

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NEUMODX MOLECULAR, INC.,  
Petitioner,

v.

HANDYLAB, INC.,  
Patent Owner.

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IPR2020-01133  
Patent 8,415,103 B2

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Before SHERIDAN K. SNEDDEN, JO-ANNE M. KOKOSKI, and  
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

KOKOSKI, *Administrative Patent Judge*.

DECISION  
Denying Institution of *Inter Partes* Review  
35 U.S.C. § 314

## I. INTRODUCTION

NeuMoDx Molecular, Inc. (“Petitioner”) filed a Petition to institute an *inter partes* review of claims 1–15 (the “challenged claims”) of U.S. Patent No. 8,415,103 B2 (“the ’103 patent,” Ex. 1200). Paper 2 (“Pet.”). HandyLab, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 20 (“Prelim. Resp.”).

Institution of an *inter partes* review is authorized by statute when “the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314 (2018); *see* 37 C.F.R. § 42.4. For the reasons set forth below, we deny the Petition and do not institute an *inter partes* review.

### A. *Real Parties-in-Interest*

Petitioner identifies NeuMoDx Molecular, Inc., QIAGEN North American Holdings, Inc., and QIAGEN N.V. as the real parties-in-interest. Pet. 1. Patent Owner identifies HandyLab, Inc. and Becton, Dickinson & Co. as the real parties-in-interest. Paper 3, 1.

### B. *Related Proceedings*

The parties indicate that the ’103 patent is asserted in *Becton, Dickinson & Co. v. NeuMoDx Molecular, Inc.*, Case No. 1:19-cv-01126-LPS (D. Del.). Pet. 1; Paper 3, 2. The ’103 patent is the subject of IPR2020-01136, also filed by Petitioner. Paper 3, 2.

### C. *The ’103 Patent*

The ’103 patent, titled “Microfluidic Cartridge,” issued April 9, 2013. Ex. 1200, codes (54), (45). The ’103 patent relates to “microfluidic cartridges configured to carry out PCR on nucleotides of interest,

particularly from multiple biological samples in parallel, within microfluidic channels, and permit detection of those nucleotides.” *Id.* at 1:29–33. The microfluidic cartridge includes one or more sample lanes, “wherein each lane is independently associated with a given sample for simultaneous processing, and each lane contains an independently configured microfluidic network.” *Id.* at 4:41–45. Each lane can include a sample inlet port, one or more channels connecting the inlet port to a PCR reaction chamber via a first thermally actuated valve, and one or more channels connecting the PCR reaction chamber to an exit vent via a second thermally actuated valve. *Id.* at 6:59–65.

The ’103 patent teaches that the valves are initially open to allow the sample to be pumped into the PCR reaction chamber, and, upon initiating the processing of the sample, the valves are closed to isolate the sample from the channels on either side. *Id.* at 10:40–48. According to the ’103 patent, the valves “are closed prior to thermocycling to prevent any evaporation of liquid, bubble generation, or movement of fluid from the PCR reactor, during PCR.” *Id.* at 10:48–51; *see also id.* at 38:22–26 (“[T]he reaction mixture is isolated (e.g., sealed off by valves) [in the PCR reactor] to prevent evaporation or movement (leakage) of the reaction mixture during thermocycling.”). The valves also prevent “both loss of liquid or vapor thereby enabling even a partially filled reactor to successfully complete a PCR thermocycling reaction.” *Id.* at 10:51–55.

The ’103 patent further teaches that the microfluidic cartridge can be received by a bay on a diagnostic apparatus, where at least one heat source configured to heat individual sample lanes in the cartridge is coupled to the bay. *Id.* at 17:7–8, 20:10–17. The ’103 patent teaches that the bay “can also

be configured so that various components of the apparatus that can operate on the microfluidic cartridge (heat sources, detectors, force members, and the like) are positioned to properly operate on the microfluidic cartridge while the cartridge is received in the bay.” *Id.* at 20:65–21:2. “For example, a contact heat source can be positioned in the bay such that it can be thermally coupled to a distinct location at a microfluidic cartridge that is selectively received in the receiving bay.” *Id.* at 21:2–5.

Figure 16 of the ’103 patent is reproduced below.

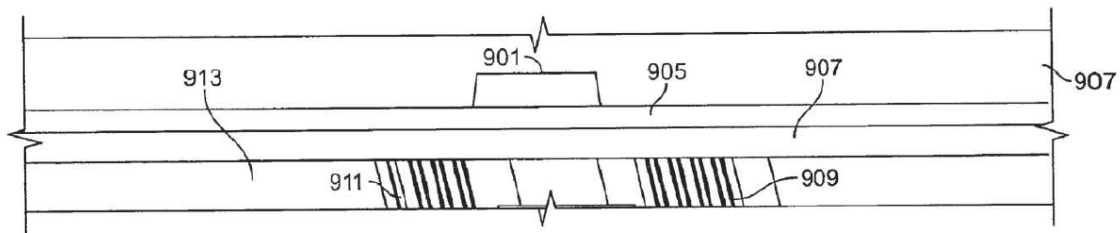


FIG. 16

Figure 16 shows a cross-sectional view of a microfluidic cartridge situated in a receiving bay, adjacent to a heater unit. *Id.* at 3:20–21. PCR chamber 901 is shown in substrate layer 907 of the cartridge. *Id.* at 23:4–5. Cartridge laminate layer 905 is directly under PCR chamber 901. *Id.* at 23:5–7. Long heaters 909 and 911, which, when viewed from above run alongside PCR chamber 901, are situated in substrate layer 913 of the receiving bay, directly under and in contact with cartridge laminate layer 905. *Id.* at 23:8–11.

#### D. Illustrative Claims

Petitioner challenges claims 1–15 of the ’103 patent. Pet. 1, 3–4. Claims 1 and 15, the only independent challenged claims, are illustrative of the claimed subject matter, and are reproduced below.

1. A method of carrying out amplification independently on a plurality of polynucleotide-containing samples, the method comprising:

introducing the plurality of samples separately into a microfluidic cartridge;

isolating the samples in the microfluidic cartridge;

placing the microfluidic cartridge in thermal communication with an array of independent heaters;  
and

amplifying polynucleotides in the plurality of samples by independent application of successive temperature cycles to each sample.

Ex. 1200, 47:8–18.

15. A method of carrying out amplification independently on a plurality of polynucleotide-containing samples, the method comprising:

introducing the plurality of samples in to a microfluidic cartridge, wherein the cartridge has a plurality of reaction chambers configured to permit thermal cycling of the plurality of samples independently of one another;

moving the plurality of samples independently of one another into the respective plurality of reaction chambers;

isolating the samples within the plurality of reaction chambers;

placing the microfluidic cartridge in thermal communication with an array of independent heaters;  
and

amplifying polynucleotides contained within the plurality of samples, by application of successive temperature cycles independently to the reaction chambers.

*Id.* at 48:26–42.

*E. The Asserted Grounds of Unpatentability*

Petitioner asserts that the challenged claims are unpatentable on the following grounds:

<b>Claims Challenged</b>	<b>35 U.S.C.</b>	<b>References/Basis</b>
1–15	§ 102(e)	Handique-Publ’941, <sup>1</sup> Handique- Prov’284 <sup>2</sup>
1–15	§ 102(b)	Ganesan-Publ’424 <sup>3</sup>
1–15	§ 103	Ganesan-Publ’424, Jensen, <sup>4</sup> Kellogg, <sup>5</sup> Yoon <sup>6</sup>
1–15	§ 102(e)	Handique-Publ’941, Handique- Prov’007 <sup>7</sup>

Pet. 3–4. Petitioner relies on the Declaration of Mark A. Burns, Ph.D. (Ex. 1101) in support of its contentions.

II. ANALYSIS

*A. Level of Ordinary Skill in the Art*

Petitioner contends that a person having ordinary skill in the art (“POSA”) “generally would have either (1) a degree in Mechanical Engineering, Bioengineering, Chemical Engineering, or a similar field, and three years of experience with microfluidic devices or systems relating to

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<sup>1</sup> U.S. Patent App. Pub. No. 2007/0292941 A1, published Dec. 20, 2007 (Ex. 1205).

<sup>2</sup> U.S. Provisional App. No. 60/859,284, filed Nov. 14, 2006 (Ex. 1206).

<sup>3</sup> U.S. Patent App. Pub. No. 2005/0084424 A1, published Apr. 21, 2005 (Ex. 1109).

<sup>4</sup> U.S. Patent App. Pub. No. 2006/0246493 A1, published Nov. 2, 2006 (Ex. 1115).

<sup>5</sup> WO 00/078455 A1, published Dec. 28, 2000 (Ex. 1055).

<sup>6</sup> U.S. Patent App. Pub. No. 2005/0112754 A1, published May 26, 2005 (Ex. 1118).

<sup>7</sup> U.S. Provisional App. No. 60/786,007, filed March 24, 2006 (Ex. 1207).

biochemical reactions/analysis, such as PCR,” or an advanced degree in the same fields “with at least one year of related experience.” Pet. 9. Patent Owner states that it “does not currently dispute Petitioner’s proposed definition.” Prelim. Resp. 10.

For purposes of this Decision, we adopt Petitioner’s proposed definition, which is undisputed on this record and consistent with the level of skill in the art at the time of the invention as reflected in the prior art in this proceeding. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown” (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

#### *B. Claim Construction*

We construe each claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b) (2019). Under this standard, claim terms are generally given their plain and ordinary meaning as would have been understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). Only those terms in controversy need to be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Neither party proposes an explicit construction for any claim term. *See* Pet. 9; Prelim. Resp. 10. For purposes of this Decision, based on the record before us, we address the interpretation of “placing the microfluidic cartridge in thermal communication with an array of independent heaters” as set forth in independent claims 1 and 15.

Patent Owner contends that “the prosecution history of the ’103 patent shows that the heaters recited in the limitation ‘placing the microfluidic cartridge in thermal communication with an array of independent heaters’ does not refer to integrated heaters.” *Id.* at 18 (citing Ex. 1200, claims 1, 15; Ex. 2016 ¶¶ 73–74). We understand Patent Owner to argue that we should apply prosecution history disclaimer to this limitation.

“[I]n a proceeding in which [a] . . . patent has been brought back to the [Office] . . . for a second review,” our reviewing court instructs us that, if in evidence, we should “consult the patent’s prosecution history.” *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015). Though “less useful for claim construction purposes” than the claim language and written description, prosecution history plays various roles in resolving uncertainties about claim scope. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1307 (Fed. Cir. 2005). When, as here, the prosecution history is used solely to support a conclusion of a disclaimer, the standard for justifying the conclusion is a high one. For prosecution disclaimer to attach, “the alleged disavowing action or statement made during prosecution must be clear and unmistakable.” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325–26 (Fed. Cir. 2003).

Patent Owner directs us to the applicant’s response to the Examiner’s rejection of the then-pending claims based on U.S. Patent No. 6,334,980



(“Hayes”), in which the applicant added the “placing the microfluidic cartridge in thermal communication with an array of independent heaters” limitation to pending independent claims 1 and 15. Prelim. Resp. 18–19 (citing Ex. 1201, 2–8; Ex. 1202, 6–8). Patent Owner points to the applicant’s explanation “that adding this limitation distinguished the claims from Hayes because the reference does not contemplate a ‘cassette in communication with an array of independent heaters.’” *Id.* at 19 (citing Ex. 1202, 7). Patent Owner then notes that the Examiner agreed that the integrated heaters described in Hayes “would not be ‘placed’ in thermal communication with an array of independent heaters as required by the claims,” and withdrew the rejection. *Id.* at 20 (citing Ex. 1203, 3).

Upon reviewing the statements made by the applicant of the ’103 patent during the original prosecution, we agree with Patent Owner that integrated heaters are not within the scope of the “placing the microfluidic cartridge in thermal communication with an array of independent heaters” limitation of claims 1 and 15. The Examiner rejected then-pending claim 1 as being anticipated by Hayes, stating that Hayes discloses a method that comprises introducing the plurality of samples separately into a microfluidic cartridge, isolating the samples in the microfluidic cartridge upon loading the samples into individual chambers, and amplifying polynucleotides by thermocycling until the PCR reaction is complete. Ex. 1201, 3–4. The applicant responded by amending the claim to add the “placing the microfluidic cartridge in thermal communication with an array of independent heaters” limitation. Ex. 1202, 3. The applicant explained:

Hayes teaches a “compact unitary reaction and analysis chamber” (10). Hayes, col. 4, line 6. The apparatus includes three reaction chambers (40, 41, 42) positioned in a substrate

(20). Circumventing each reaction chamber is a U-shaped heater (50, 51, 52). The apparatus “incorporates reaction chambers, heaters and analysis chambers into a miniature self-contained compact structure or cassette.” Hayes, col. 3, ll. 10–12. Thus, the heaters and reaction chambers used in Hayes are part of the same cassette.

*Id.* at 7. The applicant further stated:

In contrast to the integrated cassette disclosed in Hayes, amended Claim 1 recites “placing the microfluidic cartridge in thermal communication with an array of independent heaters.” It is not contemplated in Hayes to place the cassette in communication with an array of independent heaters because the heaters in Hayes are already incorporated into the structure of the cassette.

*Id.*; *see also id.* at 9 (arguing that Hayes does not disclose the limitations of amended claim 15 for the same reasons). Upon withdrawing the Hayes anticipation rejection in light of the amendment, the Examiner stated that Hayes’ “microfluidic device comprises integrated heaters which are independently controllable, and therefore, the microfluidic device would not be ‘placed’ in thermal communication with an array of independent heaters.” Ex. 1203, 2.

We are persuaded, on this record, that there is a clear and unmistakable disclaimer of claim scope that excludes heaters that are integrated into the microfluidic cartridge. The applicant explicitly states that “the heaters and reaction chambers used in Hayes are part of the same cassette,” and that “[i]t is not contemplated in Hayes to place the cassette in communication with an array of independent heaters because the heaters in Hayes are already incorporated into the structure of the cassette.” Ex. 1202, 7. The Examiner confirms that heaters that are integrated in the microfluidic device “would not be ‘placed’ in thermal communication with an array of

independent heaters.” Ex. 1203, 2. These statements are not amenable to any reasonable interpretation other than that “placing the microfluidic cartridge in thermal contact with an array of independent heaters” does not include heaters that are already integrated in the microfluidic device.

Accordingly, on this record, we adopt Patent Owner’s position that “placing the microfluidic cartridge in thermal contact with an array of independent heaters” does not include heaters that are integrated in the microfluidic device.

*C. Grounds Based on Ganesan-Publ’424*

Petitioner contends that claims 1–15 are anticipated by Ganesan-Publ’424. Pet. 31–52. Petitioner also contends that the subject matter of claims 1–15 would have been obvious over Ganesan-Publ’424 alone or in combination with Jensen, Kellogg, or Yoon. Pet. 59–84.

*1. Overview of Ganesan-Publ’424*

Ganesan-Publ’424 relates to microfluidic devices, and systems and methods for operating microfluidic devices. Ex. 1109 ¶ 2. The “[m]icrofluidic devices generally include a substrate that defines one or more microfluidic networks, each including one or more channels, process modules, and actuators.” *Id.* ¶ 58. The process modules and actuators are typically thermally actuated; “[f]or example, a process module can include a reaction chamber or lysing chamber that is heated by a heat source.” *Id.* ¶ 59. Ganesan-Publ’424 teaches that process modules can be configured to amplify DNA by PCR. *Id.* ¶ 69. Ganesan-Publ’424 also describes microfluidic systems that include the microfluidic device, as well as the heat sources, thermally actuated modules, fluid control elements, and actuators of the microfluidic device. *Id.* ¶ 75.

Ganesan-Publ'424 further teaches that during operation of the microfluidic system, “heat sources and temperature sensors are typically disposed within thermal contact of a localized region of” the microfluidic device. *Id.* ¶ 79. These components can be integral with the microfluidic device, “e.g., the components are fabricated within and/or upon one or more substrates that also define the microfluidic network.” *Id.* “Alternatively or in combination, the components are fabricated within or upon another portion of” the microfluidic system, such as a chip carrier that is mated with the microfluidic device “to bring the heat sources and elements of the microfluidic network into thermal communication.” *Id.* The microfluidic device mated with the chip carrier can then be inserted into, or removed from, an interface hardware receptacle. *Id.* ¶ 82.

Ganesan-Publ'424's Figure 3 is reproduced below.

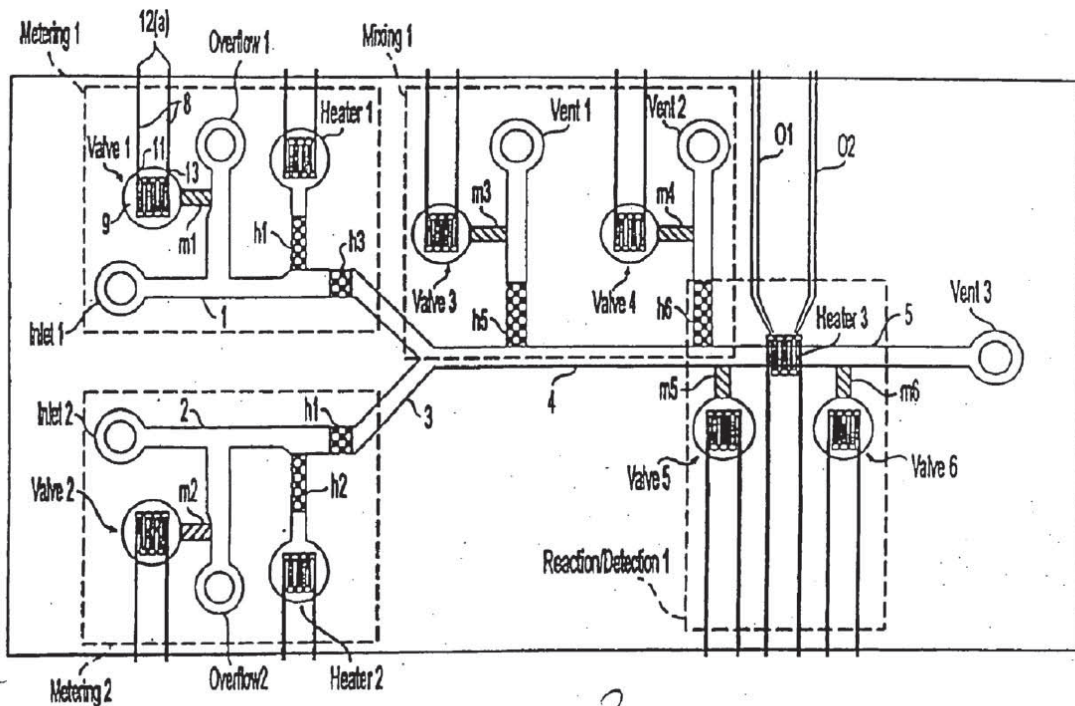


Fig. 3

Figure 3 schematically illustrates the general structure of an exemplary microfluidic device. The microfluidic device includes a microfluidic network with “four separate sub-assemblies: two micro-droplet metering sub-assemblies, metering1 and metering2; one mixing sub-assembly, mixing1; and one reaction/detection sub-assembly, reaction/detection1.” *Id.* ¶ 88. Sub-assemblies metering1 and metering 2 include, respectively, inlet1 and inlet 2, overflow1 and overflow2, valve1 and valve2, heater1 and heater2, and passage 1 and passage2. *Id.* ¶ 89. Sub-assembly mixing1 includes heater1, heater2, valve3, valve4, vent1, vent2, Y-shaped passage3, and passage4, and sub-assembly reaction/detection1 includes valve5, valve6, and passage5. *Id.*

“Operation of the sub-assemblies generally result from the coordinated operations of their component actuators under the control of an external controller, DAQ 26 [not pictured].” *Id.* ¶ 90. Fluid is introduced into inlet1 to first hydrophobic region h3, DAQ 26 instructs sub-assembly metering1 to measure a determined-volume micro-droplet from the fluid, and sub-assembly metering2 operates similarly to extract a measured micro-droplet from fluid introduced at inlet2. *Id.* DAQ 26 then supplies current to heater1 and heater2 to generate pressure and propel the two micro-droplets through Y-shaped passage3 and along passage4 to a stable position in passage5, causing the two micro-droplets to merge, mix, and form a single, larger micro-droplet. *Id.* ¶ 92. Next, DAQ 26 supplies current to valve5 and valve6 to close the valves and isolate the micro-droplet along passage5, and directs sub-assembly reaction/detection1 to stimulate a reaction in the micro-droplet by supplying current to heater3, which heats the micro-droplet. *Id.*

¶ 93. DAQ 26 “then monitors the results of the stimulated reaction by optically detecting radiation conducted by optical paths.” *Id.*

2. *Anticipation*

Petitioner contends that Ganesan-Publ’424 discloses all of the elements of independent claims 1 and 15. Pet. 37–44, 51–52. With respect to the “placing the microfluidic cartridge in thermal communication with an array of independent heaters” limitation of the claims, Petitioner first points to Ganesan-Publ’424’s Figure 3, and contends that it “depicts the array of heaters formed by Heater1, Heater2, Heater3 and the heaters for the valves,” and that, “[w]hen microfluidic device 10 is mated with cartridge 20, the components of device 10 are placed in thermal communication with the heat sources formed within cartridge 20.” Pet. 41 (citing Ex. 1109 ¶ 82; Ex. 1101 ¶¶ 342–343).

Petitioner also contends that Ganesan-Publ’424 “discloses that the heaters may be fabricated within the substrate of device 10 itself, or they may be formed within other portions of the system 99.” *Id.* (citing Ex. 1109 ¶ 79; Ex. 1101 ¶ 344). Petitioner contends that Ganesan-Publ’424’s Figure 11 depicts a heater substrate that is separate from the microfluidic substrate that defines a microfluidic network between layers. *Id.* (citing Ex. 1109 ¶¶ 158–161; Ex. 1101 ¶ 344). Finally, Petitioner contends that Ganesan-Publ’424 incorporates parent application Ganesan-Prov’264,<sup>8</sup> which Petitioner contends discloses that heater/sensors may be formed separately from a microfluidic device. *Id.* at 42–43 (citing Ex. 1208, 12:20–25).

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<sup>8</sup> U.S. Provisional App. No. 60/491,264, filed July 31, 2003 (Ex. 1208).

Patent Owner argues that because the heaters in both of Figures 3 and 11 of Ganesan-Publ'424 “are part of the cartridge assembly in both of these embodiments, Petitioner fails to identify a disclosure in Ganesan-Publ'424 of ‘placing the microfluidic cartridge in thermal communication with an array of independent heaters’ as recited in the challenged claims.” Prelim. Resp. 16 (citing Ex. 2016 ¶ 71). Patent Owner argues that Ganesan-Publ'424's integrated heaters are “analogous to the Hayes configuration that was overcome during prosecution with the amended language,” and that a microfluidic cartridge with integrated heaters is already “in thermal communication with those heaters” so “placing” is not necessary. *Id.* at 20 (citing Ex. 1203, 3; Ex. 2016 ¶ 76).

The '103 patent states that a microfluidic cartridge includes “a plurality of microfluidic networks, each network having various components configured to carry out PCR on a sample.” Ex. 1200, 4:35–40. It also includes “one or more sample lanes in parallel, wherein each lane is independently associated with a given sample for simultaneous processing, and each lane contains an independently configured microfluidic network.” *Id.* at 4:41–45. The '103 patent also teaches that, “[i]n use, a microfluidic cartridge, as described herein, is typically thermally associated with an array of heat sources configured to operate the components (e.g., valves, gates, and PCR reactor) of the microfluidic networks.” *Id.* at 8:55–58.

When the microfluidic device in Ganesan-Publ'424's Figure 3, in which the heaters are integrated, is mated with a chip carrier cartridge, it forms a microfluidic cartridge, which, in turn, has integrated heaters. *See* Ex. 1109 ¶¶ 79, 82. As set forth above, we determine that the claim element “placing the microfluidic cartridge in thermal communication with an array

of independent heaters” does not encompass such integrated heaters. Accordingly, we agree with Patent Owner that Ganesan-Publ’424’s Figure 3 does not meet the “placing the microfluidic cartridge in thermal communication with an array of independent heaters” limitation of independent claims 1 and 15.

Likewise, Ganesan-Publ’424’s Figure 11, reproduced below, also depicts a microfluidic cartridge with integrated heaters.

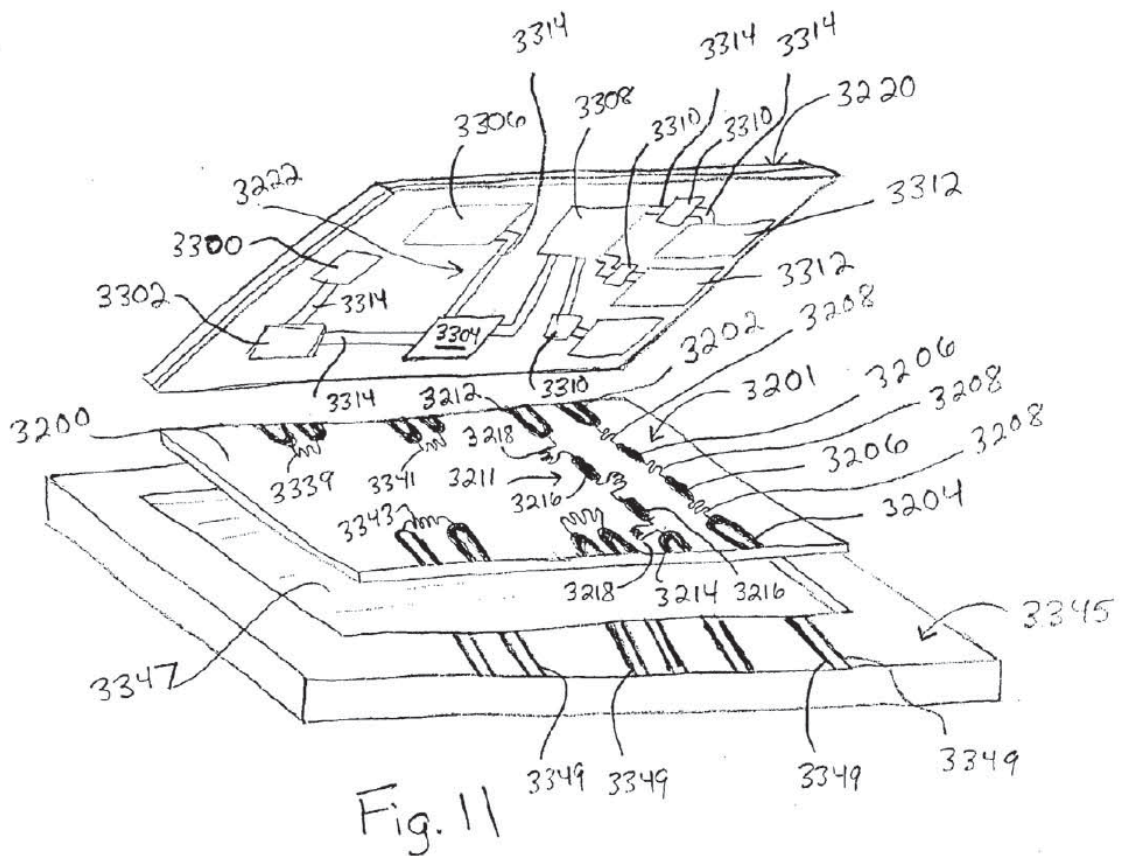


Figure 11 depicts “a portion of a microfluidic system having a microfluidic device defining a microfluidic network in thermal communication with heat sources of a substrate.” Ex. 1109 ¶ 55. Substrate 3200, which includes heat sources 3339, 3341, and 3343, “is received by (or is integral with) a chip carrier cartridge 3345.” *Id.* ¶¶ 157–158. Cartridge 3345 includes



connections 3349 that “are generally in communication with” an external controller configured to operate the heat sources. *Id.* ¶ 158. In use, substrate 3200 (which is integrated with cartridge 3345) mates with microfluidic device 3220 comprising microfluidic network 3222 such that “active regions 3208 and 3218 are disposed in thermal communication with thermally actuated elements of the microfluidic network.” *Id.* ¶ 161. This combination of cartridge 3345, substrate 3200, and microfluidic device 3220 forms a microfluidic cartridge in which the heaters in substrate 3200 are integrated. The microfluidic cartridge in Figure 11, therefore, integrates an array of independent heaters; it is not placed in thermal communication with an array of independent heaters.

To the extent that Petitioner also relies on Ganesan-Prov’264 to establish anticipation by Ganesan-Publ’424, we determine that such reliance is improper. Petitioner relies on Ganesan-Prov’264’s statement that “one or more heater/sensors may be formed as part of a device configured to operatively receive a microfluidic device” to support its contention that Ganesan-Publ’424’s heater array “may be formed integrally with the network-containing microfluidic substrate, or may be formed separately in a testing device into which the microfluidic substrate is placed or another part of the system.” Pet. 42–43.

We have considered Petitioner’s reliance on Ganesan-Prov’264, and we disagree with Petitioner’s contention that it necessarily forms a part of Ganesan-Publ’424 for purposes of anticipation. Our reviewing court

has held that anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention

without undue experimentation. Material not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document. Incorporation by reference provides a method for integrating material from various documents into a host document—a patent or printed publication in an anticipation determination—by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein. *To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.*

*Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (citations omitted; emphasis added). Thus, only subject matter identified with detailed particularity forms part of Ganesan-Publ’424 for purposes of anticipation. Ganesan-Publ’424 generally incorporates Ganesan-Prov’264 by reference, and Petitioner does not point us to any subject matter from Ganesan-Prov’264 that is identified with particularity within Ganesan-Publ’424. Ex. 1109 ¶ 1 (listing related applications, including Ganesan-Prov’264, and stating that “[a]ll of the foregoing applications are incorporated herein by reference”); Pet. 42–43. Accordingly, we do not address Petitioner’s contentions with regard to Ganesan-Prov’264 in determining whether Petitioner establishes a reasonable likelihood of showing that Ganesan-Publ’424 anticipates independent claims 1 and 15.

Claims 1 and 15 require “placing the microfluidic cartridge in thermal communication with an array of independent heaters.” Ex. 1200, 47:14–15, 48:38–39. Petitioner must show that the array of independent heaters is separate from the microfluidic cartridge to meet this claim requirement. For

the reasons set forth above, Petitioner fails to show that Ganesan-Publ'424 does so. Thus, we determine that the Petition does not establish a reasonable likelihood that Petitioner would prevail in showing that independent claims 1 and 15, and claims 2–14 that depend, directly or indirectly, from claim 1, are anticipated by Ganesan-Publ'424.

### 3. *Obviousness*

Petitioner argues that “[c]laims 1–15 are invalid as obvious based upon the obvious duplication of the microfluidic network of Ganesan-Publ'424 . . . in view of Ganesan-Publ'424 alone or in combination with Jensen, Kellogg, or Yoon, for the reasons given” in Petitioner’s anticipation challenge based on Ganesan-Publ'424, and provides additional arguments that include Jensen, Kellogg, and Yoon for a number of the claims. Pet. 64–84. Petitioner does not rely on Jensen, Kellogg, or Yoon to remedy the deficiencies identified above with respect to Petitioner’s allegation that Ganesan-Publ'424 anticipates claims 1–15. *See id.* at 64–66 (discussing claim 1), 84 (discussing claim 15). Accordingly, we determine that Petitioner does not establish a reasonable likelihood that it would prevail in showing that claims 1–15 would have been obvious over Ganesan-Publ'424 alone or in view of Jensen, Kellogg, or Yoon.

#### *D. Anticipation by Handique-Publ'941 and Handique-Prov'007*

Petitioner contends that claims 1–15 are anticipated by Handique-Publ'941 and Handique-Prov'007, which is incorporated by reference therein. Pet. 74–78. Petitioner states that in addition “to incorporating Ganesan-Publ'424 by reference, Handique-Publ'941 incorporates by reference Handique-Prov'007 filed March 24, 2006.” *Id.* at 74 (citing Ex. 1205 ¶¶ 1, 320). Petitioner also states that “Handique-Prov'007 itself

incorporates by reference Handique-Pat’391,” and contends that “Handique-Pat’391 and Ganesan-Publ’424 disclose the same microfluidic network for PCR amplification” as discussed with respect to Petitioner’s challenge that claims 1–15 are anticipated by Ganesan-Publ’424. *Id.* at 75 (citing Ex. 1207, 39:28–30; Ex. 1101 ¶ 392). Petitioner then states that, “[a]s the microfluidic device and network shown in Handique-Pat’391 and Ganesan-Publ’424 was already analyzed in Ground 2 above, Claims 1–15 of the ’103 Patent are anticipated by Handique-Prov’007 for all the reasons given in Ground 2 above and in this Ground 4.” *Id.* at 78.

Pursuant to 35 U.S.C. § 312(a)(3), a petition must identify, “in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim.” Upon review of the Petition and the supporting evidence, we determine that the Petition does not articulate, with reasonable clarity, the evidence that supports Petitioner’s contention that Handique-Publ’941, and Handique-Prov’007 incorporated by reference therein, discloses all of the elements of claims 1–15 of the ’103 patent.

Petitioner’s only support for its contentions is its reference to the arguments made with respect to Ground 2 (anticipation by Ganesan-Publ’424), but, as Patent Owner notes, “Ground 2 does not cite to any disclosures in Handique-Publ’941 or Handique-Prov’007.” Prelim. Resp. 36. Additionally, Petitioner does not map the disclosures of Handique-Publ’941 or Handique-Prov’007 to the elements of the claims, as it does for the other asserted grounds. *See* Pet. 74–78. We determine, therefore, that the Petition does not provide meaningful “particularity” sufficient for the panel to ascertain where, specifically, Petitioner identifies

each limitation of the challenged claims in Handique-Publ'941 and Handique-Prov'007 that is incorporated therein.

In any event, we determined that Petitioner does not establish a reasonable likelihood of showing that Ganesan-Publ'424 anticipates claims 1–15. *See* Section II.C.2, above. Petitioner does not provide any additional arguments with respect to, or disclosures in, Handique-Publ'941 and Handique-Prov'007 that remedy the deficiencies identified above with respect to Petitioner's allegation that Ganesan-Publ'424 anticipates claims 1–15. *See* Pet. 74–78.

Accordingly, we determine that Petitioner does not establish a reasonable likelihood that it would prevail in showing that claims 1–15 are anticipated by Handique-Publ'941 and Handique-Prov'007 that is incorporated by reference therein.

*E. Anticipation by Handique-Publ'941 and Handique-Prov'284*

Petitioner contends that claims 1–15 are anticipated by Handique-Publ'941 and Handique-Prov'284 that is incorporated by reference therein. Handique-Publ'941 was filed on March 26, 2007, and published on December 20, 2007. Ex. 1205, codes (22), (43).

Petitioner's challenge actually relies on the disclosure of Handique-Prov'284. Pet. 15–31. Petitioner argues that

provisional applications incorporated by reference in a U.S. publication are not only considered part of the publication disclosure, but are accorded prior art status in their own right because they became publicly available at the time of the publication, by virtue of it being incorporated by reference by the U.S. publication.

*Id.* at 10 (citing 37 C.F.R. § 1.14(a)(1)(vi); *Flex Logix Techs., Inc. v. Venkat Konda*, PGR2019-00042, Paper 14 n.5 (PTAB Sept. 19, 2019)).

37 C.F.R. § 1.14(a)(1)(vi) provides, in relevant part, that if an unpublished pending<sup>9</sup> provisional application is identified in a U.S. patent application publication (such as Handique-Publ'941), a copy of the “unpublished pending application may be provided to any person, upon written request and payment of the appropriate fee.” Accordingly, once Handique-Publ'941 published, Handique-Prov'284 that is incorporated by reference therein became open to the public for inspection. Handique-Prov'284 therefore is prior art by virtue of the fact that it became publicly available due to its incorporation into Handique-Publ'941, and in addition is prior art because it is part of Handique-Publ'941 itself.

Petitioner contends that Handique-Prov'284 discloses all of the elements of claims 1–15. Pet. 15–30. Patent Owner argues that, “[t]o the extent that the Handique-Publ'941 is prior art, it is only prior art under 35 U.S.C. § 102(e) because the '103 patent is entitled to its earliest priority date.” Prelim. Resp. 51. Patent Owner does not present any arguments in the Preliminary Response addressing the specific merits of Petitioner's contentions. *See generally* Prelim. Resp. Having reviewed all of Petitioner's assertions regarding claims 1–15, as well as the supporting evidence, we determine that Petitioner has demonstrated a reasonable likelihood of establishing that claims 1–15 are anticipated by Handique-Prov'284, which is incorporated by reference in Handique-Publ'941. Pet. 15–30.

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<sup>9</sup> 37 C.F.R. § 1.14(iv) applies to unpublished abandoned applications identified in a U.S. patent application publication, and also provides that a copy of the application-as-filed “may be provided to any person upon written request and payment of the appropriate fee.”

### III. CONCLUSION

“Office guidance issued on June 5, 2018 explains that the Board may consider the number of claims and grounds that meet the reasonable likelihood standard when deciding whether to institute an *inter partes* review under 35 U.S.C. § 314(a).” *Chevron Oronite Co. LLC v. Infineum USA L.P.*, IPR2018-00923, Paper 9 at 10–11 (PTAB Nov. 7, 2018) (informative) (citing *SAS Q&As*, Part D, Effect of *SAS* on future challenges that could be denied for statutory reasons (June 5, 2018)). Petitioner establishes a reasonable likelihood of prevailing as to the challenged claims on one ground, but does not demonstrate a reasonable likelihood of prevailing as to the challenged claims on the three other asserted grounds.

Even when a petitioner demonstrates a reasonable likelihood of prevailing with respect to one or more claims, institution of review remains discretionary. *SAS Inst. v. Iancu*, 138 S.Ct. 1348, 1355 (2018) (“§ 314(a) invests the Director with discretion on the question *whether* to institute review”); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“First of all, the PTO is permitted, but never compelled, to institute an IPR proceeding.” (citing 35 U.S.C. § 314(a))). In this case, the one ground where Petitioner establishes a reasonable likelihood of prevailing is based on a reference that, at best, qualifies as prior art under 35 U.S.C. § 102(e), which is susceptible to antedating by Patent Owner. At this stage of the proceeding, Patent Owner does not assert it would not try to antedate the reference. *See* Prelim. Resp. 51–56. On this record, instituting a trial with respect to all four grounds based on evidence and arguments directed to one ground based on a reference that Patent Owner may try to antedate is not an efficient use of the Board’s time and resources. Accordingly, we

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determine that, in the interests of efficient administration of the Office and integrity of the patent system, the entire Petition should be denied, and we do not institute an *inter partes* review.

#### IV. ORDER

In consideration of the foregoing, it is hereby  
ORDERED that the Petition is *denied* and no trial is instituted.

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