

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TOMO SAITO and MIKIO IKEDA

Appeal No. 1997-2387
Application No. 08/082,373¹

ON BRIEF

Before WINTERS, SPIEGEL, and ADAMS, Administrative Patent Judges.
SPIEGEL, 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 through 7, 9, 10 and 12 through 19, which are all of the claims pending in this application.² Claims 1 and 4 are illustrative and read as follows.

¹ Application for patent filed June 28, 1993. According to appellants, this application is a continuation-in-part of application 07/606,205 filed October 31, 1990, now abandoned.

²Appellants withdrew claims 8, 11 and 16 from consideration on appeal (see reply brief, page 2) and cancelled claims 8, 11 and 16 in the amendment filed July 26, 1996 (Paper No. 20). Although the examiner authorized entry of the amendment in a hand-written notation thereon, i.e., "OK to enter SCW," the amendment has not been physically entered. Therefore, upon return of the application to the jurisdiction of the examiner, this clerical oversight should be corrected.

1. An indirect agglutination immunoassay comprising the steps of:

contacting, in a container, a test sample containing a desired analyte and a reagent comprising sensitized magnetic-material containing particles containing iron, wherein said sensitized magnetic-material containing particles have immobilized thereon an antigen or antibody which specifically binds to said desired analyte,

precipitating said sensitized magnetic-material containing particles by the application of magnetic force,

allowing said container to stand at an inclination, and

detecting the presence or absence of an immune reaction from the absence or presence, respectively, of slippage of the precipitated sensitized magnetic-material containing particles on the bottom of said container.

4. An apparatus for conducting an indirect agglutination immunoassay comprising:

- (a) a container for immunoassay, and sensitized magnetic-material containing particles having immobilized thereon an antigen or antibody,
- (b) a magnetic sedimentation means for magnetically precipitating the components containing the magnetic particles at the bottom of the container, and
- (c) an inclination means for allowing the container to stand at an inclination after removal of the magnetic sedimentation means.

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The references relied on by the examiner are:

Bernoco et al. (Bernoco)	4,148,607	Apr. 10, 1979
Forrest	4,438,068	Mar. 20, 1984
Chagnon et al. (Chagnon)	4,628,037	Dec. 9, 1986
Sakuma	4,770,855	Sep. 13, 1988

Japanese Patent Applications

Japan Kokai (JP '161) ³	59-1951161	Nov. 6, 1984
Japan (Takahashi abstract) ⁴	4-369477A	Dec. 22, 1992

An additional reference relied on by appellants (brief, p. 13) is:

Eur. Patent Application	030 087	Jun. 10, 1981
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³We refer to the English language translation prepared by the United States Patent and Trademark Office in April 1991 and supplied to appellants with the examiner's supplemental answer.

⁴At page 3 of the answer, the examiner lists "3-173093 TAKAHASHI (Japan) 12-1992" as the "prior art of record relied upon in the rejection of the claims under appeal." While, it appears that the examiner is relying on the actual Japanese document, we cannot find an English language translation of this document in this record. Rather, what we find is an English abstract. Thus, it appears that the examiner and appellants have been relying upon the English abstract. Consequently, our decision is also based on a consideration of the English abstract.

Upon return of the application, the examiner should clarify the record as to what evidence of obviousness is relied upon in support of the prior art rejections of record. Furthermore, when relying on non-English documents as evidence of obviousness, a full translation should always be used when readily available. See *In re Meinhardt*, 392 F.2d 273, 280, 157 USPQ 270, 275 (CCPA 1968) ("...it is proper for the court and necessarily, the board, to consider everything that a reference discloses.").

Finally, the examiner stated "that since claim 7 now recites a flat bottomed well, which was not disclosed in the parent application or the translated priority documents, it receives ... [a] June 28, 1993 [filing date]" (answer, p. 8, para. 1). Thus, the Takahashi abstract qualifies as prior art against claim 7.

ISSUES⁵

Claims 1-3, 9, 10, 12-15 and 17-19 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bernoco in view of JP '161. Claims 4 and 6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Forrest. Claim 5 stands rejected under 35 U.S.C. § 103 as being unpatentable over Forrest in view of Sakuma. Claim 7 stands rejected under 35 U.S.C. § 103 as being unpatentable over Forrest in view of the Takahashi abstract.

We reverse all four rejections.

In reaching our decision in this appeal we have given careful consideration to the appellants' specification and claims and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's answer (Paper No. 18, mailed March 8, 1996) and to the supplemental examiner's answer (Paper No. 21, mailed August 7, 1996) for the examiner's reasoning in support of the rejections to the appellants' brief (Paper No. 17, filed December 13, 1995) and to appellants' reply brief (Paper No. 19, filed May 8, 1996) for the appellants' arguments thereagainst.

⁵The final rejection of claims 1-3 and 8-19 under 35 U.S.C. § 112, first and second paragraphs, was withdrawn by the examiner in view of appellants' arguments (answer, p. 2). The withdrawal from consideration on appeal and subsequent cancellation of claims 8, 11 and 16 renders moot the final rejections of claims 8, 11 and 16 under 35 U.S.C. § 112, first and second paragraphs, and under 35 U.S.C. § 103 as unpatentable over Bernoco in view of JP '161 as applied to claims 1-3, 9, 10, 12-15 and 17-19, and further in view of Chagnon.

OPINION

1. Rejection of claims 4 and 6 under § 102(b) as anticipated by Forrest

Anticipation requires that all elements of the claimed invention be described, either expressly or under the principles of inherency, in a single prior art reference. In re Paulsen, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994); In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

Forrest discloses an assembly for use in immunoassays utilizing magnetically attractable particles, comprising two independent components, (a) a plurality of test tubes fixed to a planar support member and (b) a substantially planar base member having one or more magnet means permanently located therein, wherein the assembly can be manually inverted without movement of the test tubes relative to the planar support or the base (abstract; c. 2, ll. 11-50). According to the examiner, the support member which holds the test tubes "is inherently capable of resting on its side and the bottom of the test tubes, effectively providing an incline. (see Figure 1)" (answer, sentence bridging pp. 6-7).

The dispositive question is whether claim 4 and its dependent claims all require an apparatus having three separate components, i.e., a container, a magnetic sedimentation means and an inclination means separate from the container for tilting the container, as argued by appellants (brief, pp. 19-21; reply brief, pp. 6-9); or, whether the claimed

inclination means can be integrated with the container as argued by the examiner (supplemental answer, p. 4, ll. 13-16).

Here, when reading the apparatus claims in light of the specification, we agree with appellants that "Claim 4, and all claims dependent thereon, require a separate device, an 'inclination means' which allows 'the container' to stand at an inclination after removal of the magnetic sedimentation means" (reply brief, p. 6, ll. 14-17).⁶ Therefore, since Forrest does not disclose or suggest a separate inclination means as required by claim 4 and its dependent claims, the rejection of claims 4 and 6 under § 102(b) as anticipated by Forrest is reversed.

2/3. Rejections of claims 5 and 7 under § 103 as unpatentable over Forrest in view of Sakuma and the Takahashi abstract

To establish a prima facie case of obviousness, there must be both some suggestion or motivation to modify the reference or combine reference teachings and a reasonable expectation of success. Furthermore, the prior art must teach or suggest all the claim limitations. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

The examiner relies on Sakuma (Prior Art Figures 1 and 2) to show the conventional use of v-shaped reaction vessels in the art of agglutination immunoassay

⁶See e.g., specification Reference Example 2, especially p. 18, ll. 3-7; Example 2, especially p. 20, ll. 15-20; and Example 3, especially p. 22, ll. 5-10.

(answer, p. 7, ll. 4-7). The examiner relies on the Takahashi abstract to show use of a flat-bottomed reaction vessel in conjunction with a semispherical magnet to form a sedimentation image which does not depend on the shape of the bottom of the reaction vessel (answer, p. 7, ll. 19-22). However, neither Sakuma nor the Takahashi abstract remedy the deficiency in Forrest. Since none of Forrest, Sakuma or the Takahashi abstract disclose or suggest an apparatus comprising the separate inclination means required by claim 4 and its dependent claims, the rejections of claims 5 and 7 under § 103 over Forrest in view of Sakuma and Forrest in view of the Takahashi abstract, respectively, are reversed.

4. Rejection of claims 1-3, 9, 10, 12-15 and 17-19 under § 103 as unpatentable over Bernoco in view of JP '161

Bernoco discloses that, when using a group of vessels disposed in rows in a perpendicular arrangement, e.g., in a rectangle or a square on a support, the "agglutination after centrifugating for any given kind of [agglutination] reaction is not the same for each vessel" because it is impossible to arrange the axis of each vessel completely coaxially with the direction of the centrifuging force (c. 1, ll. 21-40). Bernoco obviates this problem by providing a process and apparatus wherein "the direction of the centrifugal force is completely coaxial with the axis of the vessel" (c. 1, ll. 55-61). More specifically, in the process of Bernoco

...(a) a specimen for analysis is mixed with one or more reagents in a vessel of progressively decreasing cross-section; (b) the mixture is incubated; (c) the incubated mixture is then centrifuged at least one [sic, once] so as to hurl the particles onto the vessel base, the same being disposed substantially in the direction of the centrifugal force, with the result that the agglutinated particles stick to the vessel base whereas the unagglutinated elements remain free thereon, whereafter (d) centrifuging is stopped and ... the nature of the reaction which has occurred is determined by observing the presence or absence of the agglutinated or non-agglutinated elements, after a time interval sufficient for their separation. [C. 1, l. 64 - c. 2, l. 12.]

I. If the reaction is positive, agglutination is complete and the agglutinates remain stuck to the vessel base portion 7;

II. If the reaction is completely or partly negative, the non-agglutinated elements, e.g.[,] the non-agglutinated red globules, slide down from the vessel base 7 along the inclined wall 6 (FIG. 1).

The slide-down [i.e., slippage] does not start immediately upon the cessation of centrifuging but usually starts after a short wait. Also, the rate of sliding may vary according to the nature and intensity of the reaction occurring, and so measurement of the rate of sliding gives further information on the extent of negative reactions. [C. 4, ll. 49-61.]

The chart in column 4 illustrates various combinations of specimens and reagents useful for routine blood grouping, including combinations of a plasma specimen with a sensitized particulate reagent, i.e., "globules" having A₁, A₂, B or O antigens thereon.

JP '161 describes 1-100 μ ferromagnetic circular particles which can immobilize various proteins, e.g., antigen, antibody and enzyme, and sugar groups (translation, p. 2), and can be used "as the carrier of the indirect passive flocculation reaction, and the flocculating reaction time is reduced to about half" (translation, sentence bridging pp. 11-12).

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According to the examiner, it would have been obvious to use the ferromagnetic particles of JP '161 as the particle reagent of Bernoco and the magnetic separation of JP '161 in place of the centrifugal separation of Bernoco because the ferromagnetic particles of JP '161 are physically and chemically uniform and stable, economically mass produced and specifically suggested as suitable carriers for agglutination reactions whereby agglutination reaction time can be shortened by about half and because the process of Bernoco not only encompasses both simple and complex agglutination reactions but also makes possible reliable automated measurements using very small amounts of reagents and specimen. Noting that the process of Bernoco determines agglutination by the amount of slippage observed after sedimentation, the examiner concludes that one of ordinary skill in the art "would have been capable of providing the [necessary] inclination means ... subsequent to separation." [Answer, p. 5, para. 2.]

Here, we agree with appellants that the examiner has not established a prima facie case of obviousness because the fact that the prior art reference could be so modified to show the patented invention would not have made the modification obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). First, the examiner has not explained what would have motivated one of ordinary skill in the art to modify the process and apparatus of Bernoco, directed to providing coaxially directed centrifugal force to agglutination

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reactions, by totally doing away with said centrifugation. The centrifugal agglutination apparatus of Bernoco would be no more. Second, the shortened agglutination reaction times alluded to by JP '161 might be due to an increased density of ferromagnetic particles relative to other prior art reagent particles, which may result in quicker sedimentation of the ferromagnetic particles upon standing. Third, since the relative speed of centrifugally accelerated separation depends on factors including the distance from the center of rotation to the bottom of the vessel in the rotor cavity or bucket during centrifugation and the speed of rotation of the rotor, the skilled artisan might just as easily have modified either one of these two factors rather than completely replacing the coaxially directed centrifugal separation step of Bernoco with a magnetic separation step. Finally, when a reference is relied on to support a rejection even in a "minor capacity," ordinarily that reference should be positively included in the statement of rejection. In re Hoch, 428 F.2d 1341, 1342 fn 3, 166 USPQ 406, 407 fn 3 (CCPA 1970). Thus, we have not considered the Davis disclosure in this rejection (answer, p. 9). Accordingly, we find that the examiner has not carried her burden of establishing a prima facie case of obviousness and has relied on impermissible hindsight in making his determination of obviousness. In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) (It is impermissible to engage in hindsight reconstruction of the claimed invention, using

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the applicant's structure as a template and selecting elements from references to fill the gaps.).

Having concluded that the examiner has not established a prima facie case of obviousness, we do not reach appellants' evidence of unexpected results (brief, pp. 15-16).

The rejection of claims 1-3, 9, 10, 12-15 and 17-19 under § 103 as unpatentable over Bernoco in view of JP '161 is reversed.

OTHER ISSUES

35 U.S.C. § 112, sixth paragraph, provides explicit guidance for interpreting terms written in a "means-plus-function" format.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

If the specification lacks a disclosed "corresponding structure" for performing the function recited in the claims, neither an actual means nor means that are "equivalent" to the actual means can be determined and the claims are indefinite under § 112, second paragraph.

Here, claim 4 contains terms written in a "means-plus-function" format. Upon return of this application, the examiner should take a step back and evaluate whether the

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