

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AGILENT TECHNOLOGIES, INC.,
Petitioner,

v.

BIO-RAD LABORATORIES, INC.,
Patent Owner.

IPR2019-00271
Patent 7,148,043 B2

Before SHERIDAN K. SNEDDEN, ZHENYU YANG, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Background and Summary

This is our Final Written Decision entered pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

On November 9, 2018, Agilent Technologies, Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–18 of U.S. Patent No. 7,148,043 B2 (“the ’043 patent,” Ex. 1001). Paper 1 (“Pet.”). In our Institution Decision, we determined that there was a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim and, accordingly, instituted an *inter partes* review pursuant to 35 U.S.C. § 314 based on all challenges presented in the Petition. Paper 8 (“Inst. Dec.”). Following institution, Patent Owner filed its post-institution Patent Owner Response (Paper 11, “PO Resp.”), Petitioner filed its Reply to Patent Owner’s Response (Paper 14, “Reply”), and Patent Owner filed its Sur-Reply (Paper 16, “Sur-Reply”). No motion to amend was filed in this proceeding. An oral hearing was held on March 18, 2020, and a transcript of that hearing has been entered into the record. Paper 21 (“Tr.”).

For the reasons set forth below, having considered all the evidence and arguments of record, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1–18 of the ’043 patent are unpatentable under 35 U.S.C. § 103.¹

¹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application from which the ’043 patent issued was filed before this date, the pre-AIA version of § 103 applies.

B. Related Proceedings

As related matters, Petitioner identifies two *inter partes* review proceedings directed to U.S. Patent No. 8,236,504 (“the ’504 patent”)—a continuation of the ’043 patent—both of which were terminated by settlement (IPR2017-00054 and IPR2017-00055), and another concluded litigation related to the ’504 patent, *Bio-Rad Laboratories, Inc. v. Thermo Fisher Scientific Inc.*, C.A. No. 16-358 (D. Del.) (RGA) (stipulated dismissal December 19, 2017). Pet. 1.

Petitioner also filed petitions challenging the ’504 patent (IPR2019-00266) and U.S. Patent No. 8,835,118 (IPR2019-00268). Pet. 2. We denied institution of *inter partes* review based on those petitions. See IPR2019-00266, Paper 8 (PTAB May 16, 2019); IPR2019-00268, Paper 8 (PTAB May 16, 2019). Petitioner further identifies a series of patent applications, all of which are continuations that originate with the ’043 patent. Pet. 1–2.

C. The ’043 Patent (Ex. 1001)

The ’043 patent, titled “Systems and Methods for Fluorescence Detection with a Movable Detection Module,” is directed to a fluorescence detection system, having a movable excitation and detection module, for use with a thermal cycler. Ex. 1001, 1:7–10. It issued from an application filed May 8, 2003. *Id.*, (22).

The ’043 patent states that both thermal cyclers and fluorometers, for use with fluorescent-labeled samples, were known in the art and used for the amplification of nucleic acids in procedures such as polymerase chain reaction (PCR). *Id.* at 1:11–54. It also acknowledges the teachings in the prior art of an integrated optical reader with a thermal cycler. *Id.* at 1:55–63.

According to the '043 patent, then—“[e]xisting fluorimeters suffer from various drawbacks,” and the '043 patent discloses “an improved fluorimeter for a thermal cycler that overcomes these disadvantages.” *Id.* at 1:64, 2:41–42.

Figure 2 of the '043 patent, reproduced below, depicts an embodiment of a lid assembly for a thermal cycling apparatus.

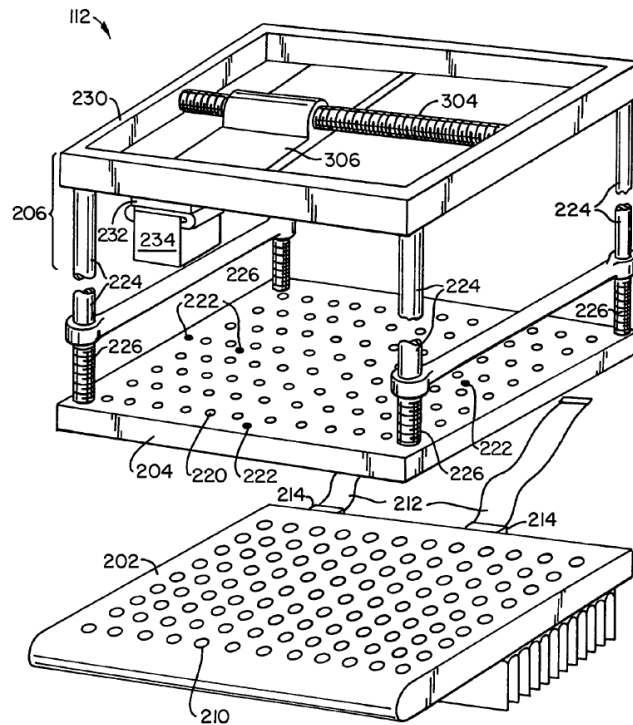


Figure 2 depicts lid assembly 112 that includes sample unit 202, lid heater 204, and fluorometer assembly 206. *Id.* at 4:25–26. Sample unit 202 contains a number of sample wells 210 and further includes heating elements, heat exchange elements, and mechanical and electrical connection elements. *Id.* at 4:47–51. In addition, lid heater 204, coupled to lid 122, has holes 220, matching the size and spacing of sample wells 210. *Id.* at 4:56–59.

The '043 patent further describes shuttle 232, movable in two dimensions, which holds detection module 234 “so as to position detection module 234 in optical communication with different ones of the sample wells 210 in sample unit 202 through the corresponding holes 220 in lid heater 204.” *Id.* at 5:36–42. The '043 patent describes stepper motors and lead screws along the x and y axes to move shuttle 232 to a desired position above samples wells 210. *Id.* at 5:49–67. Detection module 234 includes multiple independently controlled fluorescent excitation/detection channels (also referred to as “excitation/detection pairs”). *Id.* at 6:41–45.

Figure 6, reproduced below, depicts a side view of one of the excitation/detection channels that are part of detection module 234.

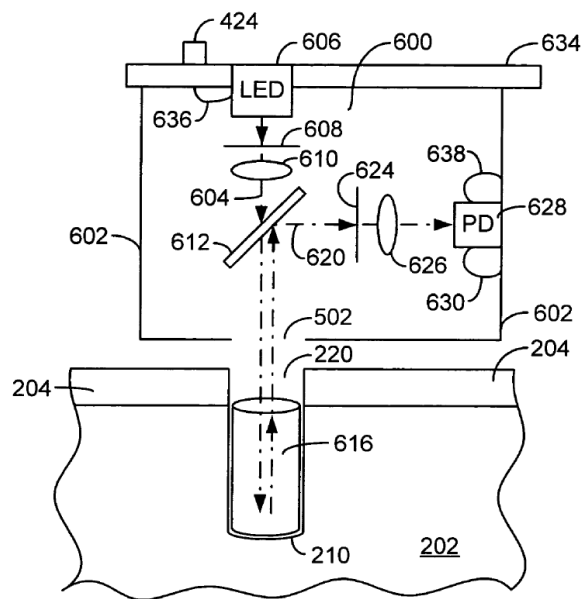


Figure 6 shows that each excitation/detection channel includes light source 606 (e.g., a light-emitting diode (LED)), lens 610, beam splitter 612, detection-path lens 626, and photodetector 628. *Id.* at 7:6–11. The components of excitation light path 604 are arranged to direct excitation light of a desired wavelength into a reaction vessel 616 held in a sample well 210 of sample block 202. *Id.* at 7:15–18. Excitation light that enters

reaction vessel 616 excites the fluorescent label or probe therein, which fluoresces, thereby generating light of a different wavelength. *Id.* at 7:28–30. Some of this light then exits the reaction vessel along detection light path 620 and is directed by beam splitter 612 through filter 624 and lens 626 onto the active surface of photodiode 628. *Id.* at 7:30–36.

D. Illustrative Claim

Among the challenged claims, claims 1 and 12 are independent, and are reproduced below:

1. A fluorescence detection apparatus for analyzing samples located in a plurality of wells in a thermal cycler, the apparatus comprising:
 - [a] a support structure attachable to the thermal cycler; and
 - [b] a detection module movably mounted on the support structure, the detection module including a plurality of excitation/detection pairs, each excitation/detection pair including:
 - [c] an excitation light generator disposed within the detection module; and
 - [d] an emission light detector disposed within the detection module;
 - [e] wherein, when the support structure is attached to the thermal cycler and the detection module is mounted on the support structure, the detection module is movable so as to be positioned in optical communication with different wells of the plurality of wells.

Ex. 1001, 15:9–25 (bracketed letters added for reference).

12. A method for detecting the presence of a target molecule in a solution, the method comprising:
 - [a] preparing a plurality of samples, each containing a fluorescent probe adapted to bind to a target molecule;
 - [b] placing each sample in a respective one of a plurality of sample wells of a thermal cycler instrument, the thermal

cycler instrument having a detection module movably mounted therein, the detection module including a plurality of excitation/detection pairs, each excitation/detection pair including an excitation light generator disposed within the detection module and an emission light detector disposed within the detection module;

[c] stimulating a reaction using the thermal cycler instrument; and

[d] scanning the plurality of sample wells to detect a fluorescent response by moving the detection module and activating at least a first one of the plurality of excitation/detection pairs,

[e] wherein during the step of scanning, the detection module is moved such that one or more of the excitation/detection pairs is sequentially positioned in optical communication with each of the plurality of sample wells.

Id. at 16:5–27 (bracketed letters added for reference).

E. The Asserted Grounds of Unpatentability

We instituted *inter partes* review in this proceeding based on the following grounds as presented in the Petition:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
I	1–17	103	Li ² , Miller ³ , Randrianarivo ⁴
II	6	103	Li, Miller, Randrianarivo, Bjornson ⁵
III	18	103	Li, Miller, Randrianarivo, Heffelfinger ⁶
IV	1–6, 10–17	103	Pantoliano ⁷ , Miller

² Li et al., Chinese Pub. No. CN1379236 A, published November 13, 2002 (Ex. 1011) (English translation in Ex. 1012).

³ Miller et al., U.S. 5,528,050, issued June 18, 1996 (Ex. 1013).

⁴ Randrianarivo et al., PCT Pub. WO 00/22418, published April 20, 2000 (Ex. 1015) (English translation in Ex. 1016).

⁵ Bjornson et al., U.S. 5,125,748, issued Jun. 30, 1992 (Ex. 1017).

⁶ Heffelfinger et al., U.S. 5,784,152, issued July 21, 1998 (Ex. 1019).

⁷ Pantoliano et al., U.S. 6,303,322 B1, issued Oct. 16, 2001 (Ex. 1021).

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
V	7–9	103	Pantoliano, Miller, Gambini ⁸
VI	18	103	Pantoliano, Miller, Heffelfinger

Petitioner further relies upon the declaration of James P. Landers, Ph.D., in support of its challenges. Ex. 1008. Patent Owner relies upon the declaration of Dean P. Neikirk, Ph.D., to oppose Petitioner’s challenges. Ex. 2001.

II. ANALYSIS

A. Level of Skill in the Art

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art. Petitioner contends:

[A] person of ordinary skill in the art (‘POSITA’) would typically have had (i) an undergraduate degree (e.g., B.Sc. or B.A.) in physics, engineering (e.g., biomedical, mechanical and/or chemical), analytical or physical chemistry, biochemistry, chemistry, biology, molecular biology or a related field in biological or chemical sciences, and (ii) have had at least about one year of experience in the design or manufacture of biological analysis instruments, including (but not limited to) optical components for fluorescence detection, for example, in thermocyclers and scanners, or equivalent classwork and practical experience in a Ph.D. or Master’s program,

and “would have had knowledge of the scientific literature concerning the design and manufacture of analytical instruments for biological applications.” Pet. 13–14.

⁸ Gambini et al., PCT Pub. WO 99/60381, published Nov. 25, 1999 (Ex. 1022).

In our Institution Decision, we adopted Petitioner’s definition of the level of ordinary skill in the art as it was undisputed at the time and consistent with the evidence of record, including the level of skill reflected in the prior art of record. Inst. Dec. 10; *see Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Patent Owner does not contest the level of skill in the art as adopted by the Board (PO Resp. 4–5), and we continue to apply that same skill level in our analysis for this Final Written Decision. We further find that both parties’ experts are qualified to provide opinions about the ’043 patent from the perspective of the POSITA.

B. Claim Construction

Based on the filing date of the Petition (November 6, 2018), the Board interprets claim terms in the ’043 patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2018); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142–46 (2016).⁹ Under the broadest reasonable construction standard, claim terms are generally given their ordinary and customary meaning, as would have been understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249,

⁹ On October 11, 2018, the USPTO revised its rules to harmonize the Board’s claim construction standard for interpreting claims in trial proceedings before the Patent Trial and Appeal Board with the standard used in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)). This rule change, however, applies to petitions filed *on or after November 13, 2018*, and, therefore, does not apply to this proceeding. *Id.*

1257 (Fed. Cir. 2007). “Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). “Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

In its Petition, Petitioner does not propose constructions for any claim terms and asserts the claims “do not require further construction for purposes of this Petition.” Pet. 14. In its Reply, Petitioner maintains that no construction is necessary, but should the Board construe them, the terms “wells”/“sample wells” should be understood as “where the samples to be analyzed are placed.” Reply 3. Patent Owner, however, has argued that “Petitioner’s obviousness theory implicitly utilizes claim constructions that are not supported by the intrinsic record, most notably for the claim term ‘sample wells.’” PO Resp. 5. According to Patent Owner, the terms “wells”/“sample wells” should be construed to mean “a depression, open on one end and closed on the opposite end, into which a reaction vessel can be placed,” and should not be construed to be the same as “holes.” *Id.* at 7 (citing Ex. 2001 ¶ 37); Sur-Reply 3. Having considered the evidence and arguments of record, we are persuaded by Patent Owner’s proposed construction.

Although we agree that “wells”/“sample wells” are where the samples to be analyzed are placed in the device, we find Petitioner’s definition to be incomplete as it does not require any particular structure. We decline to adopt Petitioner’s purely functional claim construction and find that a

POSITA would have understood “wells”/“sample wells” to require a certain structure as described in the ’043 patent. In this regard, the specification of the ’043 patent consistently uses the term “wells” to refer to the structures that cradle the sample tubes in the “thermal cycler” or “sample unit” and that are closed at one end. *See, e.g.*, Ex. 1001, Abstract (“A fluorescence detection apparatus for analyzing samples located in a plurality of wells in a thermal cycler and methods of use are provided.”); *id.* at 2:47–50 (describing “[a]ccording to one aspect of the invention, a fluorescence detection apparatus for analyzing samples located in a plurality of wells in a thermal cycler”); *id.* at 3:12–13 (“Each sample is placed in a respective one of a number of sample wells of a thermal cycler instrument.”); *id.* at 4:26–27 (“Sample unit 202 contains a number of sample wells 210 arranged in a regular array.”). All the embodiments of the invention described in the ’043 patent refer to sample wells depicted with a closed end. *See, e.g., id.* at Fig. 6 (sample well 210). We further agree with Patent Owner that the specification draws a distinction between “wells” in which the samples are placed for analysis and “holes” through which light passes to reach the sample. *See, e.g., id.* at 4:56 (“Lid heater 204 has holes 220 therethrough.”); *id.* at 5:42 (referring to “holes 220 in lid heater 204”); *id.* at 6:52–53 (“Openings 502, 504, 506, 508 may simply be holes through the bottom surface of detection module 234.”).

Patent Owner’s proposed construction is supported by the testimony of its expert, Dr. Neikirk. Ex. 2001 ¶¶ 35–44. As noted by Dr. Neikirk,

The design of the apparatus described in the ’043 patent supports [Patent Owner’s] construction of the term “well.” In every embodiment, the thermal cycler is consistently the furthest component from the detection module, and the

detection module is in optical communication with the top of the wells. *See, e.g.*, Ex. 1001 Fig. 6. The samples are also placed into the wells through the opening in the top. *Id.* Therefore, I cannot identify any reason for light to pass all the way through the wells of the thermal cycler. That is, light enters and exits through the same end of the well as the sample is placed, such that only one opening is beneficial to the functioning of the fluorescence detection module.

In fact, it would not be beneficial for the sample wells to be open at the end opposite the end in optical communication with the detection module, as such an opening would risk light being allowed into the sample well from the opposite end, which may negatively impact the fluorescence signal received by the detector.

Id. ¶¶ 42–43.

Petitioner’s expert, Dr. Landers, did not propose any specific claim constructions in the sole declaration he provided in this proceeding. Ex. 1008 ¶¶ 74–77. At his deposition, he indicated that he was applying a definition of “well” based on what the prior art Li reference taught rather than how that term would normally be understood in the art:

Q. You don’t think there is any wells in Figure 1?

A. Which definition of “well”?

Q. Whatever definition you want to apply.

A. I’m applying the Li definition of well, ***which is not a sample well, it’s just an opening, a hole.***

Ex. 2003, 30:19–31:3 (emphasis added). Dr. Landers acknowledged that “[j]ust about every other reference” describes the term “well” as “something that supports a sample like a micro well titer plate.” *Id.* at 31:4–17. Other than the Li reference it relies upon as prior art, Petitioner does not point to any other extrinsic evidence, such as dictionary definitions, to support its

position that a POSITA would have understood “wells” to include open-ended structures.

In view of the foregoing, we construe the terms “wells”/“sample wells” to mean “a depression, open on one end and closed on the opposite end, into which a reaction vessel can be placed,” as Patent Owner proposes. We do not find it necessary to construe any other claim terms to address the disputed issues in this proceeding.

C. Overview of the Prior Art

Before turning to Petitioner’s asserted grounds, we provide an overview of the asserted references.

1. Li (Ex. 1011; Ex. 1012)

Li is a Chinese patent application published on November 13, 2002. Ex. 1011. A certified English translation of Li has been provided, and we rely upon that certified translation in our analysis. Ex. 1012.¹⁰ Li describes a device for quantitative analysis of target gene concentration through PCR. Ex. 1012, 5:5–6. Li describes the device comprises a thermal cycling unit, a fluorescence detection unit, and a control circuit, which are all disposed in a housing, and a computer disposed outside the housing, where the fluorescence detection unit is located *below* the thermal cycling unit. *Id.* at 7:29–8:1.

¹⁰ Although, as discussed below, there is a dispute over whether the “wells” referred to in Li would be understood to be the same as the “wells” referred to in the ’043 patent, there is nothing of record to suggest that the certified translation of Li is inaccurate.

Figure 3 of Li, reproduced below, depicts a cross-sectional view of the fluorescence quantitative PCR analyzing system.

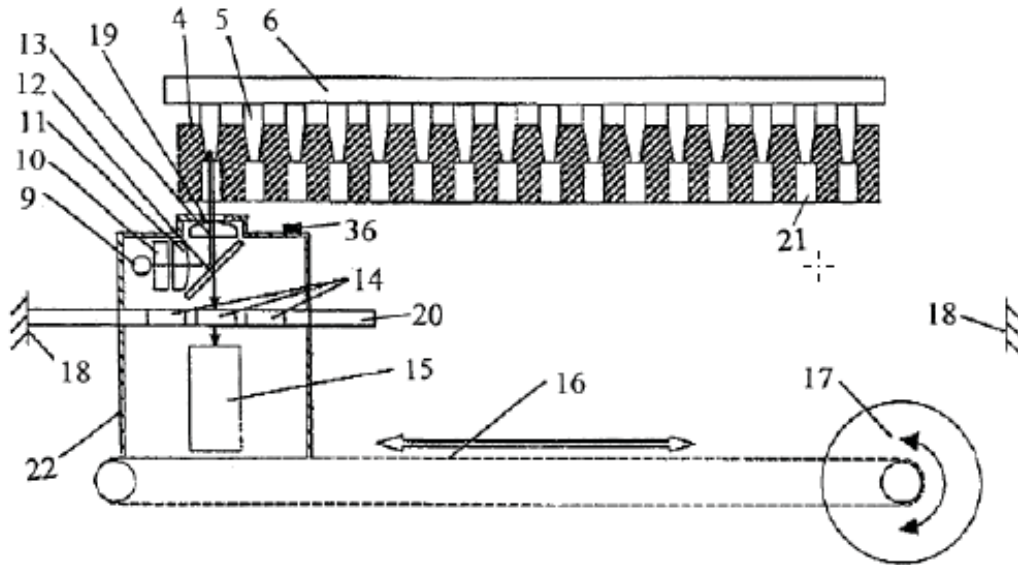


Figure 3 shows the fluorescence quantitative PCR analyzing system including a thermal cycling unit, which comprises “a variable temperature metal module” (4), “a row of wells” (21), and a “thermoelectric regulator” (3) attached to the variable temperature metal module, a heat sink, and a fan. *Id.* at 8:5–6. The tube (5) for holding reactants is disposed in what Li describes as a “well” (21), and is covered with heatable lid (6) that has a heater to prevent reactants from evaporating from the tube. *Id.* at 8:8–12.

2. Miller (*Ex. 1013*)

Miller describes a movable compact scan head having multiple scanning modalities that supports two or more optical systems within a small space. *Ex. 1013*, 1:53–56. Each optical system within the scan head may be designed for a specific stimulation and detection modality. *Id.* at 1:56–58. According to Miller, possible modalities for the invention described therein

include stimulation and detection of storage phosphor emission, fluorescence including chemi-fluorescence, reflection, and transmission. *Id.* at 1:58–60. Miller describes that, by incorporating the elements into a movable scan head, as opposed to a movable scanning mechanism within the optical system, a lightweight, high speed, and extremely versatile scanning system is achieved. *Id.* at 2:65–3:2. The invention described by Miller may be used for analysis of storage phosphor screens and samples within membranes, electrophoretic gels, and microtiter sample plates, among others. *Id.* at 3:2–5.

Figure 3 of Miller, reproduced below, depicts a view of movable scan head 10.

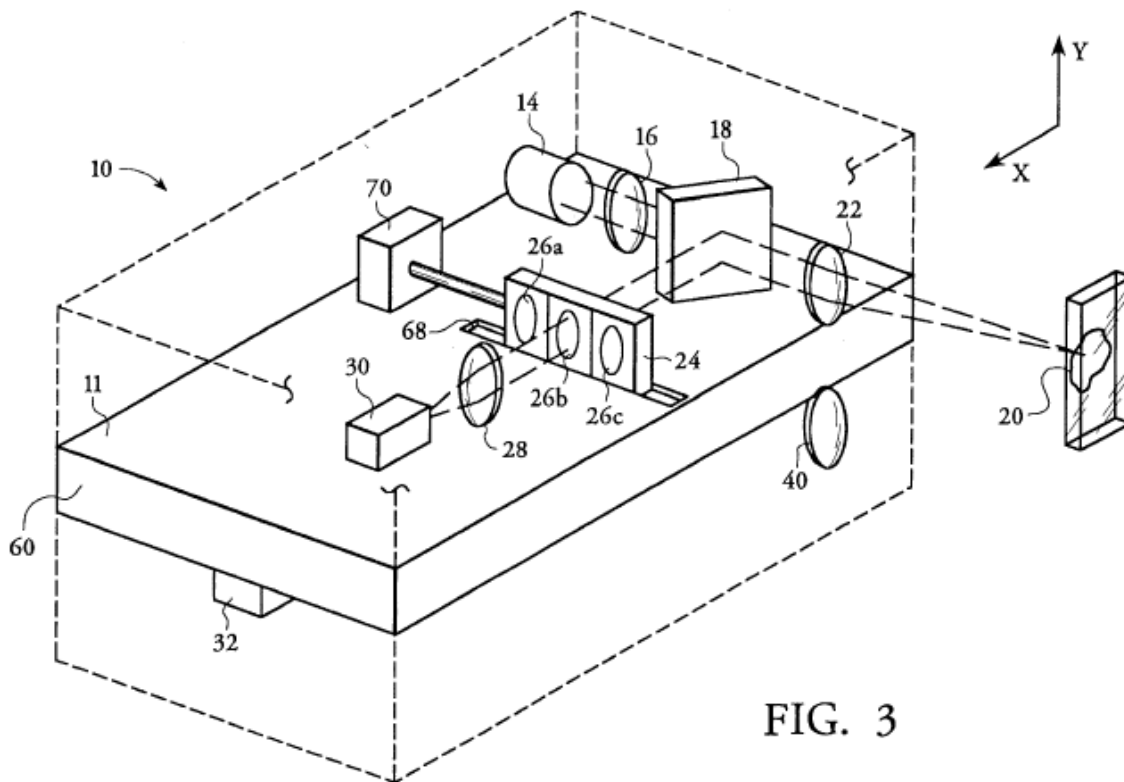


FIG. 3

Figure 3 shows a movable scan head with laser diode light source 10 and photodetector 30. *Id.* at 3:41–51, 5:53–67. As depicted above and in

other figures of Miller, laser diode 14 provides an exciting or stimulating beam of a first wavelength, which passes through collimating lens 16 and then through beam splitter 18. *Id.* at 3:40–44. After passing through beam splitter 18, the stimulating beam passes through objective 22 and is focused onto a spot of sample 20 to cause signal radiation to be returned from the sample. *Id.* at 3:44–48. The signal radiation emitted from sample 20 is thereafter directed back toward beam splitter 18, which is then reflected toward a detection path and passed through a filter (26a, 26b, or 26c) and focusing lens 28 onto detector 30. *Id.* at 3:58–4:16.

Additionally, with reference to Figure 8, Miller describes an alternate embodiment of the scan head with multiple stimulating beams, wherein a second laser diode may provide a different stimulating wavelength or other optical property than the first source. *Id.* at 6:8–30, Fig. 8. Miller further states that simultaneous reading of a sample according to more than one channel may occur. *Id.* at 7:1–2.

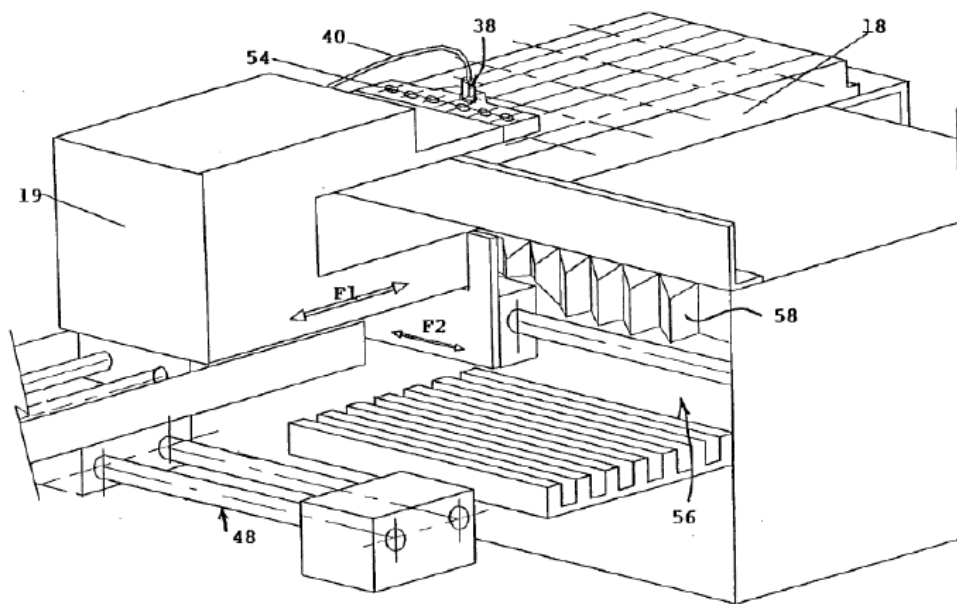
3. *Randrianarivo* (Ex. 1016)

Randrianarivo describes an optical measuring head, particularly for an automatic laboratory chemical or biochemical reaction analyzer designed to determine the dosing of components contained in samples after mixing with reagents in wells of a reaction analysis plate. Ex. 1016, 1:11–14. The optical measuring head includes both a “colorimetric”¹¹ analysis detector

¹¹ Although Randrianarivo at times refers to “colorimetric” analysis, we agree with Petitioner that “it is apparent from the context of the reference, which discloses a light sources and photodetectors, that *Randrianarivo* is describing ‘colorimetric’ analysis.” Pet. 22 (citing Ex. 1016, Abstract; Ex. 1008 ¶ 101). This is not disputed by Patent Owner.

and a photometric analysis device (or photometer), which are mounted on a movable U-shaped support. *Id.* at 1:15–23, 3:18–25. The photometric analysis detector is described as useful for determining the dosing of components contained in samples such as blood, cerebrospinal liquid, or urine, and may be used in particular to analyze a coagulation (hemostasis) reaction in a sample of human plasma. *Id.* at 5:19–22, 8:15–26.

Figure 3 of Randrianarivo is reproduced below:



As shown above, the device of Randrianarivo includes a series of six photodiodes 54, located above a row of six light-emitting diodes (not shown), mobile support 19, and reaction analysis plate 18 seated over thermal enclosure 56. *Id.* at 8:28–9:6, 9:25–28.

4. Bjornson (Ex. 1017)

Bjornson teaches an automated multi-purpose laboratory work station for analytical chemistry and biological experimental assay procedures.

Ex. 1017, 5:53–57. Figure 1, reproduced below, depicts a perspective view of the multipurpose laboratory work station.

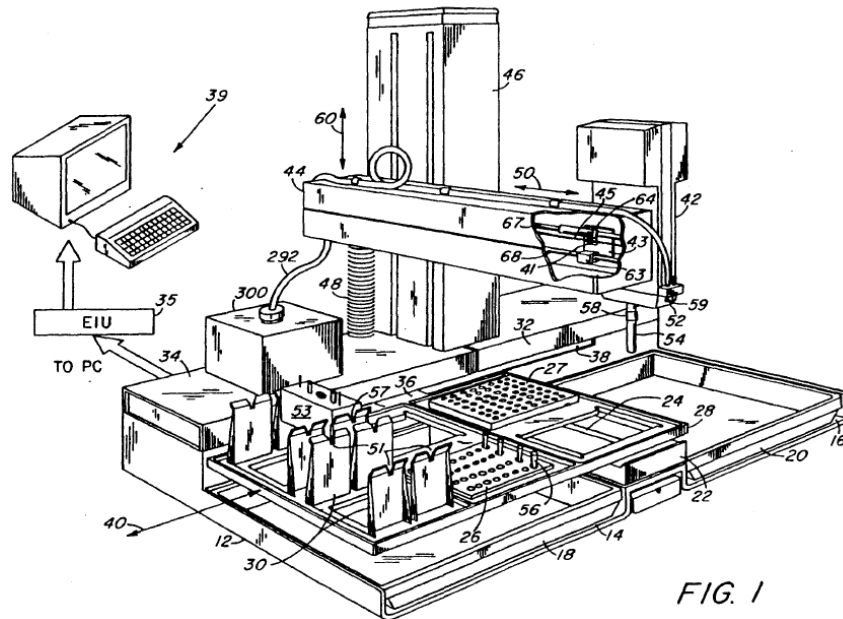


Figure 1 shows a support table, above which is elevator tower 46, vertically movable arm 44, and pod 42 movable along the arm, for three-dimensional travel. *Id.* at 10:3–15. Interchangeable modules 52 and 53 attach to pod 42. *Id.* at 9:32–37. One optional attachment is a transducer for performing spectrophotometric analysis. *Id.* at 42–50; *see also id.* at 14:15–46. Fiber optic illuminators direct optical signals in the form of light or other electromagnetic radiation upward from the base into the underside of microtiter plates or other receptacles. *Id.* at 9:5–11.

5. Heffelfinger (Ex. 1019)

Heffelfinger discloses a method and apparatus for measuring the luminescence, fluorescence, and absorption of a sample in which the excitation and/or detection wavelengths are tunable. Ex. 1019, 1:11–15. Heffelfinger's device includes a microplate reader capable of making

readings within multiple locations within each sample well of the microplate. *Id.* at 2:24–27. Heffelfinger explains the system can be placed in a continuous mode, where “readings are taken in a continuous fashion as the system scans through a microplate.” *Id.* at 8:32–36. Figure 1 of Heffelfinger is reproduced below, depicts a perspective view of the scanning mechanism.

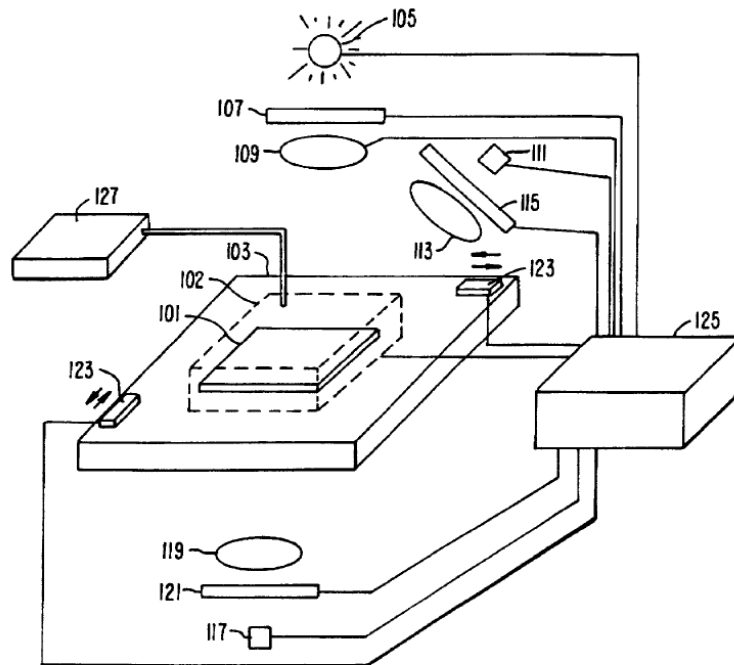


Figure 1 shows the elements of the mechanism of the microplate reader, including light source 105, focusing optics 109, sample 101, detectors 111 (above, right) and 117 (below), positioners 123, and data processor 125. *Id.* at 3:21–4:22.

6. *Pantoliano (Ex. 1021)*

Pantoliano describes a method and an apparatus for performing thermal shift assays. Ex. 1021, 1:23–25. Pantoliano describes “ranking the affinity of each of a multiplicity of different molecules for a target molecule

which is capable of denaturing due to a thermal change.” *Id.* at Abstract. Pantoliano further describes using fluorescence spectrometry, where an “X-Y mechanism scans the microplate with a sensitive fiber-optic probe to quantify the fluorescence in each well,” where either the samples or the probe are movable. *Id.* at 21:3–18.

Figure 31 of Pantoliano, reproduced below, depicts a top view of assay apparatus 2900.

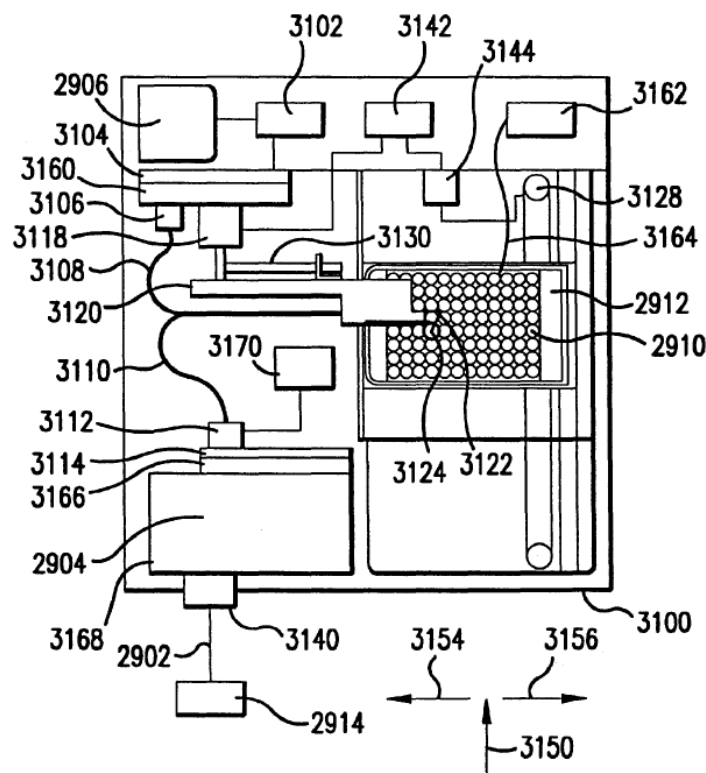


Figure 31 of Pantoliano shows light source 2906, fiber optic probe 3122, fiber optic cable 3110, samples 2910, heat conducting block 2912, photomultiplier tube 2904, and sensor armature 3120. *Id.* at 35:7–35. Pantoliano describes that electromagnetic radiation is transmitted from light source 2906 to fiber optic probe 3122 by fiber optic cable 3108, and photomultiplier tube 2904 is used to detect spectral emission from samples 2910. *Id.* at 35:24–29. Sensor armature 3120 moves in directions 3154 and

3156, and heat conducting block 2912 moves perpendicular to sensor armature 3120. *Id.* at 36:14–18. The armature can be configured with multiple fiber optic sensors to analyze a subset of samples simultaneously. *Id.* at 21:11–24. Pantoliano states that the assay apparatus described therein may be used for conducting assays on biological polymers, proteins, or nucleic acids, and may further be used to perform PCR and thermal cycling steps for any purpose. *Id.* at 42:51–52.

7. Gambini (Ex. 1022)

Gambini describes an optical instrument for quantitative monitoring of DNA replication in a PCR apparatus. Ex. 1022, 2:10–11.

Figure 1 of Gambini, reproduced below, depicts a reaction apparatus.

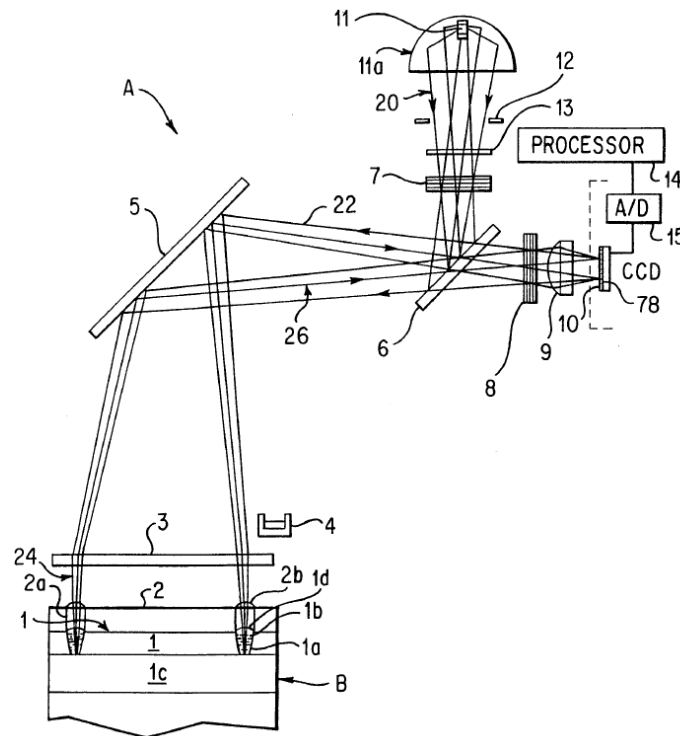


Figure 1 shows vial 1b in well 1a, light source 11, beam splitter 6, detector 78, and “fluorescent reference member 4.” Ex. 1022, 5:25–11:25.

Gambini describes using reference member 4 to compute normalized reference data, which are normalized in real time. *Id.* at 14:16–15:4.

D. Patentability Analysis

1. Grounds Based on Li (Grounds I, II, and III)

For the first set of challenges set forth in the Petition (Grounds I, II, and III), Petitioner relies primarily upon the teachings of Li (Ex. 1011; Ex. 1012). In Ground I, Petitioner contends that claims 1–17 would have been obvious over the combination of Li, Miller, and Randriarivo. Pet. 34–58. In Ground II, Petitioner contends that claim 6 would have been obvious based on the further teachings of Bjornson in combination with Li, Miller, and Randriarivo. *Id.* at 58–59. In Ground III, Petitioner contends that claim 18 would have been obvious based on the further teachings of Heffelfinger in combination with Li, Miller, and Randriarivo. *Id.* at 59–62. As it is dispositive for these challenges, we focus our analysis on whether Petitioner has met its burden with respect to the independent claims as set forth in Ground I.

At a general level, Petitioner asserts that Li discloses each of the independent claim elements, except for the requirement of “a plurality of excitation/detection pairs” (elements 1[b], 12[b]). *Id.* at 38, 40, 41. For the missing claim requirement, Petitioner relies upon Miller as disclosing an improved movable optical scanning head with a plurality of excitation/detection pairs with multiple scanning modalities, including fluorescence detection, for use in analyzing samples in various formats, including microtiter sample plates (sample wells). *Id.* at 39–40, 53–54 (citing Ex. 1013, 2:2–5, 5:24–38, 6:8–30, 6:64–7:8, Figs. 3–4, 8; Ex. 1008

¶ 155). Petitioner also asserts that Randrianarivo discloses an automatic analyzer with a plurality of sample wells and an improved optical measuring head that includes a plurality of pairs of optical sources (LEDs) and optical detectors. *Id.* at 34–35, 39 (citing Ex. 1016, 3:5–11, 4:11–21, 5:23–9:7, Figs. 1–3; Ex. 1008 ¶ 143).

Petitioner contends that a POSITA would have been motivated to combine the references because Li, Miller, and Randrianarivo “share the same general goal” of analyzing samples using light and “their approaches are compatible.” *Id.* at 35–36 (citing Ex. 1008 ¶¶ 144–145). Petitioner also contends that incorporating the moving optical scanner head of Miller would “improve the flexibility” of the system of Li. *Id.* More specifically, Petitioner contends that a POSITA would have been “motivated to combine the movable scan head of Miller with the analyzer of Li because the Miller scanning head offers a compact, versatile, lightweight, and low-cost design for rapid scanning.” *Id.* at 36 (citing Ex. 1013, 1:46–56, 2:65–3:2; Ex. 1008 ¶ 146). Additionally, Petitioner contends that a POSITA would have considered Randrianarivo’s teaching of multiple measurement systems in the same optical scanning head in order to advantageously allow the same equipment to be used for multiple analysis types to be applicable to a PCR system such as Li. *Id.* at 35 (citing Ex. 1008 ¶¶ 105–118, 144; Ex. 1016, 3:3–11, 4:18–21, 8:15–18, 8:30–9:7; Ex. 1028). Petitioner also contends that “employing a scanhead with multiple excitation/detector pairs would eliminate or at least reduce the need to re-calibrate the system when changing modules or protocols—one of the specific drawbacks cited in the challenged patent.” *Id.* at 36 (citing Ex. 1008 ¶ 147). As another reason for combining the references, Petitioner contends that a POSITA would have

understood that techniques for measuring transmittance are readily adaptable for the measurement of fluorescence, and that “instrumentation that combined transmittance and fluorescence detection within the same optical equipment were commonplace.” *Id.* at 36–37 (citing Ex. 1041, Abstract, Fig. 1, 8:30–58, 9:49–56, 10:8–12; Ex. 1065, Abstract; Ex. 1028; Ex. 1008 ¶¶ 90–91, 115–118, 151).

With respect to the requirement of a plurality of excitation/detection pairs, Petitioner contends that a POSITA would have been motivated to apply the optical head of Miller to the fluorescence detection thermocycling apparatus of Li to obtain the benefits of a “multiple-pair, flexible optical scanning head.” *Id.* at 39 (citing Ex. 1008 ¶¶ 30, 90–91, 156). Petitioner further contends that “[a] POSITA would also have been motivated to do so because the multiple pairs of Miller and Randrianarivo would reduce the need to replace the optics module and recalibrate the device to assess the response to a different excitation frequency.” *Id.* (citing Ex. 1016, 3:5–11; Ex. 1008 ¶ 157). Likewise, with respect to dependent claim 2 (which recites “wherein each emission light detector is configured to detect a different range of wavelengths”), Petitioner contends that a POSITA would have been motivated to apply the teachings of Miller and Randrianarivo “so that the detector apparatus is configurable to detect different ranges of wavelengths,” and also to “enable a POSITA to use a more diverse range of fluorophores, monitor a wider array of reactions, and do so without the need to re-calibrate the apparatus every time a single-element module was changed.” *Id.* at 42 (citing Ex. 1008 ¶¶ 167–168; Ex. 1013, Fig. 1, 3:40–4:14; Ex. 1016, 6:1–8, 8:5–9:7, 10:4–9, Figs. 1, 2, 4).

Petitioner contends that a POSITA would have had a reasonable expectation of success in combining the teachings of Miller, Li, and Randrianarivo because doing so represented a combination of familiar elements according to known methods. *Id.* at 37 (citing Ex. 1008 ¶ 152). Petitioner also contends that a POSITA would have had a reasonable expectation of success because each reference involves a movable detection module and either discloses fluorescence detection or could be readily adapted to do so. *Id.* at 39–40 (citing Ex. 1008 ¶¶ 90–91, 106–118, 157).

Patent Owner raises several arguments against Petitioner’s challenges based on Li. First, Patent Owner argues that Li does not disclose “wells” under the proper claim construction. PO Resp. 10–14. Second, Patent Owner argues that Petitioner does not present its obviousness combination with the requisite particularity. *Id.* at 14–23. Third, Patent Owner argues that a POSITA would not have been motivated to combine Li, Miller, and Randrianarivo, and the references do not share common goals or compatible approaches. *Id.* at 23–30. Fourth, Patent Owner argues that Petitioner has not established a reasonable expectation of success for such a combination. *Id.* at 30–34.

We have considered the evidence and arguments of record and determine that Petitioner has not demonstrated by a preponderance of the evidence that the challenged claims would have been obvious based on the combination of Li, Miller, and Randrianarivo. In particular, we find that Li does not teach a device with “wells” or “sample wells” under the proper claim construction. We further find that Petitioner has not demonstrated with sufficient particularity that a POSITA would have been motivated to modify Li’s device to include the claimed “wells.”

Independent claim 1 of the '043 patent recites a “fluorescence detection apparatus for analyzing samples located in a plurality of wells in a thermal cycler.” Ex. 1001, claim 1.¹² Likewise, independent claim 12 recites “placing each sample in a respective one of a plurality of sample wells.” *Id.* at claim 12. As discussed above, we have construed “wells”/“sample wells” to mean “a depression, open on one end and closed on the opposite end, into which a reaction vessel can be placed.” Li does not teach this requirement.

Although the certified translation of Li refers to elements 21 of the disclosed apparatus as a “plurality of wells,” those elements are not closed on one end as required by our construction. Thus, notwithstanding the terminology used by Li, we agree with Patent Owner that elements 21 do not qualify as the claimed “wells.” PO Resp. 11. As explained by Dr. Niekirk:

Rather than use “wells,” Li has holes that traverse the temperature cycling unit. Li is constructed so that the sample tubes are placed into the temperature cycling unit from the top, and the fluorescence detection unit is in optical communication with the sample tubes from the bottom via the holes. The fluorescence detection unit is placed on a belt that moves in one direction located below the samples and is concealed in an enclosure beneath the sample wells. As such, Li does not suggest the possibility of detaching and replacing the detection module. Rather than employing a shuttle that is translated in two directions using a stepper motor coupled to multiple lead screws. In using holes rather than wells, it is my opinion that Li discloses an overall system very different from the claimed invention of the '043 patent.

¹² The parties do not dispute that the preamble is limiting. *See* Pet. 38 (arguing that Li discloses the preamble of claim 1); PO Resp. 10 (arguing that Li does not disclose “wells” as recited in the preamble). We likewise determine that the preamble is limiting as it provides antecedent basis for “wells” recited in the body of the claim. *See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002).

Ex. 2001 ¶ 52. Furthermore, Dr. Landers acknowledged that the elements referred to as “wells” in Li are actually “holes.” Ex. 2003, 30:19–31:3 (“I’m applying the Li definition of well, which is not a sample well, it’s just an opening, a hole.”); *id.* at 22:15–23:1 (“In Figure 3 of Li, the tubes sit into some support structure that holds the samples, which in this case is tubes. And below those tubes are holes.”). Dr. Landers thus acknowledged that Li uses the term “wells” differently from how elements 21 would normally be understood in the art. *Id.* at 30:19–31:17.

We recognize, as Petitioner points out, that Li also explicitly refers to another element (19) as a “hole.” Reply 19; Ex. 1012, 8:20 (identifying “a hole 19 provided on top of the housing”). But the fact that Li describes another aperture through which the light passes in order to reach the sample as a “hole” does not transform the structure of elements 21 described in Li into what is required under our construction of “wells”/“sample wells.”

We also recognize that the other prior art references relied upon by Petitioner teach sample-holding structures that appear to satisfy our construction of “wells”/“sample wells.” For instance, Miller teaches that a device described therein may be used to analyze samples contained in “microtiter sample plates.” Ex. 1013, 3:2–4. Randrianarivo teaches placing the samples mixed with reagents in the “wells of a reaction analysis plate.” Ex. 1016, 1:11–14. With respect to claim element 1[e] requiring that the “detection module is movable so as to be positioned in optical communication with different wells of the plurality of wells,” Petitioner contends that “the optical measuring head (10) of *Randrianarivo* is movably mounted so that it can be positioned in optical communication with each of the plurality of wells (16).” Pet. 41 (citing Ex. 1016, 7:1–15; Ex. 1008

¶ 165). But Petitioner does not clearly rely upon the structures of Miller or Randrianarivo to assert that the claim requirement for “wells” or “sample wells” is satisfied. As discussed above, Petitioner’s obviousness theory with respect to Ground I only requires a modification of Li’s apparatus to include “a plurality of excitation/detection pairs.” To the extent that Petitioner’s contentions are based on further modifications to Li, we agree with Patent Owner that Petitioner fails to satisfy the particularity requirement of 35 U.S.C. § 312(a)(3). PO Resp. 14–23; *see Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (“[T]he Petitioner has the burden from the onset to show *with particularity* why the patent it challenges is unpatentable.” (emphasis added)).

For the foregoing reasons, Petitioner has not demonstrated by a preponderance of the evidence that the combination of Li, Miller, and Randrianarivo as set forth in Ground I renders claims 1–17 obvious. Petitioner does not rely upon the teachings of Bjornson or Heffelfinger to remedy the deficiencies in Ground I. Accordingly, we also determine that Petitioner has not met its burden with respect to Grounds II and III.

2. Grounds Based on Pantoliano (Grounds IV, V, and VI)

For the second set of challenges set forth in the Petition (Grounds IV, V, and VI), Petitioner relies primarily upon the teachings of Pantoliano (Ex. 1021). In Ground IV, Petitioner contends that claims 1–6 and 10–17 would have been obvious over the combination of Pantoliano and Miller. Pet. 62–76. In Ground V, Petitioner contends that claims 7–9 would have been obvious based on the further teachings of Gambini in combination with Pantoliano and Miller. *Id.* at 76–78. In Ground VI, Petitioner contends that

claim 18 would have been obvious based on the further teachings of Heffelfinger in combination with Pantoliano and Miller. *Id.* at 79. As it is dispositive for these challenges, we again focus our analysis on whether Petitioner has met its burden with respect to the independent claims as set forth in Ground IV.

At a general level, Petitioner argues that Pantoliano discloses a thermal cycling apparatus with a plurality of wells that includes an overhead movable optical analysis head that can be positioned in optical communication with the plurality of wells. *Id.* at 63 (citing Ex. 1021, 21:3–26, 42:51–63, Figs. 31, 35; Ex. 1008 ¶ 232). Petitioner acknowledges that Pantoliano does not explicitly disclose source/detector pairs within the analysis head housing, but relies upon Miller as teaching this element. *Id.* (citing Ex. 1013, Abstract, 2:65–3:5; Ex. 1008 ¶ 232). Petitioner provides an analysis as to how each claim element is taught or otherwise suggested by this combination of references. *Id.* at 65–76.

Petitioner contends that a POSITA would have been motivated to combine the teachings of Pantoliano and Miller because they share the same goal of analyzing samples using light, in particular fluorescence, and their approaches are compatible. *Id.* at 63 (citing Ex. 1008 ¶ 233; Ex. 1021, 21:3–26, 42:51–62; Ex 1013, Abstract; Ex. 1022, Abstract, 2:10–3:18, 13:6–8). More specifically, Petitioner contends that a POSITA would also have been motivated to combine the movable scan head of Miller with the analyzer of Pantoliano because the Miller scanning head offers an “improved moving optical head scanner for use in a variety of experimental applications[,] including fluorescence detection,” and discloses a “compact, versatile, lightweight, and low-cost design for rapid scanning.” *Id.* at 64 (citing

Ex. 1013, 1:6–8, 1:46–56, 2:65–3:2, 7:10–27; Ex 1008 ¶ 234). Petitioner further contends that a POSITA would have had a reasonable expectation of success because “[i]ncluding multiple pairs within the optical analysis head was a well-known approach.” *Id.* (citing Ex. 1016, 5:23–9:7; Ex. 1024 ¶¶ 70–71, Fig. 5; Ex. 1008 ¶¶ 30, 235).

With respect to these challenges, Patent Owner argues that Pantoliano fails to disclose numerous claimed features, including the requirement for a plurality of excitation/detection pairs within a detection module. PO Resp. 45–46. Patent Owner contends that Pantoliano does not address the problems solved by the ’043 patent, including providing a detachable detection module to allow for different applications, simplifying the sample well calibration process, and providing the ability to probe multiple labels in parallel using different wavelengths of light. *Id.* at 47–48. Patent Owner further argues that a POSITA would not have been motivated to combine Pantoliano and would not have had a reasonable expectation of success in such a combination. *Id.* at 49–58.

We have considered the evidence and arguments of record and determine that Petitioner has not demonstrated by a preponderance of the evidence that the challenged claims would have been obvious based on the combination of Pantoliano and Miller.

With respect to the requirement of “a plurality of excitation/detection pairs” (elements 1[b], 12[b]), Petitioner acknowledges that Pantoliano does not disclose a device with an “on-head light generator or light detector,” and relies upon Miller as disclosing “a compact movable head that includes a plurality of excitation/detection pairs.” Pet. 65–66. Petitioner, however, only identifies generalized motivations to combine the teachings of the

references, including the assertion that they share the same goal, that their approaches are compatible, and that Miller offers a “compact, versatile, lightweight, and low-cost design for rapid scanning.” *Id.* at 64. We agree with Patent Owner that the asserted reasons are conclusory and insufficient to support a motivation to combine Pantoliano and Miller. *See, e.g., TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) (“[A] conclusory assertion with no explanation is inadequate to support a finding that there would have been a motivation to combine” (quoting *In re Van Os*, 844 F.3d 1359, 1361–62 (Fed. Cir. 2017))); *Microsoft Corp. v. Enfish, LLC*, 662 F. App’x 981, 990 (Fed. Cir. 2016) (“[The] Board correctly concluded that [the petitioner] did not articulate a sufficient motivation to combine. With respect to [certain challenged claims], [the petitioner] gave no reason for the motivation of a person of ordinary skill to combine [the two references] except that the references were directed to the same art or same techniques.”).

As noted in our Institution Decision, the Petition does not explain clearly why the POSITA would have chosen to use Miller’s design with multiple light generators within the same scan head in lieu of the fiber optic system taught by Pantoliano, which could already be used to analyze multiple samples simultaneously. Inst. Dec. 31. In our Institution Decision, we also took into account the testimony of Petitioner’s expert, Dr. Landers, who provides more detail in his declaration as to why there were known problems with the use of optical-fiber-based systems, such as those taught by Pantoliano, including the fact that fiber optics lose the ability to transmit certain frequencies of light over time and that light transmission characteristics could change when fiber optics are physically moved. *Id.* at

32; Ex. 1008 ¶¶ 30–31, 115 n.8. Petitioner, however, did not rely upon that testimony to support a motivation to combine Pantoliano and Miller. *See* Pet. 35 (citing foregoing portions of Landers declaration only with respect to Ground I). Moreover, as explained below, even if Dr. Landers’ declaration statements concerning the known drawbacks of fiber optics systems are taken into account, we are not persuaded that those alleged drawbacks would have provided a sufficient motivation to combine the teachings of Pantoliano and Miller in the manner asserted by Petitioner.

We agree with Patent Owner that the goals and structure of the apparatus taught by Pantoliano are significantly different from the claimed invention. We further agree with Patent Owner that a preponderance of the evidence does not support a motivation to modify Pantoliano’s apparatus to include Miller’s scan head based on either a desire to detect multiple wavelengths simultaneously or to solve any problems associated with the fiber optics used in Pantoliano’s apparatus.

Although Pantoliano mentions in one instance that “the assay apparatus of the present invention can be used to perform polymerase chain reaction” (Ex. 1021, 42:57–58), it is primarily directed to performing “thermal shift assays” used to assess the extent of thermal denaturation of proteins under various conditions. *Id.* at 1:23–25 (“[T]he present invention relates to a method and apparatus for performing assays, particularly thermal shift assays.”); *id.* at 5:5–25 (describing a method of simultaneously heating “[a] multiplicity of containers” and “measuring in each of the containers a physical change associated with the thermal denaturation of the target molecule resulting from heating”). Dr. Neikirk explains that thermal shift assays can be used to assess various parameters of a target protein, such as

stability under certain conditions, shelf-life, crystallization tendencies, the affinity of the target protein for other molecules, and optimal refolding conditions. Ex. 2001 ¶ 138. According to Dr. Neikirk, the apparatus of Pantoliano would not benefit from the ability to deliver and detect multiple light wavelengths in the same sample because “fluorescence is used in Pantoliano to assess whether and to what extent a protein has denatured, not to detect and quantify various types of target molecules” or to “distinguish between molecules.” *Id.* ¶¶ 155–157.

As noted above, the embodiment of Pantoliano relied upon by Petitioner utilizes fiber optic cables to transmit light and detect spectral emissions from the sample. Ex. 1021, 35:7–35, Fig. 31. Dr. Landers identified two main problems with such optical-fiber-based systems: (1) “fiber optics lose the ability to transmit certain frequencies of light over time” and (2) “light transmission characteristics change when fiber optics are physically moved.” Ex. 1008 ¶¶ 31–32; *see also id.* ¶ 115 n.8. We are not persuaded that these issues with fiber optics would have served as a motivation to combine Pantoliano with Miller in the manner asserted by Petitioner. Dr. Neikirk testifies that “at the time of the invention, practitioners were still employing fiber optics as a way to deliver specific wavelengths of light to samples despite the known problems with fiber optics.” Ex. 2001 ¶ 159. Indeed, as noted by Dr. Neikirk, Miller itself discloses embodiments that utilized fiber optics. *See id.* ¶ 160; Ex. 1013, 5:35–42 (describing an alternate embodiment in which the detector is “positioned remotely and connected to the scan head via an optical fiber”).

As to the issue of transmission decay over time with fiber optics, Dr. Landers confirmed that this was only an issue at low wavelengths (300–500

nm range) and this did not apply to the higher wavelengths associated with most fluorophores used in real time PCR. Ex. 2003, 124:5–11, 125:11–19; Ex. 2001 ¶ 161. Furthermore, to the extent there was any problem with signal variations associated with the use of fiber optics, we are persuaded by Dr. Neikirk that it would not have been considered a significant problem that would have motivated a move away from fiber optics to a system in which there were a plurality of excitation/detection pairs in the same scan head. Ex. 2001 ¶ 163. Rather, as explained by Dr. Neikirk, the prior art chose to continue using fiber optics and proposed using different solutions such as making mathematical adjustments to account for the variations. *Id.* ¶¶ 163–165.

Petitioner does not point to any evidence that calls into question the foregoing testimony of Dr. Neikirk. Rather, in its Reply, Petitioner only contends that “[a]lthough Pantoliano does not explicitly disclose source/detector pairs within the analysis head housing, Pantoliano was readily combinable with Miller to achieve that desirable objective.” Reply 11. Petitioner, however, does not explain clearly what “desirable objective” would have been achieved by such a combination. Moreover, even if certain aspects of Pantoliano were “readily combinable” with Miller, we find that to be insufficient to support a conclusion of obviousness for the reasons stated above.

In sum, for the foregoing reasons, Petitioner has not demonstrated by a preponderance of the evidence that the combination of Pantoliano and Miller as set forth in Ground IV renders claims 1–6 and 10–17 obvious. Petitioner does not rely upon the teachings of Gambini or Heffelfinger to

remedy the deficiencies in Ground IV. Accordingly, we also determine that Petitioner has not met its burden with respect to Grounds V and VI.

III. CONCLUSION¹³

Petitioner has not demonstrated by a preponderance of the evidence that claims 1–18 of the '043 patent would have been obvious based on the challenges presented in the Petition. In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–17	103	Li, Miller, Randrianarivo		1–17
6	103	Li, Miller, Randrianarivo, Bjornson		6
18	103	Li, Miller, Randrianarivo, Heffelfinger		18
1–6, 10–17	103	Pantoliano, Miller		1–6, 10–17
7–9	103	Pantoliano, Miller, Gambini		7–9
18	103	Pantoliano, Miller, Heffelfinger		18
Overall Outcome				1–18

¹³ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*, 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

IV. ORDER

Accordingly, it is hereby:

ORDERED that Petitioner has not demonstrated by a preponderance of the evidence that claims 1–18 of the '043 patent are unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, any party to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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