

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte OM P SURUJBALLI, ANNA ROMANOWSKA,
MICHAEL E. JOLLEY, and MOHAMMAD SARWAR NASIR

Appeal 2008-3928
Application 10/492,998
Technology Center 1600

Decided: November 17, 2008

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
LORA M. GREEN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1, 3-5, 7, and 11-14, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a method for detecting *M. bovis*-infected animals (claims 1, 3, and 4); a tracer for detecting *M. bovis* antibodies in a fluorescence polarization assay (claims 5, 7, and 11-13); and a kit for detecting *M. bovis* antibodies in a sample taken from an animal (claim 14).

Claim 1 is illustrative and reads as follows:

1. A method for detecting *M. bovis*-infected animals, the method comprising:
 - adding a tracer to a sample from an animal to form a mixture, wherein the tracer is formed by labeling a polypeptide of *M. bovis* protein MPB70 with a fluorophore, and wherein the polypeptide consists of an amino acid sequence selected from the group consisting of SEQ. ID[.] NO.:2 and SEQ. ID[.] NO.:6;
 - measuring the fluorescence polarization of the mixture;
 - measuring the fluorescence polarization of a control;
 - comparing the fluorescence polarization of the mixture to the fluorescence polarization of the control; and
 - detecting the presence of *M. bovis* antibodies in the animal from the measured fluorescence polarization of the mixture.

The Examiner relies on the following prior art references to show unpatentability:

Leahy et al.	US 5,635,346	Jun. 3, 1997
Wood et al.	US 5,693,500	Dec. 2, 1997

Min Lin et al., *Modification of the Mycobacterium bovis Extracellular Protein MPB70 with Fluorescein for Rapid Detection of Specific Serum Antibodies by Fluorescence Polarization*, 3 CLINICAL AND DIAGNOSTIC LABORATORY IMMUNOLOGY 438-443 (1996).

The rejection presented by the Examiner is as follows:

Claims 1, 3-5, 7, and 11-14 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Lin, Wood, and Leahy.

We reverse.

ISSUE

Does the combination of Lin, Wood, and Leahy teach a polypeptide of *M. bovis* protein MPB70 that *consists of* an amino acid sequence selected from the group consisting of SEQ. ID. NO.:2 and SEQ. ID. NO.:6?

FINDINGS OF FACT

1. Claim 1 is directed to a method for detecting *M. bovis*-infected animals.

The method of claim 1 comprises the following five steps:

- a. adding a tracer to a sample from an animal to form a mixture;
- b. measuring the fluorescence polarization of the mixture;
- c. measuring the fluorescence polarization of a control;
- d. comparing the fluorescence polarization of the mixture to the fluorescence polarization of the control; and
- e. detecting the presence of *M. bovis* antibodies in the animal from the measured fluorescence polarization of the mixture.

Claim 1 requires that the tracer is formed by labeling a polypeptide of *M. bovis* protein MPB70 with a fluorophore. In addition, claim 1 requires that the polypeptide consists of an amino acid sequence selected from the group *consisting of* SEQ. ID. NO.:2 and SEQ. ID. NO.:6.

2. Lin teaches MPB70 covalently conjugated with fluorescein for use as a probe to detect anti-MPB70 antibodies, using selected sera from three *M.*

bovis-infected species as a model in a fluorescence polarization assay (Lin 441: col. 2, ll. 14-18).

3. Lin teaches that MPB70 “contains at least three separate *M. bovis*-specific epitopes” (Lin 438: col. 2, ll. 3-5).
4. The Examiner finds that Lin does not teach an MPB70 polypeptide (Ans. 3).
5. Wood teaches “the diagnosis of *Mycobacterium bovis* infection in a susceptible animal, compris[ing] the detection in said animal of antibodies against the MPB-70 protein” (Wood, Abstract).
6. Wood teaches that the term MPB-70 “include[s] not only the full protein, but also any polypeptides derived therefrom which have the antigenicity of MPB-70 and therefore can be used in the assays described herein in the same manner as MPB-70 protein itself” (Wood, col. 2, ll. 20-24).
7. The Examiner finds that Leahy

teaches improved methods of diagnosing Non-A Non-B hepatitis that features the use of novel peptide fragments derived from polypeptide antigens reactive to antibodies present in the sera of infected patients. In producing the peptides, the portions of the polypeptide that contribute to high background is deleted, resulting in assays with high signal to background ration [sic].

(Ans. 4.)

LEGAL PRECEDENT

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based

upon the prior art. On appeal to this Board, Appellants must show that the Examiner has not sustained the required burden.¹

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”

KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1740 (2007). However,

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

Id. at 1741.

ANALYSIS

Based on the combined teachings of Wood, Leahy, and Lin (FF 2-7) the Examiner concludes that

[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to modify the FPA [(fluorescence polarization assay)] methods taught by Lin et al for detection of *M. bovis* antibodies [sic] in a sample to include the use of labeled fragments of MPB70 because (i) Lin et al teach it is within the skill of the art to use fluorescence

¹ See (1) *Ex parte Yamaguchi*, Appeal 2007-4412, slip op. at 5 and 23 (BPAI Aug. 29, 2008); (2) *Ex parte Fu*, Appeal 2008-0601, slip op. at 5 and 20 (BPAI Mar. 31, 2008); (3) *Ex parte Catan*, Appeal 2007-0820, slip op. at 3 and 21 (BPAI Jul. 3, 2007) and (4) *Ex parte Smith*, Appeal 2007-1925, slip op. at 4, 9 and 23 (BPAI Jun. 25, 2007). Opinions in support of the decisions in these four appeals are (a) precedential opinions of the Board and (b) available on the USPTO website.

polarization assays featuring the full-length protein to detect such antibodies in a sample, (ii) [Wood] . . . teaches that in comparable immunological assays it is within the skill of the art to use a fragment of MPB70 to assay for anti-MPB70 antibodies in a sample and that it is desirable to use synthetic fragments of MPB70 in order to reduce endogenous cross-reactions and (iii) [Leahy] . . . teaches that one can reduce the level of background binding in fluorescence polarization assays analogous to those claimed [sic] by using optimized fragments of the target protein.

(Ans. 4.)

Appellants contend that Lin fails to teach a MPB70 protein fragment (App. Br. 3). We agree (FF 4). Appellants contend MPB70 protein contains at least three *M. bovis*-specific epitopes (App. Br. 4). We agree (FF 3).

Appellants contend that “Wood does not teach using any and all polypeptide fragments of MPB70 protein. To the contrary, Wood teaches only those polypeptides that have the *antigenicity* of MPB70 protein” (App. Br. 3). We Agree (FF 6). Appellants contend that “[a]s would be understood by one of ordinary skill in the art, a polypeptide of MPB70 protein will have the same antigenicity as the full-length MPB70 protein when it contains all of the protein’s epitopes” (App. Br. 4). The Examiner does not dispute this contention. Appellants contend that the smallest fragment taught by Wood “that carried all of the specific epitopes” is the “C4a fragment” (*id.*) The Examiner does not dispute this contention.

Appellants contend that “polypeptides consisting of SEQ. ID[.] NO.:2 or SEQ. ID[.] NO.: 6 are not taught by Lin in view of Wood because they do not include all three epitopes” (App. Br. 5). The Examiner does not dispute this contention.

Appellants contend that Leahy “does not refer to the MPB70 protein or any other antigen of *M. bovis*” (App. Br. 5). The Examiner does not dispute this contention. Appellants recognize that Leahy teaches the use of polypeptides in immunoassays wherein regions of the polypeptide that contribute to nonspecific binding, high background and false positives are deleted (*id.*). Nevertheless, Appellants contend that Leahy “would not have led one of ordinary skill in the art to the specific amino acid sequences recited in the instant claims” (*id.*). We are not persuaded by the Examiner’s response that Leahy “teaches methods for determining which portions of a polypeptide is [sic] reactive to antibodies present in sera of infected patients” (Ans. 7). If a MPB-70 polypeptide is required to have the antigenicity of MPB-70 (FF 6) and there is no dispute on this record that all three *M. bovis*-specific epitopes (FF 3) are required for a polypeptide to have the antigenicity of MPB-70; then *even if* portions of MPB-70 that contribute to nonspecific binding, high background and false positives are deleted from the polypeptide – the resulting MPB-70 polypeptide must still contain all three *M. bovis*-specific epitopes. As discussed above, there is no dispute on this record that SEQ. ID. NO.: 2 and SEQ. ID. NO.: 6 do not include all three *M. bovis*-specific epitopes.

CONCLUSION OF LAW

The evidence of record fails to establish that the combination of Lin, Wood, and Leahy teach a polypeptide of *M. bovis* protein MPB70 that *consists of* an amino acid sequence selected from the group consisting of SEQ. ID. NO.:2 and SEQ. ID. NO.:6.

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The rejection of claims 1, 3-5, 7, and 11-14 under 35 U.S.C. § 103(a) as unpatentable over the combination of Lin, Wood, and Leahy is reversed.

CONCLUSION

In summary, we reverse the rejection of record.

REVERSED

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