variety of sources, the examiner has provided no evidence and pointed to no facts which would reasonably suggest the use of these methods in a process of the type presently claimed.

At page 6, the examiner has offered an explanation as to why one of ordinary skill in the art would have been motivated to isolate genes from a higher organism using probes corresponding to related genes from a lower organism. These statements are long on reasons why one of ordinary skill in the art would want to arrive at the claimed method and short on the facts which would reasonably support a conclusion that it would have been obvious to perform the method presently claimed. We do not question that one would have been motivated to seek out genes in humans which are associated with disease conditions. However, the determinative question is whether the prior art reasonably suggests doing so in the manner called for by the claims.

It is the initial burden of the patent examiner to establish that claims presented in an application for a patent are unpatentable. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In order to establish a prima facie case of obviousness within the meaning of 35 U.S.C. § 103, there must be some reason,

suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the substitutions required. That knowledge can not come from the applicants' invention itself. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). The extent to which such suggestion must be explicit in or may be fairly inferred from, the references, is decided on the facts of each case, in light of the prior art and its relationship to the invention. It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention using applicants' disclosed invention as a template and selecting elements from references to fill the gaps. In re Gorman, 933 F.2d 983, 986-987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). Here, the examiner has provided no facts or evidence which would have reasonably led one of ordinary skill in this art to the method of isolating unknown structural homologues of genes identified in a phylogenetically related animal in the manner claimed. Where, as here, the examiner fails to establish a prima facie case of obviousness, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). The rejection of claims 38-54, 58-60, 66-81, and 85-87 under 35 U.S.C. § 103 is reversed.

Other Issues

Upon return of this application to the examining group, we would urge the examiner to step back and consider anew the claims pending in this application. We note that claims 38 and 66 are directed to a method of identifying a structural homologue in a first organism which is structurally homologous with a gene first identified in a second organism wherein probes, based on the nucleotide sequence of said gene, are used in the genome of a third organism which is phylogenetically positioned between the first and second organism. The resulting homologues are identified (steps b-d) and probes based on these structural homologues are used to detect hybridization signals in the genome of an additional organism which is phylogenetically located between the first organism and the first additional organism. (step e). Steps b-e are repeated until said structural homologue of said first organism is identified. (step f). It is unclear to us, how the structurally homologous gene of the first organism is to be identified when the probes identified through the claimed process are never used to probe the genome of the first organism. Each step of the claimed process is performed on an intermediate organism (steps a-f) and there is no provision or requirement that the genome of the first organisms ever be probed. We leave to the examiner in the first instance to determine whether the disclosure in support of the claims on appeal would enable one skilled in this art to practice the invention without undue experimentation in the absence of a step where the previously identified structural homologues are used to screen or probe the genome of the first

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organism.

SUMMARY

To summarize, the appeal as to claims 1-26 and 30-32 is dismissed. The decision of the examiner to reject claims 38-54, 58-60, 66-81, and 85-87 under 35 U.S.C. § 112, second paragraph is reversed. The decision of the examiner to reject claims 38-54, 58-60, 66-81, and 85-87 under 35 U.S.C. § 103 is reversed.

REVERSED

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Administrative Patent Judge)	
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)	BOARD OF PATENT
WILLIAM F. SMITH)	
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