

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SAMUEL C. MOK, BIN YE, and DANIEL W. CRAMER

Appeal 2008-2127
Application 10/869,027
U.S. Patent Application Publication 2005/0009120
Technology Center 1600

Decided: June 03, 2008

Before RICHARD TORCZON, SALLY GARDNER LANE, and
MICHAEL P. TIERNEY *Administrative Patent Judges.*

LANE, *Administrative Patent Judge.*

DECISION ON APPEAL

I. STATEMENT OF THE CASE

The appeal is from a Final Rejection of claims 1-11. 35 U.S.C. § 134. We have jurisdiction under 35 U.S.C. § 6(b). We reverse and enter new grounds of rejection.

The application was filed June 17, 2004.

The Examiner relied on the following references:

<u>Name</u>	<u>Number</u>	<u>Date</u>
Monahan, et al.	2003/0087250	May 8, 2003
Paulse, et al.	6,675,104	Jan. 6, 2004

Appellants appealed the rejection of claims 1, 2, and 4-11 under 35 U.S.C. § 102(b) over Monahan. Appellants did not separately argue for the patentability of any of the rejected claims and asserted that “all claims stand or fall together.” (App. Br. at 2). We review claim 1 as a representative claim. *See Bd. R. 41.37(c)(1)(vii).*

Appellants also appealed the rejection of claim 3 under 35 U.S.C. § 103 over the combination of the teachings of Monahan and Paulse.

II. FINDINGS OF FACT

The record supports the following findings of fact as well as any other findings of fact set forth in this opinion, by at least a preponderance of the evidence.

1. Claim 1 recites:

A method of diagnostically evaluating a woman for the presence of ovarian cancer, comprising:

- (a) obtaining a urine sample from said woman;
- (b) assaying said urine sample for the concentration of osteopontin present;
- (c) comparing the results obtained from the assay of step (b) with results obtained from the assay of one or more control samples; and
- (d) concluding that said woman is at increased risk of having ovarian cancer if the concentration of osteopontin in said urine sample is higher than the concentration in said control sample or samples.

2. Claim 3 recites:

The method of claim 1, wherein the concentration of osteopontin in said urine sample is determined by surface enhanced laser desorption/ionization-mass spectrometry.

3. Monahan discloses:

In one embodiment, the invention provides a diagnostic method of assessing whether a patient has ovarian cancer or has higher than normal risk for developing ovarian cancer, comprising the steps of comparing the level of expression of a marker of the invention in a patient sample and the normal level of expression of the marker in a control, e.g., a sample from a patient without ovarian cancer.

(Monahan at ¶ [0015]).

4. Table 1 of Monahan “lists all of the markers of the invention, which are over-expressed in ovarian cancer cells compared to normal (i.e., non-cancerous) ovarian cells” (Monahan at ¶ [0068]).

5. Table 1 of Monahan lists approximately 180 genes along with the proteins the genes express. (Monahan at pp. 7-10; Table 1).

6. Table 1 of Monahan includes the following:

OV48	OPN-a: secreted phosphoprotein-1 (osteopontin, bone sialoprotein)
OV49	OPN-b: secreted phosphoprotein-1 (osteopontin, bone sialoprotein)
OV50	OPN-c: secreted phosphoprotein-1 (osteopontin, bone sialoprotein)

(Monahan at p. 9).

7. Monahan teaches that the overexpression of a marker can be determined in “a patient sample.” (Monahan at ¶ [0015]).

8. Monahan teaches that a patient sample can be an “ovary-associated body fluid,” (Monahan at ¶ [0054]), including:

blood fluids (e.g. whole blood, blood serum, blood having platelets removed therefrom, etc.), lymph, ascitic fluids, gynecological fluids (e.g. ovarian, fallopian, and uterine secretions, menses, vaginal douching fluids, fluids used to rinse ovarian cell samples, etc.), cystic fluid, urine, and fluids collected by peritoneal rinsing (e.g. fluids applied and collected during laparoscopy or fluids instilled into and withdrawn from the peritoneal cavity of a human patient).

(Monahan at ¶ [0128]).

9. Monahan teaches “the cancerous state of human ovarian cells is correlated with changes in the levels of expression of the markers of the invention.” (Monahan at ¶ [0149]).

10. Paulse teaches that “methods for analyzing mass spectra . . . may also be used to identify potential markers associated with a biological status.” (Paulse at col. 3, ll. 5-12).

11. The analysis taught by Paulse can be of “[a]ny suitable biological samples includ[ing] tissue . . . urine . . .” (Paulse at col. 7, ll. 22-26).

12. Paulse teaches using the techniques it discloses for analyzing “biological statuses,” including “disease states includ[ing], e.g., cancer . . . [wherein] [m]ore specific cancer statuses include, e.g., . . . ovary cancer.” (Paulse at col. 8, ll. 28-41).

13. Paulse teaches that the “[t]he mass spectrometer may use any suitable ionization technique. The ionization techniques may include for example, . . . surface enhanced laser desorption/ionization (SELDI) . . .” (Paulse at col. 9, ll. 51-56).

III. ISSUES

The issues are:

(1) whether Appellants have shown that the Examiner erred in rejecting claims 1, 2, and 4-11 under 35 U.S.C. § 102(b) as being unpatentable over Monahan, and

(2) whether Appellants have shown that the Examiner erred in rejecting claim 3 under 35 U.S.C. § 103 as being unpatentable over Monahan and Paulse.

IV. LEGAL PRINCIPLES

Claimed subject matter is anticipated by the teachings of a reference only if the claimed subject matter is identically disclosed or described by the teachings of the reference. *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) (“The identical invention must be shown in as complete detail as is contained in the patent claim.”). To be anticipated, the claimed subject matter must be disclosed “clearly and unequivocally” in the reference. *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A 1972) (“Thus, for the instant [anticipation] rejection... to have been proper, thereference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.”).

On the other hand, under 35 U.S.C. § 103, claimed subject matter may be obvious where a limited number of options is provided by the reference and one skilled in the art would have had reason to select any one of the options for the purpose of obtaining the result reported in the reference.

KSR Int'l. Co. v. Teleflex Inc., 127 S.Ct. 1727, 1742 (2007) (“When there is

a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.”), *See also Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (“That the [prior art] patent discloses a multitude of effective combinations does not render any particular formulation less obvious. This is especially true because the claimed composition is used for the identical purpose taught by the prior art.”).

A combination of references renders claimed subject matter obvious

[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.

KSR, 127 S.Ct. at 1740.

V. ANALYSIS

Claims 1, 2 and 4-11:

Claim 1 recites:

A method of diagnostically evaluating a woman for the presence of ovarian cancer, comprising:

- (a) obtaining a urine sample from said woman;
- (b) assaying said urine sample for the concentration of osteopontin present;
- (c) comparing the results obtained from the assay of step (b) with results obtained from the assay of one or more control samples; and
- (d) concluding that said woman is at increased risk of having ovarian cancer if the concentration of osteopontin in said urine sample is higher than the concentration in said control sample or samples.

(FF¹ 1).

Monahan discloses 180 genes as markers that are overexpressed in ovarian cancer cells. (FF 3-5). Three of these genes are osteopontin genes. (FF 6). Monahan also teaches that any of at least 14 listed “ovary-associated body fluids” can be used to screen for ovary cancer cell marker genes. (FFs 7 and 8). One of these fluids is urine. (*Id.*).

The Examiner asserted that “Monahan specifically teaches that an analysis of osteopontin protein levels in urine can be used to diagnose ovarian cancer.” (Ans. at 5-6). But, the Examiner did not cite to, nor did we find, any teaching in Monahan that associates osteopontin specifically with urine. As in *Arkley*, there is “nothing in the teachings relied upon by the Patent Office which ‘clearly and unequivocally’ directs those skilled in the art to make this selection nor any indication that [the prior art] ever made the selection himself.” *Arkley*, 455 F.2d at 588. Instead, the Examiner has engaged in “picking and choosing” prohibited in *Arkley* to support the rejection under 35 U.S.C. § 102(b). We reverse the rejection.

On the other hand, one skilled in the art would have had reason to select urine as a bodily fluid for assaying levels of osteopontin since Monahan teaches that osteopontin is a known marker gene for ovarian cancer, and that urine is an “ovary-associated fluid” known to be assayed for ovarian cancer. Those of skill in the art would have had reason to expect success in this diagnostic method because Monahan teaches that ovarian cancer is correlated with the level of expression of markers. (FF 9). Because Monahan provides a “finite number of identified, predictable

¹ Finding of Fact.

solutions," *KSR, supra*, it would have rendered the claimed method obvious. We enter a new ground of rejection for claims 1, 2, and 4-11 under 35 U.S.C. § 103 in view of Monahan.

Claim 3:

Claim 3 depends from claim 1 and requires that the concentration of osteopontin in the urine be determined by surface enhanced laser desorption/ionization mass-spectrometry.

Those skilled in the art would have understood that biological markers (FF 10) could have been analyzed in urine (FF 11) to evaluate ovarian cancer (FF 12), using surface enhanced laser desorption/ionization-mass spectrometry (FF 13). Thus we agree that claim 3 is properly rejected over the combination of the teachings of Monahan and Paulse.

We have considered Appellants' arguments in response to the rejection under 35 U.S.C. § 102 as applied to the new rejections under 35 U.S.C. § 103 and find them to be unpersuasive.²

First, Appellants argued that Monahan is not properly applied against the claimed subject matter since Monahan does not provide an enabling disclosure (Reply Br. at 2). The new ground of rejection is based on obviousness, not anticipation, and thus Monahan "is prior art for all that it teaches." *Beckman Instruments v. LKB Produkter AB*, 892 F.2d 1547, 1551, (Fed. Cir. 1989); See also *Symbol Tech., Inc. v. Opticon, Inc.* 935 F.2d 1569, 1578 (Fed. Cir. 1991).

² We note that Appellants presented the same arguments against the rejection of claim 3 under 35 U.S.C. 103 as were presented against the rejection under 35 U.S.C. § 102(b), additionally adding that "Paulse does not even mention osteopontin and therefore does nothing to make the workability of a urine-based assay any more obvious." (App. Br. at 6).

At any rate, Appellants have not directed us to evidence sufficient to show that Monahan lacks an enabling disclosure. Attorney argument is not evidence. *See In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997).

Second, Appellants argued that under a rejection for anticipation, if Monahan was considered to be enabling of the claimed method, Appellants should be entitled to a priority date that precedes Monahan because “Appellants had identified a correlation between cellular overexpression of osteopontin and ovarian cancer prior to the time the Monahan reference was filed [in an earlier filed application].” (App. Br. at 5). However, as we understand Appellants’ statements, there is no dispute that Appellants’ earlier applications did not provide an enabling disclosure for the claimed subject matter which is directed specifically to analysis of urine samples. *See* Reply Br. at 3. Appellants’ agreement that their own earlier applications lacked an enabling disclosure for the presently claimed subject matter is not evidence that Monahan did not provide an enabling disclosure.

VI. ORDER

Upon consideration of the record and for the reasons given, the Examiner’s rejection of claims 1, 2, and 4-11 under 35 U.S.C. § 102(b) over Monahan is REVERSED; and

the Examiner’s rejection of claim 3 under 35 U.S.C. § 103 over Monahan and Paulse is AFFIRMED;

We enter a new grounds of rejection for claims 1, 2, and 4-11 under 35 U.S.C. § 103 over Monahan and for claim 3 under 35 U.S.C. § 103 over Monahan and Paulse for reasons set forth herein. 37 C.F.R. § 41.50(b).

37 C.F.R. § 41.50(b) provides that, “[a] new grounds of rejection pursuant to this paragraph shall not be considered final for judicial review.”

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37 C.F.R. § 41.50(b) also provides that the Appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of proceedings as to the rejected claims:

- (1) Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner ...
- (2) Request that the proceeding be reheard under 37 C.F.R. § 41.52 by the Board upon the same record.

REVERSED; NEW GROUNDS ENTERED 37 C.F.R. § 41.50(b)

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