

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte GOPAL CHANDRA MAJUMDER,
MAHITOSH MANDAL, and
SASWATI BANERJEE

Appeal No. 2002-0449
Application No. 09/037,409

ON BRIEF

Before WINTERS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-8 and 10-18, all of the claims remaining. Claims 1, 13, and 18 are representative and read as follows:

1. An isolated sperm motility-promoting glycoprotein macromolecule having a molecular mass of 66 kda and purified to homogeneity.
13. A process for the preparation of the isolated sperm motility-promoting glycoprotein macromolecule of claim 1, said process comprising:

fractionating at least one of buffalo serum and buffalo plasma to provide a fractionated preparation; and

purifying the sperm motility-promoting glycoprotein from the fractionated preparation by chromatography and electrophoresis.

18. A method for enhancing sperm motility in-vitro comprising adding a pharmaceutical composition to sperm in-vitro, wherein said pharmaceutical composition comprises:

the isolated sperm motility promoting glycoprotein macromolecule of claim 1, and

a pharmaceutically acceptable excipient,

to thereby enhance sperm motility.

The examiner relies on the following references:

Harris et al. (Harris), Protein purification methods - a practical approach, pp. 9-63 (1989)

Mandal et al. (Mandal), "Stimulation of Forward Motility of Goat Cauda Epididymal Spermatozoa by a Serum Glycoprotein Factor," Biology of Reproduction, Vol. 41, pp. 983-989 (1989)

Claims 1-8 and 10-18 stand rejected under 35 U.S.C. § 103 as obvious in view of Mandal and Harris.

We reverse.

Background

"One of the main reasons of human male infertility is due to low order of sperm motility with normal cell count." Specification, page 1. "Forward motility-promoting protein isolated from buffalo blood serum has the potential for the treatment of human infertility (due to low sperm motility)." Id. The specification discloses a "motility-promoting protein macromolecule having a molecular mass of 66 kda and a process for the isolation of said promoting protein from buffalo serum/plasma." Id., page 3. The protein is also disclosed to have "the potential

for improving the breeding of farm animals with special reference to buffalo; a milch animal of great economic importance in many countries.” Id., page 4.

Discussion

The claims are directed to an isolated “sperm motility-promoting glycoprotein macromolecule having a molecular mass of 66 kda and purified to homogeneity” (claim 1), as well as methods of making and using such a glycoprotein.

The examiner rejected all of the claims as obvious over Mandal and Harris. He characterized Mandal as teaching a sperm motility-promoting glycoprotein that reasonably appears to be the same as the glycoprotein disclosed in the instant specification. See the Examiner’s Answer, page 3. He acknowledged that “[t]he Mandal et al[.] article does not teach purifying the factor to homogeneity, and does not teach Appellants’ claimed method of purifying the protein.” Id.

The examiner cited Harris as “disclos[ing] that protein purification using a variety of different purification techniques in various orders is well-known in the art.” Id. He concluded that

[i]t would have been obvious to one of ordinary skill in the art at the time Appellants’ invention was made to purify the factor of the Mandal et al[.] article to homogeneity using the purification techniques outlined in the Harris et al[.] text because it is routine and desirable to purify proteins in order to produce an uncontaminated product having high specific activity and because the purification techniques of the Harris et al[.] text are of wide applicability in the purification of proteins in general.

Id., pages 3-4.

Appellants do not dispute that the glycoproteins of Mandal and the instant specification are the same. They argue, however, that the examiner has not met his burden of “show[ing] that the [Harris] reference provides guidance in selecting a particular purification scheme (from among the many combinations and permutations disclosed) to isolate a particular protein from a particular medium sufficient to have provided one of ordinary skill in the art with a reasonable expectation of success without undue experimentation.” Appeal Brief, pages 7-8.

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). “[A] proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have had a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant’s disclosure.” In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1443 (Fed. Cir. 1991) (citation omitted).

In this case, we agree with Appellants that the references relied on by the examiner do not support a prima facie case under § 103. Rather, the references appear to support only an “obvious to try” rationale. “An ‘obvious-to-try’ situation

exists when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued." In re Eli Lilly & Co., 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). "[O]bvious to try' is not the standard under § 103." In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988).

In this case, the examiner reasoned that those of skill in the art would have found it obvious to apply some combination of the general protein purification techniques disclosed by Harris to the partially purified glycoprotein disclosed by Mandal, in order to purify the glycoprotein to homogeneity. The examiner has not adequately explained, however, how the cited references would have taught "how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued." Cf. Lilly, 902 F.2d at 945, 14 USPQ2d at 1743. In the absence of such guidance, the references might make the claimed invention obvious to try, but they do not make it unpatentable under 35 U.S.C. § 103. The rejection is reversed.

Other Issues

1. Enablement

None of the claims on appeal are limited to a protein from a particular species, or a protein purified by a specific process, or a protein having a specific amino acid sequence. Thus, for example, claim 1 appears to read on any homogeneously purified glycoprotein having a molecular weight of 66 kilodaltons

and having the physiological effect of promoting sperm motility. The specification exemplifies a single glycoprotein (from buffalo serum) meeting these criteria, and indicates that an immunologically cross-reactive protein has been detected in the sera of four other species. See page 5. The specification discloses no other physical or chemical characteristics of these other proteins.

“[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (emphasis added). “Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.” In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). These factors include “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” Id.

Upon return of this case, the examiner should consider whether, in light of the guidance provided by the specification and the knowledge of those skilled in the art, undue experimentation would have been required to practice the full scope of the claims.

2. Written description

The examiner should also consider whether the instant claims are supported by an adequate written description. The Federal Circuit has recently addressed the application of the written description requirement to DNA-related inventions. See Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that “the written description requirement can be met by ‘showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.’” Id. at 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

While the invention at issue in Enzo was DNA, the holding of that case would also seem to apply to a claimed protein. The court adopted a standard for determining the sufficiency of descriptive support from the USPTO’s Written Description Examination Guidelines. See 296 F.3d at 1324, 63 USPQ2d at 1613 (citing the Guidelines). The Guidelines apply to proteins as well as DNAs. See id. (citing Guidelines’ example of an antibody defined by its binding affinity). See also id. at 1328-29, 63 USPQ2d at 1616 (“Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is

claimed. . . . The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.”).

The examiner should consider whether the instantly claimed products, and their methods of making and use, are adequately described in the instant specification.

Summary

The examiner has not shown that the claimed protein, purified to homogeneity, would have been obvious in light of the prior art. We therefore reverse the rejection under 35 U.S.C. § 103. However, we recommend that, on return of this case, the examiner consider whether the claims meet the enablement and written description requirements of 35 U.S.C. § 112, first paragraph.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Eric Grimes)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
)	
Lora M. Green)	
Administrative Patent Judge)	

Appeal No. 2002-0449
Application No. 09/037,409

Page 9

Caesar Rivise Bernstein Cohen &
Pokotilow LTD
1635 Market Street
12th Floor Seven Penn Center
Philadelphia, PA 19103-2212

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