THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte WILLIAM C. COPELAND
and TERESA S.F. WANG

_____

Appeal No. 94-2742
Application 07/792,600[1]

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HEARD: April 9, 1997

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Before WILLIAM F. SMITH, METZ, and ELLIS, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

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[1] Application for patent filed November 15, 1991.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 through 8. Claims 9 through 14 are pending in the application but have been withdrawn from consideration by the examiner.

Claims 1, 2, and 6 are illustrative of the subject matter on appeal and read as follows:

1. A purified and isolated nucleic acid sequence encoding a human polymerase " catalytic polypeptide.

2. A purified and isolated DNA sequence encoding a human polymerase " catalytic polypeptide, said DNA sequence comprising the DNA sequence set out in Figure 3 (SEQ ID NO:1) and its complementary sequence.

6. A purified and isolated DNA sequence comprising a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of the human polymerase " catalytic polypeptide (SEQ ID NO:31) to allow possession of the property of processive DNA replication.

The references relied upon by the examiner are:

Smith et al. (Smith) 4,745,051 May 17, 1988

Wong et al. (Wong), “Human DNA polymerase " gene expression is cell proliferation dependent and its primary structure is similar to both prokaryotic and eukaryotic replicative DNA polymerases,” The EMBO Journal, vol. 7, no. 1, pp. 37-47 (1988)

Claim 1 stands rejected under 35 U.S.C. § 102(b) as anticipated by Wong. Claims 1 through 8 stand rejected under 35 U.S.C. § 103 as unpatentable over Wong in view of Smith. We affirm the anticipation rejection and reverse the obviousness rejection. In addition, we make new grounds of rejection under 37 CFR § 1.196(b).

ANTICIPATION REJECTION

Claim 1 is directed to a purified and isolated nucleic acid sequence which encodes a human polymerase " catalytic polypeptide. The examiner points to the results at a Northern blot analysis of human messenger RNA (mRNA) set forth in Figure 4 at page 41 of Wong. That hybridization yielded a single 5.8 kb band which Wong states is sufficient to encode a polypeptide of 165-180 kd. The examiner has concluded that the 5.8 kb mRNA is a native human mRNA encoding human polymerase " catalytic polypeptide.

In responding to this rejection in the Reply Brief (Paper No. 26, February 22, 1995), appellants argue at page 2 that "[i]t is not clear that the 5.8 kb fragment actually encodes the protein" and that the Northern blot procedure used by Wong did not result in the "isolation" of the 5.8 kb mRNA. Finally, appellants argue in the sentence bridging pages 2-3 of the Reply Brief that Wong did not "sequence" the 5.8 kb mRNA.

In our view, the description in Wong of the 5.8 kb mRNA identified in the Northern blot analysis of Figure 4 is sufficient to shift the burden to appellants to establish that that

mRNA fragment is not a “nucleic acid sequence encoding a human polymerase " catalytic polypeptide.” See In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) (PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical.0 Appellants first argument that it is not clear that the 5.8 kb fragment “actually encodes the protein” is answered by Best. The Patent and Trademark Office is not in a position to do the experimental work necessary to answer that question in a factual manner. Rather, under the circumstances of this case, it is reasonable to shift that burden to appellants.

As to appellants second argument that even if the 5.8 kb fragment encodes the polymerase, identifying that fragment in a Northern blot does not constitute the isolation of the sequences required by claim 1. Appellants rely upon a dictionary definition that isolation means that the mRNA must be “in a free state.” Assuming arguendo that the dictionary definition is relevant in citing this issue, appellants reliance upon that definition leads to the next question, i.e., in a free state relative to what standard? It is commonly used in patent prosecution, the phrase “purified and isolated” in reference nucleic acid sequences or amino acid sequences is used to distinguish the claimed sequence from the sequence as it appears in nature. In its broadest sense, then the phrase “purified and isolated” as used in claim 1 merely means that the claimed nucleic acid sequence

encoding an human polymerase " catalytic polypeptide has been purified and isolated from its native cellular source. The phrase does not connote any particular degree of purification or isolation beyond that. Thus, the 5.8 kb mRNA fragment in the Northern blot analysis of Wong can be considered to have been "purified and isolated."

Appellants last argument concerning the fact that Wong did not sequence the 5.8 kb mRNA fragment is irrelevant. That fragment has a defined sequence. As set forth in In re Donohue, 632 F.2d 123, 125, 207 USPQ 196, 199 (CCPA 1980)(citations omitted), "for a publication to constitute an anticipation of an invention and, thus, to bar the grant of a patent under 35 U.S.C. § 102, it must be capable, when taken in conjunction with the knowledge of those skilled in the art to which it pertains, of placing that invention in the possession of the public." Here, appellants have not established that the procedures set forth in Wong are not reproducible, i.e., one could not obtain the 5.8 kb mRNA identified in Figure 4.

The anticipation rejection of claim 1 is affirmed.

OBVIOUSNESS

In relying upon Wong as evidence of obviousness, the examiner does not rely upon the 5.8 kb mRNA discussed above in regard to the anticipation rejection of claim 1. Rather, the examiner focusses upon the various cDNA fragments described in Wong. In so doing, the examiner acknowledges at page 3 of the Examiner's Answer that "Wong et al. do not teach the native, correct nucleotide sequence nor a single cDNA encoding human DNA polymerase alpha . . .." The examiner relies upon Smith only for its disclosure of methods for expressing a polypeptide. The examiner does not rely upon Smith to acknowledge the efficiencies of Wong in regard to teaching "a single cDNA encoding human DNA polymerase alpha." The examiner's conclusion of obviousness is stated at page 3 of the Examiner's Answer as follows:

> It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to obtain a nucleic acid which correctly encoded human DNA polymerase " (based on the teaching of Wong et al.), and to clone said nucleic acid into a viral vector so that DNA polymerase " would be expressed in a host cell (such as the baculovirus/ insect cell expression system disclosed by Smith et [sic, al.]).

Conspicuous by its absence in the examiner's statement of the rejection under 35 U.S.C. § 103 is any explanation as to why on the basis of the evidence of obviousness relied upon, Wong and Smith, one of ordinary skill in the art would have arrived at what the examiner acknowledges to be missing from this prior art, i.e., "a single cDNA encoding

human DNA polymerase alpha." Absent such a fact based explanation, the examiner's rejection is fatally defective.

The rejection under 35 U.S.C. § 103 is reversed.

NEW GROUNDS OF REJECTION UNDER 37 CFR § 1.196(b)

Under the provisions of 37 CFR § 1.196(b), we make the following new grounds of rejection.

1. Written description.

Claims 1, 3/1, 4/3/1, 5/1, and 6 through 8 are rejected under 35 U.S.C. § 112, first paragraph, as lacking written description.

The above identified claims are all directed to either a nucleic acid sequence or a DNA sequence which is identified in the claim only by function. As set forth in Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), "In claims to genetic material, however, a generic statement as to [human polymerase " catalytic polypeptide], without more, is not an adequate written description of the genus because it does not distinguish the claim genus from others, except by function. It does not specification define any of the genes that fall within its definition."

2. Enablement.

Claims 1, 3/1, 4/3/1, 5/1, and 6 through 8 are rejected under 35 U.S.C. § 112, first paragraph, as being nonenabled.

These claims are directed to either a genus of nucleic acid sequences encoding a human polymerase " catalytic polypeptide or a DNA sequence which encodes a polypeptide having an amino acid sequence sufficiently duplicative of that of the human polymerase " catalytic polypeptide to allow possession of the property of processive DNA replication. The specification of this application only describes a single DNA sequence which encodes human polymerase " catalytic polypeptide. As set forth in Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991), it is necessary that applicant provide "a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims. For DNA sequences, that means disclosing how to make and use enough sequences to justify grant of the claims sought."

Here, as in Amgen, applicant appears to be in effect, every possible analog of a gene which encodes human polymerase " catalytic polypeptide on the basis of the disclosure which describes only that gene.

TIME PERIODS FOR RESPONSE

In addition to affirming the examiner's rejection of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides, "A new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 CFR § 1.197(b) provides:

> (b) Appellant may file a single request for rehearing within two months from the date of the original decision . . . .

37 CFR § 1.196(b) also provides that appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

Should appellants elect to prosecute further before the Primary Examiner pursuant to 37 CFR § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If appellants elect prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for reconsideration thereof.

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

AFFIRMED-IN-PART - 37 CFR § 1.196(b)

William F. Smith)
Administrative Patent Judge)
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) BOARD OF PATENT
Andrew H. Metz) APPEALS AND
Administrative Patent Judge) INTERFERENCES
)
)

)
Joan Ellis)
Administrative Patent Judge)

Peter G. Carroll
Medley & Carroll
220 Montgomery St., Suite 2200
San Francisco, CA 94104