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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE
THE PATENT TRIAL AND APPEAL BOARD

Ex parte KERRY WILSON,¹
Kalyan Handique, Sundaresh N. Brahmasandra, and
Jeff Williams

Appeal 2015-000044
Application 12/218,416
Technology Center 1700

Before CATHERINE Q. TIMM, MARK NAGUMO, and
WESLEY B. DERRICK, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* NAGUMO.

Opinion Dissenting filed by *Administrative Patent Judge* DERRICK.

NAGUMO, *Administrative Patent Judge*.

DECISION ON APPEAL

Kerry Wilson, Kalyan Handique, Sundaresh N. Brahmasandra, and
Jeff Williams (“Wilson”) timely appeal under 35 U.S.C. § 134(a) from the

¹ The real party in interest is identified as Handy Lab, Inc. (Appeal Brief, filed 17 March 2014 (“Br.”), 3.)

Final Rejection² of claims 36, 40–46, and 67, which are all of the pending claims. We have jurisdiction. 35 U.S.C. § 6. We reverse.

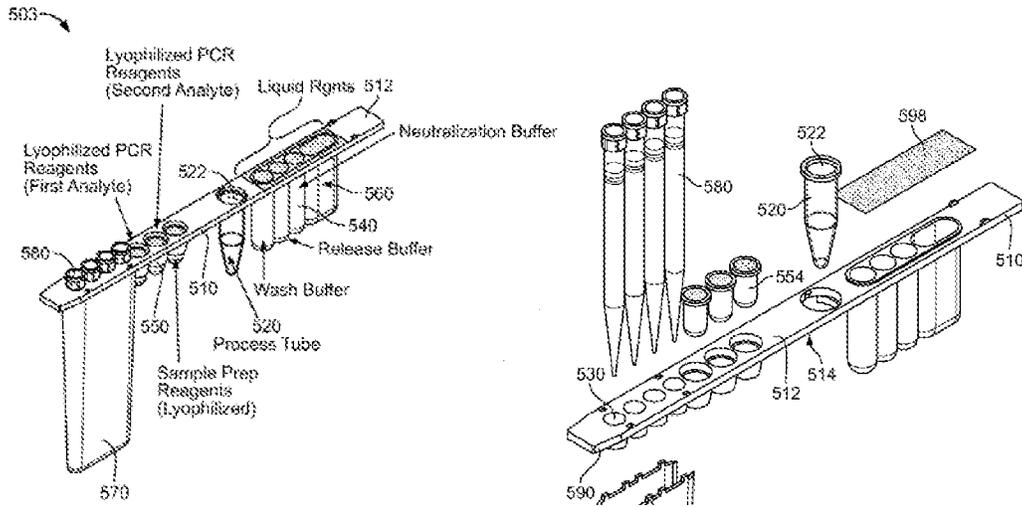
OPINION

A. Introduction³

The subject matter on appeal relates to “holders that hold reagents for preparing biological samples for amplifying and detecting polynucleotides extracted from the samples.” (Spec. 1 [0002].) The Specification teaches that sample preparation for PCR [polymerase chain reaction] is time-consuming and labor-intensive, but does not require specialized skills, whereas PCR and nucleotide detection have required “specially trained individuals having access to specialist equipment.” (*Id.* at [0004].) The Specification addresses these issues by describing reagent holders “for holding and transporting reagents for various purposes, in particular sample preparation in a clinical context.” (*Id.* at 4 [0026].) The reagent holders are said to “find particular application to analyzing any nucleic acid containing sample for any purpose.” (*Id.* at [0027].) In certain embodiments, the holder is described as providing, “in a self-contained manner, all of the reagents required to prepare a PCR-ready sample” (*id.* at [0028]) and to be “configured for use by an apparatus that carries out automated sample preparation, for example, on multiple samples simultaneously” (*id.* at [0029]). More specifically, the holder comprises a connecting member capable of holding a process tube, reagent tubes, and sockets for

² Office action mailed 16 August 2013 (“Final Rejection”; cited as “FR”).

holding pipette tubes, as illustrated in Figures 3A and 3C (in part) are shown below.



{Fig. 3A shows a reagent holder **503**⁴

{Fig. 3C (upper part) shows an exploded view of the reagent holder}

Figures 3A and 3C show reagent holder **503**, to which process tube **520** is affixed (*id.* at 6 [0036]), as well as sockets **530** where pipette tips **580** may be stored (*id.*), with receptacles **550** for reagent tubes containing solid reagents such as lyophilized PCR reagents,⁵ or tubes for reagents (e.g., tubes **554** containing solid lyophilized reagents (*id.* at 6 [0039]–7 [0043]) or reagent tubes **540** containing liquid reagents

³ Application 12/218,416, *Reagent holder, and kits containing same*, filed 14 July 2008, claiming the benefit of 60/959,437, filed 13 July 2007. We refer to the “416 Specification,” which we cite as “Spec.”

⁴ Throughout this Opinion, for clarity, labels to elements are presented in bold font, regardless of their presentation in the original document.

⁵ The Specification does not provide a formal definition of the term “PCR reagents,” but gives, as an example of a PCR reagent mixture, “a polymerase enzyme and a plurality of nucleotides.” (Spec. 4 [0028].) Accordingly, we understand the term to be reasonably understood in the art as any reagent used in a PCR process.

such as release and wash buffers (*id.* at 9 [0050]). A pipette sheath **570** may be provided “to catch drips from used pipette tips, and thereby to prevent cross-sample contamination, from use of one holder to another in a similar location, and/or to any supporting rack in which the holder is situated.” (*Id.* at 7 [0047].)

Independent claim 44 is representative and reads:

A reagent holder [**503**] and reagent system *comprising*:

a single process tube [**520**];

at least three reagent tubes [**540**];

a sample lysis reagent in a first said reagent tube;

a PCR reagent in a second said reagent tube;

one or more liquid reagents in a third said reagent tube;

two or more sockets [**530**] holding pipette tips [**580**],

wherein the ratio of sockets holding pipette tips to process tubes is at least two; and

wherein the process tube, the two or more sockets configured to hold pipette tips, and the reagent tubes are all joined to a single connecting member [**510**].

(Claims App., Br. 32–33; some indentation, paragraphing, emphasis, and bracketed labels to elements shown in Figs. 3A and 3C added.)

Remaining independent claim 36 is similar but somewhat narrower, characterizing the reagent holder as “unitized,” and requiring that the single process tube, etc., be attached to a “strip.” (*Id.* at 32.)

The Examiner maintains the following ground of rejection⁶:

Claims 36, 40–46, and 67 stand rejected under 35 U.S.C. § 103(a) in view of the combined teachings of Tajima,⁷ Fassbind,⁸ and Acosta.⁹

B. Discussion

Findings of fact throughout this Opinion are supported by a preponderance of the evidence of record.

Under the present circumstances, we need only focus our attention on independent claim 44.

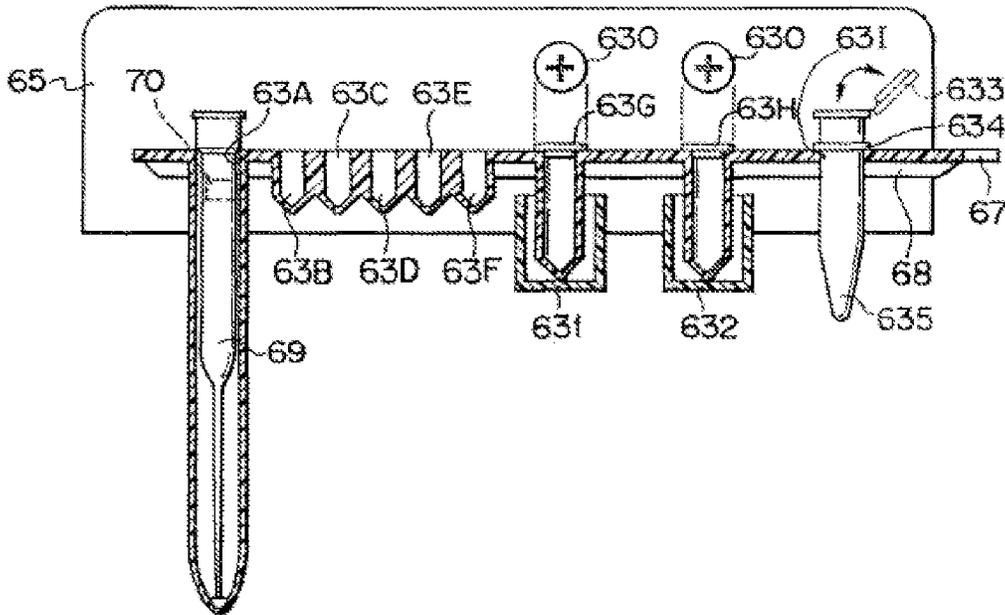
⁶ Examiner’s Answer mailed 31 July 2014 (“Ans.”).

⁷ Hideji Tajima, *Multi-vessel container for testing fluids*, U.S. Patent No. 6,602,474 B1 (2003).

⁸ Walter Fassbind and Werner Rey, *Disposable process device*, U.S. Patent No. 6,063,341 (2000).

⁹ Galo Acosta et al., *Assay work station*, U.S. Patent No. 6,254,826 B1 (2001).

Briefly, the Examiner finds that Tajima discloses in Fig. 15(b), below,



{Tajima, Fig. 15(b) shows a cross section through a strip of microplate **60**}
a reagent holder and system for PCR reactions comprising single process
tube **635**, reagent tubes **63B–F**, pipette tip holding vessel **63A**. (FR 2–3.)

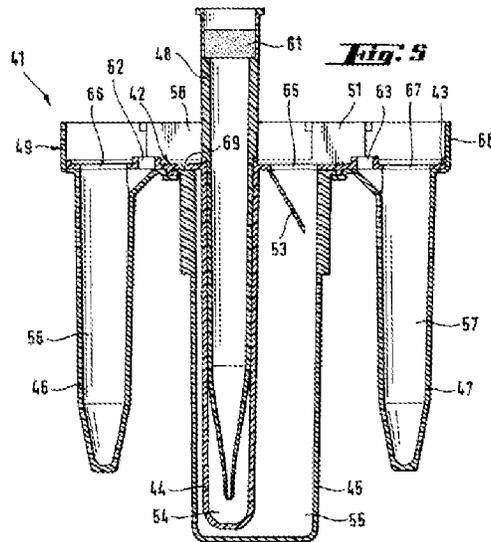
The Examiner finds that Tajima does not teach explicitly a sample lysis reagent, a PCR reagent, or a liquid reagent in first, second, and third reagent tubes, but that such reagents are taught by Fassbind. (Ans. 3, 2d full para.) The Examiner finds, however, that the PCR reagents described by Fassbind are located in a holder external to the pipetting region, but infers that those reagents “are at least close to the holder and thus part of the reagent system.” (*Id.*, last sentence.) The Examiner finds further that both Tajima and Fassbind describe reagent holders having a single pipette tip in the reagent holders, but that Fassbind describes a second pipette tip in use, namely a cannula, in addition to pipette tip **48**. “Thus,” the Examiner concludes, “the ratio of pipettes to process chamber **57** is 2:1.” (*Id.* at 4, 3d full para, last sentence.)

The Examiner finds that Acosta describes a cartridge containing multiple pipette tips in rows for sample preparation or diagnostics so that two or more of the “pipette tips may be simultaneously engaged or removed and limit contamination by single pipette usage.” (*Id.* at para. bridging 3–4, citing Acosta, col. 6, ll. 1–15 [contamination limiting element holding assembly **300**].) The Examiner finds that “the difference [i.e., between the ratio of pipettes [sic: more accurately, sockets holding pipette tips to process tubes]] is a mere duplication of known parts, without any new or unexpected results” (*Id.* at 4, 4th full para.)

On this basis, the Examiner concludes that it would have been obvious “to repeat the number of pipette tips to prevent cross contamination.” In the Answer, the Examiner cites (Ans. 2, ll. 15–16) and quotes (*id.* at 7, ll. 6–13), for the first time, the end of Tajima’s description of the embodiment illustrated in Fig. 15, which reads in most relevant part: “in the above embodiments, the number and the sort of the vessels being mounted in the microplate and the cartridge container are not limited to the above examples. It is needless to say *that the number and the sort can be varied as occasion demands*” (Tajima, col. 13, ll. 1–5; emphasis added.)

The difficulty with the appealed rejection is, as Wilson urges (Br. 18–28, parts E and F), that neither Fassbind nor Acosta provides the occasion that demands that the number of pipette sockets holding pipette tips be at least twice the number of process tubes. Although Fassbind discloses two types of transferring tips, namely a disposable pipetting tip and a pipetting cannula, Fassbind teaches that the two means of transferring liquids are not equivalent. In particular, Fassbind instructs that, “[a]ccording to the invention these transfers of liquids [between process chambers **56, 57**, waste

chamber **55**,] are effected by means of pipetting operations carried out *exclusively* with the disposable tip **48** which is part of the device **41**.” (Fassbind, col. 8, ll. 28–31; emphasis added.) Device **41** is illustrated in Fig. 5, below:



{Fassbind Fig. 5 shows in cross section a device for contamination-free automatic processing of samples and reagents}

In contrast, Fassbind continues, “steps of dispensing a liquid reagent from a reagent container external to the device into the first process chamber **56** or the second process chamber **57** are effected with a pipetting cannula *other than the disposable tip 48* which is a part of the device **41**.” (*Id.* at ll. 31–35; emphasis added.)

Thus, as described in steps A) through M) (Fassbind, col. 8, l. 36, to col. 9, l. 11), reagents such a lysis solution (step B)), a fluid biological sample (step C)), a quality standard solution (step D)), a probe solution (step E)), and a bead (solid phase) solution (step I)), all from an external container, are pipetted into processing chamber **56** (steps B)–D)) or processing chamber **57** (steps E) and I)) via a pipetting cannula of an

automatic pipetting device. The only transfers effected with disposable tip **48** are transfers from chamber **56** to chamber **57** (step G)), washing steps (step L)), and removal of target solution from process chamber **57** to an external specimen container (step M)). Notably, as the Examiner finds, Fassbind does not describe using separate cannulas or disposable pipette tips for transfers of distinct solutions.

The contamination limiting element holding assembly **300** described by Acosta, which the Examiner finds is evidence supporting the prevention of contamination achieved by changing pipette tips, performs a function similar to the cross-contamination prevention provided by Tajima's pipette sheath **570** or Fassbind's pipette parking chamber **54**. While one might imagine various reasons for using disposable pipettes for a single transfer, or only for transferring the same solution from one tube to another, the Examiner has not explained how Tajima, Fassbind or Acosta, individually or in combination, would have suggested this concept. Absent support for such a teaching or suggestion in the prior art relied on for the obviousness rejection, the rejection must be and is reversed.¹⁰

¹⁰ Cf. *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000) (“there was *no finding as to the specific understanding or principle* within the knowledge of a skilled artisan that would have motivated one with no knowledge of Kotzab's invention to make the combination in the manner claimed.”) (Emphasis added). The reliance by the Examiner (FR 4, ll. 20–24; Ans. 4, ll. 18–23) and our colleague in dissent on the “duplication of parts” rationale enunciated in *In re Harza*, 274 F.2d 669, 671 (CCPA 1960) lacks, on the present record, the requisite teachings, simple though they might be, indicating the specific understanding or principal that would have motivated the duplication. Absent such evidence, it is premature to require evidence of unexpected results.

A few remarks are in order lest our reversal be interpreted as a blanket endorsement of each of Wilson's arguments.

Wilson argues that Fassbind is not directed to PCR processing *per se*, but to the preparation of samples for PCR, and that the PCR reagent in a second reagent tube required by the claims is not taught or suggested by Tajima or Fassbind. (Br. 17–18.) This is not persuasive for at least two reasons. First, Tajima describes a device said to be useful for PCR reactions with tubes **635** for PCR and tubes **63** for treating liquids. PCR was a well-known reaction by the filing date and the dates of the references¹¹, and such specificity of disclosure would have been superfluous, particularly given the generality of the term “PCR reagent” as used in the '416 Specification. Second, the only mentions of the term “lysis” in the '416 Specification appear to be in paragraphs [0049] (“cell lysis” in tube **520**), [0062] (“liquid reagents for, e.g., lysis”), and [0104] (lyophilized sample preparation reagents (lysis enzyme mix and magnetic affinity beads)). In this context, we cannot say that the lysis reagents disclosed by Fassbind are somehow out of place, or that it would not have been obvious to provide “end-to-end” processing of samples from cell lysis to PCR analysis.

Wilson argues further that the Examiner has conflated distinct embodiments of multi-vessel containers disclosed by Tajima in order to demonstrate the obviousness of certain structures required by the claims.

¹¹ All post-date the Nobel Prize in Chemistry, 1993, awarded (one half), to Kary B. Mullis, “for his invention of the polymerase chain reaction (PCR) method”.

http://www.nobelprize.org/nobel_prizes/chemistry/laureates/1993/mullis-facts.html (last visited 24 October 2016).

(Br. 28–30.) To the extent the Examiner relies only on the embodiment illustrated in Fig. 15, however, we are not persuaded of harmful error, as each strip comprises the elements required by representative claim 44. To the extent Wilson is arguing that microplate **60** is not a single strip, given that the number of strips is arbitrary, and that parallel processing could be obtained by using plural single strips rather than strips attached by binding part **66**, we are not persuaded that Wilson shows that such a change would have been nonobvious to the artisan.

C. Order

It is ORDERED that the rejection of claims 36, 40–46, and 67 is reversed.

REVERSED

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KERRY WILSON,
Kalyan Handique, Sundaresh N. Brahasandra, and
Jeff Williams

Appeal 2015-000044
Application 12/218,416
Technology Center 1700

Before CATHERINE Q. TIMM, MARK NAGUMO, and
WESLEY B. DERRICK, *Administrative Patent Judges*.

DERRICK, *Administrative Patent Judge*, dissenting.

I must respectfully dissent from my colleagues. I am unpersuaded that the Examiner erred. In my opinion, providing however many sockets that are necessary to meet the recited “two or more sockets” and for “the ratio of sockets . . . to process tubes [to be] at least two” (claim 44) amounts to no more than duplication of an element, which has no patentable significance unless it provides a new and unexpected result. *In re Harza*, 274 F.2d 669, 671 (CCPA 1960). On this record, I am not persuaded that there is any such novel and unexpected result. Further, it appears indisputable that a socket to hold a pipette tip is a known, familiar element and, as such, the provision of further sockets is no more than a “combination of familiar elements according to known methods . . . [that] does no more

than yield predictable results” and is, therefore, “likely to be obvious.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

Turning to the cited prior art, Tajima teaches the provision of a pipette tip 69 in a socket (tip holding vessel 63A) where the pipette tip is used to perform multiple pipetting operations. *See, e.g.*, Tajima col. 12, ll.3–6, Fig. 15b. In contrast, the instant claims are directed to a reagent holder that includes two or more sockets holding pipette tips (claim 44) and the Specification describes that each of the provided pipette tips can be used to perform a subset of the required pipetting operations. Thus, even if the further provided pipette tips were to be used, it would only be to carry out the same pipetting operations performed by the single pipette tip of Tajima. While the function of the duplicated pipette tips is provided sequentially rather than simultaneously, which is more typical in such cases where prior art elements are duplicated and the resulting difference is determined to confer no patentable distinction, I discern no reversible error. *See, e.g.*, *Topliff v. Topliff*, 145 US 156, 163 (1892) (Explaining mere duplication of elements does not patentably distinguish claims from prior art including element); *Harza*, 274 F.2d at 671; *In re Abrahamsen*, 53 F.2d 893, 894 (CCPA 1931); *In re Marcum*, 47 F.2d 377, 378 (CCPA 1931). Indeed, the typical concern that duplicated elements differ in function or in their interaction with other claimed or unclaimed elements is of no import here because the duplicated elements would operate sequentially in providing the same functions as provided by the single, unduplicated element.

It follows that even if Appellants were correct that the Examiner’s further rationale that it would have been obvious to provide multiple pipette tips to avoid cross-contamination was in error, it is my opinion that the error

would be harmless as the Examiner need not establish any particular motivation to duplicate an element where duplication, without more, is prima facie obvious. Further, where an element is simply being duplicated, as in this case, it is *a priori* a combination of familiar elements and it is further apparent that the duplication yields no more than predictable results where the multiple pipette tips are used to perform the same pipetting functions by their sequential use as is provided by a single pipette tip in the cited prior art.

For these reasons, I conclude the Appellants have not shown harmful error in the appealed rejection over the combined teachings of Tajima, Fassbind, and Acosta, and I would affirm the Examiner's rejection.