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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LIN YAN and QUANZHI LI

Appeal 2015-005497
Application 13/223,737
Technology Center 1600

Before DEMETRA J. MILLS, MELANIE L. McCOLLUM and KRISTI
L. R. SAWERT, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

WE REVERSE.

STATEMENT OF CASE

According to the Specification,

This invention provides the most rapid means currently available for isolating proteins from prokaryotic and eukaryotic total cells. The protein extraction procedures have a dynamic volume ranging from 20-500 μ l. The unique features provided by this invention are especially useful in samples where cells available for protein extraction are limiting factors.

Spec. 2.

The present invention provides many advantages over the prior art in terms of speed, neatness, consistency, and protein yield. Most current protein extraction procedures are tedious and time-consuming. Many commercial protein extraction procedures require more than 30 minutes to complete. With present invention, in one embodiment, such as protein extraction under denaturing conditions, can be accomplished in less than five minutes, less than four minutes, less than three minutes, less than two minutes, or less than one minute.

Spec. 5.

The following claim is representative.

21. A method for isolating polypeptides from cells comprising:

contacting cells with a lysis buffer, wherein cell lysis occurs resulting in a viscous cell lysate, and wherein the cell lysis buffer comprises a surfactant, a detergent, or a combination thereof, and a metal chelator;

passing the viscous cell lysate through a porous filtering medium, wherein genomic DNA and debris are retained by the porous filtering medium and polypeptides present in the cell lysate pass through the porous filtering medium, and wherein the porous filtering medium comprises a pore size of at least 10 to no greater than 60 microns and a thickness of at least 0.5 millimeter to no greater than 20 millimeters; and

collecting the filtrate, wherein the filtrate comprises a non-viscous polypeptide extract comprising isolated polypeptides, wherein the isolated polypeptides comprise the polypeptides present in the cell lysate.

Cited References

Generon, *Proteus Mini Purification Spin Column Pack*, (GEN-MPS500).
Amersham, *Protein Purification Handbook*, Edition AC, Amersham Biosciences, P. 5-95.

Grounds of Rejection

Claims 21–26, 28–32, 35–37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the method of purification of total protein taught in the Proteus Mini Purification Spin Column Pack (GEN-MPS500) kit from **Generon** (herein referred to as **Generon**). Final Act. 7.

FINDINGS OF FACT

The Examiner's findings of fact are set forth in the Final Action at page 7. The following facts are highlighted.

1. Generon teaches a method of purifying total protein by using a Mini-Purification Spin Column comprising a column where the sample is deposited. They teach that following the deposit of the sample in the column with a pore size between 10-40 microns the column is fitted into any standard micro-centrifuge and centrifuged at a maximum force of 14,000g for about a minute. The protein is directly collected in the bottom of the centrifuge tube. Thus at the time of the instant application, the art teaches application of a kit for purifying

total protein using a column fitted into a standard microcentrifuge tube.

Final Act. 7.

PRINCIPLES OF LAW

In making our determination, we apply the preponderance of the evidence standard. *See, e.g., Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

“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 (Fed. Cir. 1993) (citations omitted).

Rejection 1 - Generon §103¹

We do not find that the Examiner has provided evidence to support a *prima facie* case of obviousness. The totality of the Examiner’s obviousness rejection of claim 21 is set forth in Final Action, p. 7, and is reproduced below.

Generon teaches a method of purifying total protein by using a Mini-Purification Spin Column comprising a column where the sample is deposited. They teach that following the deposit of the sample in the column with a pore size between 10-40 microns the column is fitted into any standard micro-centrifuge and centrifuged at a maximum force of 14,000g for about a minute. The protein is

¹ As best we understand, in the Final Rejection, the Examiner withdrew the obviousness rejection over Fung in favor of a New Ground of Rejection over Generon (Final Act. 6–7).

directly collected in the bottom of the centrifuge tube. Thus at the time of the instant application, the art teaches application of a kit for purifying total protein using a column fitted into a standard microcentrifuge tube. The art also teaches kits comprising a filter membrane of pore size within the limitation of claim 21.

Appellants argue that

[T]he rejection merely states what the cited art teaches; the rejection is completely devoid of identifying any reason why the person of ordinary skill would have been prompted to combine the cited art with anything else, or why the person of ordinary skill would have been prompted to modify the cited art in any way, to result in the claimed invention.

Br. 4.

The pending claims (entered in an Amendment acknowledged in the Advisory Action dated March 20, 2014 (hereinafter Advisory Action)), require, among other things “contacting cells with a lysis buffer, wherein cell lysis occurs resulting in a viscous cell lysate, and *wherein the cell lysis buffer comprises a surfactant, a detergent, or a combination thereof, and a metal chelator.*” Claim 21; emphasis added.

In the Advisory Action, the Examiner concluded

it would have been obvious to a person of ordinary skill in the art that when a cell such as a bacterial cell is lysed a viscous lysate would be produce[d] as a result of the DNA and RNA in the bacterial lysate. Furthermore bacterial lysis buffers were available at the time of the instant invention (see for example see Amersham Biosciences catalogue examples 1-4 Amersham Biosciences AB 2001). Example 1-4 of Amersham shows various lysis buffer compositions for total protein extraction with some variations designed to preserve the activity of a desired protein identified for example by a Western Blot procedure (thus total protein is extracted and a single protein can be identified by for example an immune-detection procedure). One of

ordinary skill in the art would have been able to optimize these buffers to lyse the desired cell and used the spin column taught by Generon for simplicity and convenience of the procedure.

P.2. Thus the Examiner appears to be relying on a reference, Amersham, which is not part of the stated rejection, to address limitations in claim 21. We are not persuaded that the Examiner has set forth a prima facie case of obviousness over Generon.

It is sometimes appropriate to consider extrinsic evidence to explain the disclosure of a reference. Such factual elaboration is necessarily of limited scope and probative value... [A] finding [in extrinsic evidence]... is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the [cited] reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in the reference.

Scripps Clinic & Research Found. v. Genentech Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991).

We find that the Examiner's reliance on Amersham is to fill in the gaps of the primary reference, Generon. The Examiner's rejection over Generon does not address the limitation "wherein the cell lysis buffer comprises a surfactant, a detergent, or a combination thereof, and a metal chelator." Claim 21. The Examiner points to no disclosure in Generon meeting this limitation.

Amersham is relied upon in the Advisory Action for its disclosure that, "a cell such as a bacterial cell is lysed a viscous lysate would be produce[d] as a result of the DNA and RNA in the bacterial lysate." The Examiner also finds that

the art [Amersham] discloses how to produce a lysis buffer for various types of cells and also teaches designing lysis buffers for particular cell types. For example bacterial lysis buffers were available at the time of the instant invention (see for example see Amersham Biosciences catalogue examples 1-4 Amersham Biosciences AB 2001). Example 1-4 of Amersham shows various lysis buffer compositions for total protein extraction with some variations designed to preserve the activity of a desired protein identified for example by a Western Blot procedure (thus total protein is extracted and a single protein can be identified by for example an immune-detection procedure).

Advisory Act., p. 2. Thus, Amersham is being relied on by the Examiner not to explain the disclosure of Generon, but to fill in the gaps of the primary reference with respect to the lysis buffer composition. The Examiner has not provided sufficient evidence in Generon to support a prima facie case of obviousness, and the obviousness rejection is reversed.

CONCLUSION OF LAW

The cited reference does not support the Examiner's obviousness rejections, which is reversed.

REVERSED