Paper 15

-7822 Date: September 1, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NANOCELLECT BIOMEDICAL, INC., Petitioner,

v.

CYTONOME/ST, LLC, Patent Owner.

IPR2020-00548 Patent 8,623,295

Before JO-ANNE M. KOKOSKI, WESLEY B. DERRICK, and JAMES A. WORTH, *Administrative Patent Judges*.

DERRICK, Administrative Patent Judge.

DECISION
Denying Institution of *Inter Partes* Review 35 U.S.C. § 314, 37 C.F.R. § 42.4

INTRODUCTION

Petitioner NanoCellect Biomedical, Inc., filed a Petition requesting *inter partes* review of claims 1–3, 9, 17, and 18 of U.S. Patent
No. 8,623,295 B2 ("the '295 patent"). Paper 2 ("Pet."). Patent Owner
Cytonome/ST, LLC filed a Preliminary Response. Paper 6 ("Prelim.
Resp."). As authorized, Petitioner also filed a Pre-Institution Reply (Paper 7, "Reply") and Pre-Institution Supplemental Briefing (Paper 11) and Patent
Owner, in turn, also filed a Pre-Institution Sur-Reply (Paper 8) and a
Response to Petitioner's Pre-Institution Supplemental Briefing (Paper 12).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4(a). We may not institute an *inter partes* review "unless . . . 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(a). Applying that standard, for the reasons set forth below, we decline to institute an *inter partes* review because Petitioner has not shown a reasonable likelihood that it would prevail in establishing the unpatentability of any of claims 1–3, 9, 17, and 18.

BACKGROUND

A. Real Parties in Interest

Petitioner identifies itself as the real party-in-interest. Pet. 3. Patent Owner identifies itself and Inguran, LLC, as the real parties-in-interest. Paper 4, 1.

B. Related Matters

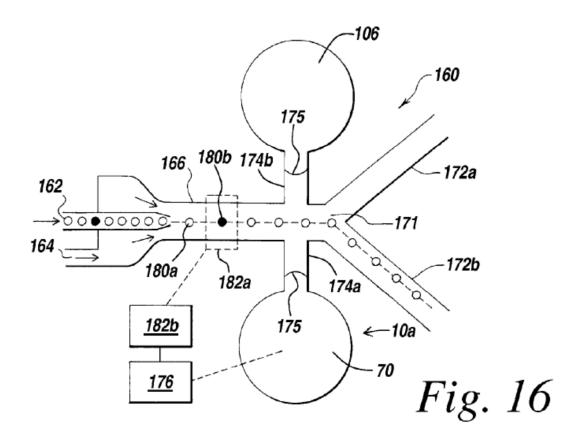
The parties identify *Cytonome/ST*, *LLC v. NanoCellect Biomedical*, *Inc.*, No. 1:19-cv-00301-UNA (D. Del.) as a related proceeding. Pet. 3; Paper 4, 1. The '295 patent is one of a number of patents asserted in that

district court proceeding. Pet. 3; Paper 4, 1. Other patents asserted are also subject to filed *inter partes* review petitions, and are identified by Petitioner as related proceedings: IPR2020-00545 (US 6,877,528 B2); IPR2020-00546 (US 9,339,850 B2); IPR2020-00547 (US 10,029,283 B2); IPR2020-00549 (US 10,029,263 B2); IPR2020-00550 (US 9,011,797 B2); and IPR2020-00551 (US 10,065,188 B2). Pet. 3; Paper 4, 1.

C. The '295 Patent (Ex. 1001)

The '295 patent is titled "Microfluidic System Including a Bubble Valve for Regulating Fluid Flow Through a Microchannel," and issued on January 7, 2014, from an application filed on September 26, 2011. Ex. 1001, at [22], [45], [54]. The '295 patent identifies related applications, including a provisional application—the earliest filed—that was filed on April 17, 2002. *Id.* at [60], [63], 1:5–19.

The '295 patent relates to "[a] microfluidic system [that] includes a bubble valve for regulating fluid flow through a microchannel." *Id.* at [57]. Figure 16, reproduced below, depicts an apparatus that provides for regulating fluid flow in a manner that allows sorting particles. *Id.* at 5:40–42.



Id., Fig. 16 (depicting a schematic of a particle sorting system). As disclosed in the '295 patent, "particle sorter 160 . . . for sorting particles, such as cells. . . . comprises a first supply duct 162 for introducing a stream of particles . . . a second supply duct 164 for supplying a carrier liquid . . . a measurement duct 166, which branches into a first branch 172a and a second branch 172b at branch point 171," and "[t]wo opposed bubble valves 10a and 10b . . . in communication . . . with the measurement duct 166 through a pair of opposed side passages 174a and 174b, respectively." Id. at 11:40–57, Fig. 16. In operation, and as depicted, "[1]iquid . . . partly fill[ing] these side passages 174a and 174b . . . form[s] a meniscus 175," and a provided "external actuator 176" "actuat[es] the bubble valves 10a, 10b, . . . momentarily caus[ing] a flow disturbance in the duct to deflect the flow therein." Id. at 11:57–61; see also Figs. 17A–17C (depicting operation of

particle sorter 160 to sort particles flowing from left to right in the figures into one or the other of first branch 172a and 172b). As to the operation of the apparatus, the '295 patent discloses that the external actuator increases pressure within one of the two opposed bubble valves causing a transient discharge of fluid from the associated side channel, which causes a sudden increase in pressure at this point in the duct, which increased pressure causes liquid to flow into the associated side channel of the second opposed bubble valves because of the resilient properties of the reservoir of the second bubble valve. *Id.* at 12:23–33.

D. Illustrative Claim

Claim 1—the sole independent claim—is illustrative of the claimed subject matter.

- 1. A microfluidic system comprising:
- a microfluidic flow channel formed in a substrate and adapted to facilitate analysis or processing of a sample having one or more particles suspended in a suspension medium flowing through the flow channel;
- a first reservoir operatively associated with the flow channel and adapted for dampening or absorbing a pressure pulse propagated across the flow channel; and
- a second reservoir operatively associated with the flow channel and adapted for generating the pressure pulse based on a change in volume or pressure in the second reservoir;
- wherein the flow channel defines a first aperture for connecting the flow channel relative to the first reservoir and a second aperture for connecting the flow channel relative to the second reservoir, wherein the first aperture is substantially opposite the second aperture.

Ex. 1001, 13:42–14:3.

E. Prior Art Relied Upon

Petitioner relies on the references listed below (Pet. 16, 18–19):

Reference	Date	Exhibit No.
WO 00/70080 ("Wada")	Nov. 23, 2000	1006
WO 97/02357 ("Anderson")	Jan. 23, 1997	1012
US 5,101,978 ("Marcus")	Apr. 7, 1992	1005

The status of these references as prior art printed publications is not contested by Patent Owner. *See generally* Prelim. Resp.

F. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of the claims on the following grounds, relying on the Declaration from Bernhard H. Weigl, Ph.D. (Ex. 1002). Pet. 5, 20–69.

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–3, 9, 18	103	Wada
1–3, 9, 17, 18	103	Wada, Anderson
1–3, 9, 17, 18	103	Marcus, Anderson

ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art "would have had a bachelor's or master's degree in the field of bioengineering, mechanical engineering, chemical engineering, or analytical chemistry; or a bachelor's or master's degree in a related field and at least three years of experience in designing or developing microfluidic systems." Pet. 14 (citing Ex. 1002 ¶¶ 46–49).

Patent Owner reserves the right to dispute Petitioner's proposed definition of the level of ordinary skill in the art, but applies Petitioner's

proposed definition "[s]olely for purposes of [the Patent Owner Preliminary Response]." Prelim. Resp. 29.

On this record, we have no reason to fault Petitioner's definition of the level of ordinary skill and, therefore, adopt it for the purposes of this Decision. We further note that the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that "specific findings on the level of skill in the art . . . [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 apply the claim construction standard from *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). 37 C.F.R. § 42.100(b) (2019).

Claim terms are generally given their ordinary and customary meaning as would be understood by one with ordinary skill in the art in the context of the specification, the prosecution history, other claims, and even extrinsic evidence including expert and inventor testimony, dictionaries, and learned treatises, although extrinsic evidence is less significant than the intrinsic record. *Phillips*, 415 F.3d at 1312–1317. Usually, the specification is dispositive, and it is the single best guide to the meaning of a disputed term. *Id.* at 1315.

Only those claim terms that are in controversy need to be construed and only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *see also U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554,

1568 (Fed. Cir. 1997) (holding claim construction is not necessary when it is not "directed to, or has been shown reasonably to affect, the determination of obviousness").

Petitioner contends that no "express claim constructions are required for the Board to conclude the asserted prior art renders the challenged claims unpatentable." Pet. 11–12. Petitioner does, however, contend that Patent Owner has made relevant "admissions about the meanings of claim terms in the asserted patents." Id. at 12. In particular, Petitioner maintains that Patent Owner's declarant in the district court proceeding has maintained "that the terms 'reservoir' and 'chamber' as used in the challenged claims ... should be understood as a physical structure that contains fluid" (id. at 12 (citing Ex. $1002 \, \P \, 43$; Ex. 1042, 20; Ex. $1043 \, \P \, \P \, 25-27, 31, 34, 44-48$)), "that the term 'absorbing' as used in the challenged claims . . . means to receive, take up, or take in the pressure pulse" (id. at 13 (citing Ex. 1043) ¶¶ 50–52; Ex. 1002 ¶ 44; Ex. 1042 1, 7–8, 18–19; Ex. 1045, 8–10, 18–20)), and "that the terms 'dampen' or 'dampening' . . . means to meaningfully dissipate so as to prevent a pressure wave from affecting the flow of the remaining particles in the stream of particles" (id. (citing Ex. 1043 ¶¶ 56– 57; Ex. 1002 ¶ 45; Ex. 1042, 13–14)).

Patent Owner contends that the terms "pressure pulse" and "first reservoir" should be construed. Prelim. Resp. 29. Patent Owner contends that that "the plain and ordinary meaning of 'pressure pulse,' . . . is a pressure increase that is inherently transient in nature" (*id.* at 30), and that "[t]he prosecution history further confirms that a 'pressure pulse' is a transient increase in pressure" (*id.* at 31). Patent Owner further contends that the '295 patent "never suggests that ["pressure pulse"] is a 'flow.'" *Id.* at 30 (citing Ex. 1001, 12:13–32). Patent Owner contends that "the Board

should confirm that the prior art must disclose the 'functional' language, . . . that [the first reservoir] must be 'adapted for dampening or absorbing a pressure pulse propagated across the flow channel." *Id.* at 32.

Petitioner responds that a "pressure pulse" is a transient increase in pressure and that these claim terms do not "require that the flow stream (as opposed to the pressure pulse it generates) cross the entire channel and enter the buffer/reservoir." Reply 3.

For the purposes of this Decision, based on the current record, we determine that the claim term "pressure pulse" means "a transient increase in pressure" because this is the plain and ordinary meaning of the term and is consistent with the use of this term in the '295 patent. We further note that this determination is consistent with the district court's determination that the claim term "pressure pulse" has its "plain and ordinary meaning." Ex. 2012, 5–6.

Turning to the claim term "reservoir," for the purposes of this Decision, based on the current record, we determine that the claim term has its plain and ordinary meaning of "a physical structure that contains fluid," but decline to reach any determination as to the nature or type of fluid as it is not necessary to resolve the issues here. *Wellman*, 642 F.3d at 1361. This determination is consistent with the construction adopted by the district court. Ex. 2012, 4–5. As to the recited reservoir being "adapted for dampening or absorbing a pressure pulse" (claim 1), this, and other, limitations are addressed to the limited extent necessary in reaching our Decision that Petitioner has not established a reasonable likelihood that it would prevail in establishing the unpatentability of at least one challenged claim. *Wellman*, 642 F.3d at 1361.

C. Principles of Law

Petitioner has asserted that each of the challenged claims of the '295 patent is unpatentable as obvious under 35 U.S.C. § 103. A claim is unpatentable under § 103 if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

"In an [inter partes review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." Harmonic Inc. v. Avid Tech., Inc., 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) as "requiring inter partes review petitions to identify 'with particularity . . . the evidence that supports the grounds for the challenge to each claim'"); cf. Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd., 821 F.3d 1359, 1369 (Fed. Cir. 2016) (quoting 35 U.S.C. § 312(a)(3)) (addressing "the requirement that the initial petition identify 'with particularity' the 'evidence that supports the grounds for the challenge to each claim'"). This burden never shifts to Patent Owner. See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc., 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing Tech. Licensing Corp. v. Videotek, Inc., 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burden of proof in inter partes review). Furthermore, Petitioner cannot satisfy its burden of proving

obviousness by employing "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

Thus, to prevail in an *inter partes* review, Petitioner must explain how the proposed combinations and/or alterations of the prior art would render them unpatentable as obvious. At this preliminary stage, we determine whether the information in the Petition shows there is a reasonable likelihood that Petitioner would prevail in establishing that at least one of the challenged claims would have been obvious over the proposed combinations and/or alterations of the prior art.

D. Overview of Prior Art

1. Wada (Ex. 1006)

Wada relates to microfluidic devices, and also describes methods and apparatus and includes "methods for providing substantially uniform flow velocity to flowing particles" and "[m]ethods of sorting members of particle populations, such as cells and various subcellular components." Ex. 1006, at [57]. An example of a device described in Wada is depicted schematically in Figure 22, reproduced below:

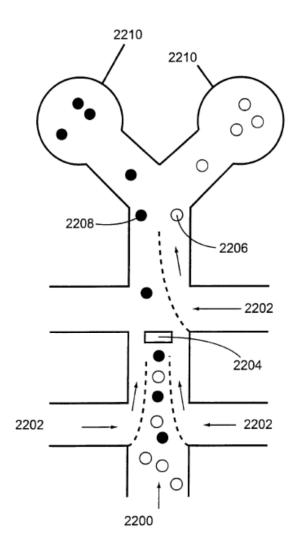


Fig. 22
SUBSTITUTE SHEET (RULE 26)

Id. at Fig. 22 (depicting a schematic representation of a particle sorting configuration). As disclosed in Wada, "cells 2200 are generally flowed into a main microchannel that includes . . . sets of opposing microchannels for focusing and/or otherwise directing the flow of cells 2200 using hydrodynamic flow 2202" and operation of the disclosed microchannels "direct[s] selected cells 2208 (e.g., fluorescently-labeled cells) and non-selected cells 2206 into, in this case, one of two microchannels, each

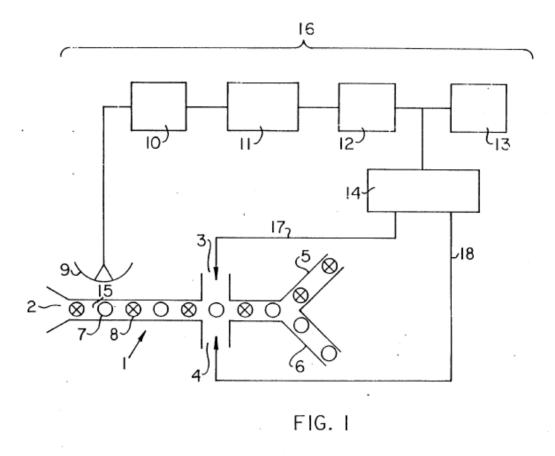
terminating in particular collection wells 2210." *Id.* at 19:24–20:2, Fig. 22. Detector 2204 is used to identify cells so that they can be sorted as required. *Id.*

2. Anderson (Ex. 1012)

Anderson relates to "a miniaturized integrated nucleic acid diagnostic device and system (522)," which "device (522) . . . is generally capable of performing . . . sample acquisition and preparation operations in combination with . . . sample analysis operation." Ex. 1012, at [57]. Anderson discloses the use of controllable microvalves and micropumps to direct fluid samples in a miniature fluidic system. See, e.g., 2:30–34, 5:14– 26, 9:24–27, 46:23–29, 63:1–13. Anderson sets forth that valves used "can employ a variety of structures, but [are] preferably . . . flexible diaphragm type valve[s] which may be displaced pneumatically, magnetically or electrically." *Id.* at 53:6–10, see also id. at 38:23–27 (identifying different ways that a diaphragm valve may be deflected to actuate). Anderson also sets forth a number of different types of pumps, and alternatives to pumps, including providing pressure or motive force to the liquid sample external to the microfluidic device. See, e.g., id. at 46:23-29, 62:18-64:31. Among the pumps disclosed, Anderson sets forth that "pumps which hav[e] a bulging diaphragm" and those "powered by a piezoelectric" actuator "may be used to move the sample through the various operations of the device." *Id.* at 62:18–63:13. Anderson further notes that such a "diaphragm pump will generally be fabricated from any one of a variety of flexible materials, e.g., silicon [sic], latex, teflon, mylar, and the like." *Id.* at 45:8–12.

3. *Marcus (Ex. 1005)*

Marcus relates to "[a] fluidic sorting device for the separation of two or more visually different materials or materials which react differently to an externally applied force. . . . [that] are suspended in a fluid." Ex. 1005, at [57]. The device includes a "machine vision apparatus" that decides whether a particle is to be sorted out, which "controls a fluidic logic element which facilitates the separation of the particles or materials." *Id.* Such a device is depicted schematically in Figure 1, reproduced below:



Id. at Fig. 1 (depicting a schematic representation of a fluidic sorting device). The device is described as including: a machine vision apparatus 16, which includes a machine vision camera lens 9, an image capture device 10, an image interpretation device 11, and a decision control device 12, and optionally a counter device 13; a fluidic controller device 14; and a fluidic logic element 1, which includes input flow port 2, control ports 3 and 4, and output ports 5 and 6. *Id.* at 3:29–48, Fig. 1. As described, the machine vision apparatus detects and arrives at a decision as to particulate matter 7

and 8, and relays that decision to fluidic controller device 14, which transmits signals via leads 17 and 18 to control ports 3 and 4 (of fluidic logic element 1) in order to sort particulate matter 7 and 8 into separate output ports 5 and 6 as required. *Id.* at 3:29–62.

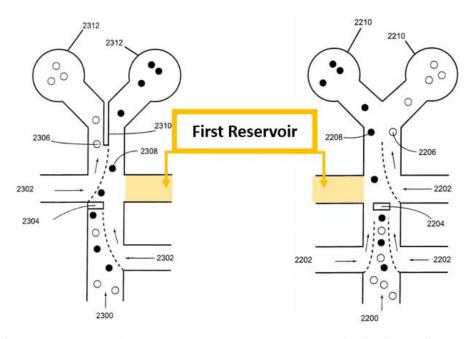
E. Asserted Unpatentability Over Wada

Petitioner contends that claims 1–3, 9, and 18 are unpatentable under 35 U.S.C. § 103 over Wada. Pet. 5, 20–42. Patent Owner disagrees. Prelim. Resp. 42–64. We focus our discussion on the dispositive claim limitations of independent claim 1.

1. Petitioner's Contentions

Petitioner first contends that "some embodiments [of Wada] . . . reasonably would have been viewed by a [person of ordinary skill in the art] as anticipating the claimed subject matter" and would, accordingly, render the claims obvious. Pet. 20–21 (citing Ex. 1002 ¶¶ 107–170; Ex. 1006, Figs. 22–23); *In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002) ("anticipation is the epitome of obviousness"). Petitioner also contends that a person of ordinary skill in the art "would have had good reason to use all the [disclosed] elements in a single embodiment and a reasonable expectation of success of thereby obtaining what is claimed." Pet. 21 (citing Ex. 1002 ¶¶ 107–111).

Petitioner relies on "Wada teach[ing] a first reservoir operatively associated with the flow channel and adapted for dampening or absorbing a pressure pulse propagated across the flow channel," as recited in claim 1. *Id.* at 26 (citing *id.* at 16–17; Ex. 1002 ¶¶ 125–139). Petitioner reproduces Figures 22 and 23 of Wada, with annotations identifying what Petitioner contends is a "first reservoir."



Id. (citing Ex. 1006, Figs. 22–23; Ex. 1002 ¶ 125) (depicting schematic representations of a particle sorting configuration of Figure 23 on the left and Figure 22 on the right, with Petitioner's annotations that highlight in yellow the areas it labels as "First Reservoir"). In each of the annotated figures, Petitioner identifies the "opposing microchannel structure disposed opposite of the actuated sorting microchannel" as a "reservoir," where the actuated microchannel has within it an arrow, which Petitioner identifies as a "pressure pulse." Id. at 26–27 (citing Ex. 1006, 19:23–20:14). Petitioner further contends that a person of ordinary skill in the art "would have recognized that the opposing microchannel structure . . . is a physical structure that contains a fluid, receives a pressure pulse, and is operatively associated with the flow channel via its fluid communication with the flow channel," and "is configured to . . . dampen and absorb the pressure pulse because the structure opening is aligned with the direction of the pressure pulse (substantially perpendicular to the main microchannel)." *Id.* at 27. Petitioner further contends that a person of ordinary skill in the art "would thus have understood that the opposed microchannel structure . . . [is] not

only a reservoir, but . . . is also . . . adapted for dampening or absorbing a pressure pulse propagated across the flow channel as recited in [claim 1]." *Id.* at 28 (citing Ex. 1002 ¶¶ 126–130 (citing Ex. 1005, Fig. 1; Ex. 1007, Fig. 2; Ex. 1016, 1:49–2:19, 5:44–54, Fig. 1; Ex. 1018, 341–42; Ex. 1032, 8:4–8; Ex. 1033, 198; Ex. 1034, 2:23–34, 39:25–34, 40:20–25; Ex. 1035, 377, 382–83).

Petitioner further relies on "Wada disclos[ing] its fluid direction components 'nudge materials across the width of a first channel' in order to 'direct sample flow towards or away from' a first flow channel, and 'into, e.g., an additional intersecting channel or . . . channel region." Pet. 28 (some internal quotations omitted) (citing Ex. 1006, 18:26–19:13). Petitioner also contends that "[w]hen the actuator in only one of the two opposed sorting microchannel structures of Wada is activated at a given time, . . . the well at the distal end of the opposite (non-actuated) microchannel dampens or absorbs the pressure pulse propagated across the flow channel." *Id.* at 29 (citing Ex. 1002 ¶¶ 133–137). Petitioner also contends on this basis that Wada teaches a structure like that in Figure 24, but including a "first reservoir" opposite branched particle sorting microchannel 2418, where Figure 24 depicts none. Pet. 27–29 (citing Ex. 1006, 49:13–20; Ex. 1002 ¶¶ 129–134).

Petitioner further contends that Wada discloses a Joule heating electrode as an exemplary actuating mechanism to generate a pressure pulse, and that such a "Joule heating [electrode] is typically . . . positioned within a well, microscale channel, or other cavity within the device" and that this would have been recognized "as teaching a chamber." Pet. 29–30 (citing Ex. 1006, 20:23–25; Ex. 1002 ¶¶ 134–138); *id.* at 28–29 (citing Ex. 1006, 7:25–29, 8:12–23, 22:30–23:24). Petitioner contends that a person of

ordinary skill in the art "would thus have had good reason to place the Joule heating electrode . . . on the substrate within a chamber at the distal end of each opposed sorting microchannel to generate a pressure pulse that will propagate across the flow channel . . . to deflect a selected particle into a selected branch of the flow channel." *Id.* at 30 (citing Ex. 1006, 43:5–14; Ex. 1002 ¶¶ 134–138).

2. Patent Owner's Contentions

Patent Owner contends that Petitioner fails to show both that Wada discloses a "second reservoir" for generating a "pressure pulse" (Prelim. Resp. 46–55) and a "first reservoir" for "dampen[ing] or absorb[ing]" the "pressure pulse" (*id.* at 55–61). Patent Owner further contends that modification of Wada so as to achieve the claimed invention would modify the operating principle of Wada's device, and that Petitioner relies on impermissible hindsight. *Id.* at 61–64.

Regarding the first reservoir, Patent Owner contends, with supporting testimony from its declarant Don W. Arnold, Ph.D., that Petitioner's reliance on Wada's Figures 22 and 23 falls short because "the 'opposing microchannels,' . . . do not 'dampen' or 'absorb' anything—they are described as useful solely for introducing 'hydrodynamic flow.'" *Id.* at 57 (citing Ex. 2001 ¶ 130–134). Patent Owner highlights Petitioner's reliance on Petitioner's characterization of "Wada's opposed side channel as 'non-actuated' and 'aligned' with the actuated side channel" and "conclu[sion] that it therefore constitutes the claimed 'reservoir,'" and Petitioner's determination, "alternatively, that [persons of ordinary skill in the art] would simply know to attach a dampening/absorbing 'reservoir.'" *Id.* at 59 (citing Pet. 26–33). Patent Owner relies on Wada teaching that the "second opposed side channel is *optional* and [is] for the expressly-stated purpose of

... 'introducing' ... 'hydrodynamic flow." *Id.* (citing Ex. 1006, 19:29–20:13). Patent Owner also contends that "Petitioner's [own] expert acknowledges as much by illustrating and discussing that precise usage"—the introduction of hydrodynamic flow. *Id.* (citing Ex. 1002 ¶¶ 129–136); *see also* Ex. 2001 ¶¶ 93–95 (citing Ex. 1006, 19:29–20:14), 126–127 (citing Ex. 1006, 22:23–24:18, Fig. 24).

Patent Owner also contends, with testimony from Dr. Arnold, that Wada's "Joule heaters are employed *solely* to induce hydrodynamic flow out of a side channel, . . . [and] Wada certainly never explains that the Joule heating wells dampen or absorb a pressure pulse or fluid." *Id.* (citing Pet. 29–30; Ex. 1006, 20:23–25; Ex. 2001 ¶¶ 74, 96–97, 127–128)).

Patent Owner also addresses a number of "background references" cited in Dr. Weigl's declaration—and in the citation to the portions of Dr. Weigl's declaration addressing both the contention that the claimed "pressure pulse" was known in the art (*id.* at 53–55) and the contention that reservoirs adapted to dampen or absorb a pressure pulse were known in the art (*id.* at 60–61).

3. Analysis

On this record, Petitioner's contention that Wada discloses a "reservoir . . . adapted for dampening or absorbing a pressure pulse propagated across the flow channel" amounts to little more than an assertion, which we find lacking in support. Figure 22 of Wada depicts top and bottom pairs of opposing microchannels that introduce hydrodynamic flow into the main microchannel through which particles to be sorted pass. *See, e.g.*, Ex. 1006, 19:27–20:2. Specifically, Wada states that "[o]ne set of opposing microchannels is typically located, e.g., upstream from detector 2204 for simultaneously introducing hydrodynamic flow 2202 from both

microchannels to focus cells 2200." *Id.* at 19:27–29. Wada also states that "[a] second set of opposing microchannels is typically located downstream from detector 2204 for introducing at least one hydrodynamic flow 2202 so as to direct selected cells 2208 . . . and non-selected cells 2206 into, in this case, one of two microchannels, each terminating in particular collection wells 2210." *Id.* at 19:29–20:2. Thus, both microchannels are for providing such hydrodynamic flow into the main microchannel, as depicted in each of Figures 22 and 23.

Wada does not indicate that any of the side microchannels is a reservoir that absorbs or dampens a pressure pulse. The required function of the side microchannels is wholly different, and there is no showing that what is required to absorb or dampen a pressure pulse is included in the disclosed structure for introducing hydrodynamic flow into the central microchannel that cells to be sorted pass through. See generally Pet. Petitioner and Dr. Weigl rely on Wada "describing that the fluid direction components 'nudge' materials across the width of the first channel," however, that is insufficient to support Petitioner's contention that "the opposed microchannel structure in each of Figures 22 and 23 is configured to receive ... and to dampen and absorb the pressure pulse." Pet. 27–29; Ex. 1002 ¶ 126. On the record before us, thus, we are not persuaded that Wada includes any reservoir adapted for dampening or absorbing a pressure pulse such as recited in the claims. As to Dr. Weigl's testimony to the contrary, we find it conclusory, largely unsupported as applied to Wada, and entitled to little weight. Dr. Weigl contends that the orientation of opposing microchannels across from one another indicates that one, or both, of them function as a reservoir that is adapted to dampening or absorbing a pressure pulse, and then points to structures in other references that are not shown to

be similar or to have the same function as support. See Ex. 1002 ¶¶ 125– 139. This position is not sufficiently supported, though, particularly where there is insufficient explanation provided as to why what Dr. Weigl contends is disclosed in the further "background references" is what is also present in Wada's disclosed structure, and what would follow based on its function. See generally Pet.; Ex. 1002. For example, while Dr. Weigl contends that the use of microchannel structure geometry with a channel, chamber or reservoir structure across the source of the transient pressure pulse for dampening or absorbing the transient pressure pulse was well known, and that it was understood that they can be used to mitigate undesirable flow fluctuations (see, e.g., Ex. 1002 ¶¶ 126–130), it simply does not follow that a pair of oppositely-oriented microchannels, as disclosed in Wada for providing fluid flow into the main microchannel, have similar structure or that they function in like manner, and Petitioner fails to set forth clearly how the structures are sufficiently similar at a level of detail sufficient to establish like function (see generally Pet.). Similarly, Petitioner's reliance on the disclosed Joule heating wells in Wada as dampening or absorbing a pressure pulse or fluid (id. at 29–31) fails to establish sufficient basis for including structure that is adapted to dampen or absorb a pressure or fluid (see generally Pet.; Ex. 1002).

As discussed above, as to "a first reservoir . . . adapted for dampening or absorbing a pressure pulse propagated across the flow channel," what Wada discloses falls short, and Petitioner provides no reasonable basis for modifying what is, in fact, disclosed in Wada to arrive at the claimed invention. *See generally* Pet. Instead, as discussed above, Petitioner merely sets forth what one of ordinary skill in the art could have done. This is not sufficient to reasonably support a ground of obviousness. *See Belden Inc. v.*

Berk-Tek LLC, 805 F.3d 1064, 1073 (Fed. Cir. 2015) ("[O]bviousness concerns whether a skilled artisan not only could have made but would have been motivated to make the combinations or modifications of prior art to arrive at the claimed invention."). Further, "[c]are must be taken to avoid hindsight reconstruction by using 'the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit." Grain Processing Corp. v. American Maize-Prods. Co., 840 F.2d 902, 907 (Fed. Cir. 1988) (quoting Orthopedic Equip. Co. v. United States, 702 F.2d 1005, 1012 (Fed. Cir. 1983)). Here, absent a sufficient explanation as to why the opposing microchannels in Wada function to dampen or absorb a pressure pulse, or would be adapted to do so, there is an insufficient showing that the ground set forth by Petitioner is not grounded on hindsight reconstruction. See Grain Processing, 840 F.2d at 907.

Petitioner fails, accordingly, to meet its burden for instituting *inter* partes review on the basis of Wada. *Harmonic Inc.*, 815 F.3d at 1363.

F. Asserted Unpatentability Over Wada and Anderson

Petitioner contends that claims 1–3, 9, 17, and 18 are unpatentable under 35 U.S.C. § 103 over Wada and Anderson. Pet. 5, 42–49. Petitioner relies on Anderson as "provid[ing] additional disclosures regarding specific actuators, including the use of a reservoir or chamber that comprises a flexible membrane suitable for generating or absorbing a pressure pulse." *Id.* at 42. Patent Owner contends that Petitioner fails to establish that Anderson discloses the limitations missing from Wada and why the two references would have been combined. Prelim. Resp. 64–68. We focus our discussion on the dispositive limitations of independent claim 1.

1. Petitioner's Contentions

Petitioner relies on Wada directing a person of ordinary skill in the art "to Anderson to provide additional details on actuators useful to provide fluid flow in Wada's microfluidic channels." Pet. 42–43 (citing Ex. 1006, 43:13–14; Ex. 1002 ¶¶ 173–177). In particular, Petitioner relies on Wada "stat[ing]: Examples of microfabricated pumps have been widely described in the art. See, e.g., published international Application No. WO 97/02357," and notes that "WO 97/02357 is the Anderson reference." *Id.* at 44–45 (citing Ex. 1012, 43:13–14); Ex. 1012, at [11].

On this basis, Petitioner contends that a person of ordinary skill in the art would have "looked to Anderson" and "had good reason to employ, in the microfluidic system taught by Wada, a micropump comprising a flexible membrane, as taught by Anderson, in each of the opposing sorting microchannel structures (i.e., first and second reservoirs), including at the distal end of the structures." *Id.* at 45–46. Petitioner relies on Anderson disclosing particular, suitable pumping devices, those with a diaphragm or which comprise a diaphragm pump, including those made from any of a number of exemplary flexible materials. *Id.* (citing Ex. 1012, 38:17–27, 45:3–12, 63:1–13). Petitioner further contends that when actuating one of the opposed microchannel structures to generate a pressure pulse to sort a particle, the "non-actuated opposed sorting microchannel structure will dampen or absorb the pressure pulse and act as the recited first reservoir." Id. at 46. Petitioner also contends that "[i]t would have been obvious for each of the reservoirs to include a resilient wall, including a deflectable membrane, for facilitating dampening or absorbing of the pressure pulse (in the non-actuated reservoir) and for increasing pressure (in the actuated reservoir)." Id.

On this basis, Petitioner contends that Anderson further renders obvious the recited "first reservoir . . . adapted for dampening or absorbing a pressure pulse propagated across the flow channel." *Id.* at 44–45 (citing Ex. 1002 ¶¶ 173–177).

2. Patent Owner's Contentions

Patent Owner contends that the combination with Anderson fails to remedy the deficiencies of Wada because the "actuators and pumps in Anderson" apply constant pressure and, thus, fail to provide "pulses" and "do not 'dampen or absorb' anything." Prelim. Resp. 64–65. Patent Owner further contends that Petitioner fails to show that a person of ordinary skill in the art would have had reason to combine Wada and Anderson. *Id.* at 65–68.

3. Analysis

On this record, Petitioner fails to sufficiently establish that it would have been obvious to modify Wada with the teachings of Anderson as would be required to meet the claims. As set forth above, Petitioner has failed to sufficiently establish both that Wada disclosed a "first reservoir . . . adapted for dampening or absorbing a pressure pulse propagated across the flow channel," and that one of ordinary skill in the art would have modified Wada so as to include such. Petitioner's proposed combination with Anderson does not remedy these deficiencies, in large part, because the actuators and micropumps in Anderson are not shown to be limited to those that would dampen or absorb a pressure pulse. *See generally* Pet.; Ex. 1012. Petitioner does identify actuators and pumps that include a diaphragm in Anderson, and that such diaphragm pumps include a flexible material as a diaphragm. Pet. 45–46. What is lacking, however, is a sufficient reason for a person of skill in the art to pick a diaphragm pump instead of any of the other

micropumps disclosed in Anderson, and then include it in Wada's device. *See, e.g.*, Ex. 1012, 2:30–34, 5:14–26, 9:24–27, 46:23–29, 63:1–13. Further, while Petitioner relies on the inclusion of a flexible element as meeting the limitation, it is not clear that even a micropump including a flexible diaphragm is adapted to dampen or absorb a pressure pulse simply because it includes a flexible element, as Anderson discloses that the deflectable diaphragm flexible elements can be deflected by a variety of methods, not all of which would appear to allow for deflection by a pressure pulse. *See, e.g.*, Ex. 1012, 38:23–27.

In sum, as above, Petitioner sets forth merely what the skilled artisan could have made, and not a sufficient basis for what they would have been motivated to make. *See Belden Inc.*, 805 F.3d at 1073. Also as above, there is an insufficient showing that the ground set forth by Petitioner is not grounded on hindsight reconstruction. *See Grain Processing*, 840 F.2d at 907.

Petitioner fails, accordingly, to meet its burden for instituting *inter* partes review on the basis of Wada and Anderson. *Harmonic Inc.*, 815 F.3d at 1363.

G. Asserted Unpatentability Over Marcus and Anderson

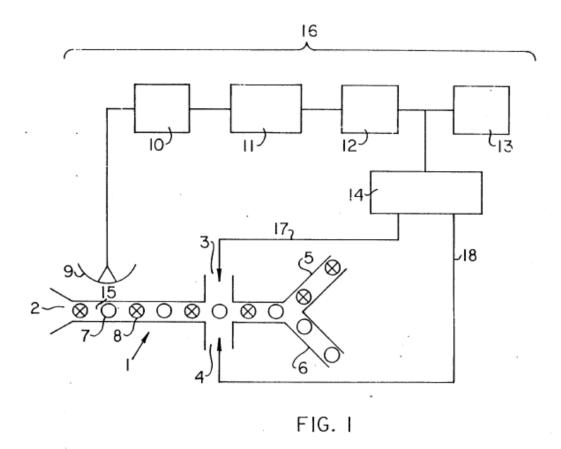
Petitioner contends that claims 1–3, 9, 17, and 18 are unpatentable under 35 U.S.C. § 103 over Marcus and Anderson. Pet. 5, 50–69. Petitioner relies on Marcus's description of a fluidic sorting device that combines conventional sensors, fluidic sorting devices, and fluidic logic elements produced using conventional micromachining technology, and on Anderson's disclosure of conventional fluidic sorting components for use in microfluidic systems. *Id.* at 50–51. Patent Owner contends that Petitioner fails to establish that Marcus and Anderson disclose the recited "pressure

pulse" and "first reservoir . . . adapted for dampening or absorbing a pressure pulse propagated across the flow channel," and fails to establish that a person of ordinary skill in the art would have had reason to combine Marcus and Anderson to achieve the claimed invention. Prelim. Resp. 68–74. We again focus our discussion on the dispositive limitations of claim 1.

1. Petitioner's Contentions

Petitioner contends that Marcus and Anderson disclose or suggest all limitations of claims 1–3, 9, 17, and 18. Pet. 50–69.

Petitioner relies on Marcus disclosing, and depicting in Figure 1, a device with fluidic element control ports 3 and 4 controlled by a fluidic controller device 14, and contends that a person of ordinary skill in the art would have recognized that, upon direction by the fluidic controller device 14, fluid control ports 3 and 4 propagate a pressure pulse across the flow channel to facilitate analysis of a particle sample. Pet. 54–56 (citing Ex. 1002 ¶¶ 202–209; Ex. 1005, 3:37–62, Fig. 1). Figure 1 of Marcus is reproduced below.



Ex. 1005, Fig. 1 (depicting a schematic representation of a fluidic sorting device).

Petitioner further relies on Figure 1 as "depict[ing] a reservoir in the form of an opposing microchannel structure disposed opposite the actuated sorting microchannel structure (through which the actuator selectively applies a pressure pulse represented by the arrow associated with fluidic control port 4)." *Id.* at 56–57 (citing Ex. 1005, 3:28–62; Ex. 1002 ¶¶ 210–216). Petitioner asserts that a person of ordinary skill in the art "would have understood the opposed microchannel structure (3) is configured to receive the pressure pulse (flow from fluidic control port 4) and to dampen or absorb the pressure pulse because the structure opening is aligned with the direction of the pressure pulse (substantially perpendicular to the main microchannel)." *Id.* at 57–58 (citing Ex. 1005, Fig. 1; Ex. 1002 ¶ 213).

Petitioner further asserts that "[t]his symmetrical geometry, . . . was well-reported and well known in the art as allowing for more precise flow manipulations during particle sorting" (*id.* at 58–59 (citing Ex. 1002 ¶¶ 210–216)), and, on this basis, that a person of ordinary skill in the art "would have recognized that Marcus' first reservoir is configured for absorbing or dampening the pressure pulse" (*id.* at 59 (citing Ex. 1002 ¶¶ 202–217)).

2. Patent Owner's Contentions

Patent Owner contends that "Marcus provides no specifics on its 'sorting apparatus,'" except that "it is comprised of 'conventional and commercially available components' and instructs both 'control ports 4 and 3' to sort particles, as depicted generically in Figure 1." Prelim. Resp. 68– 69 (citing Ex. 1005, 3:9–12, 3:57–62, Fig. 1). In particular, Patent Owner contends that "Marcus . . . certainly never describes employing a crosschannel 'pressure pulse'" (id. at 69 (citing Ex. 2001 ¶¶ 151–158)), and that there is no basis for control ports 3 or 4 in Marcus being adapted to dampen or absorb a pressure pulse (id. at 70–71). Patent Owner highlights that Marcus depicts both control port 3 and 4 as indicating supplied flow, and argues that "the mere fact that control ports are 'aligned' does not mean one of them 'dampen[s] or absorb[s]' fluid or pressure." Id. at 71 (citing id. at 55–61; Ex. 2001 ¶ 166). Patent Owner further contends that Anderson does not address or remedy these deficiencies in Marcus (id. at 69–70, 71) and that "Petitioner is again endow[ing] structures with the claimed functions based on hindsight" (id. at 71). Patent Owner also contends that Petitioner's rationale to combine Marcus and Anderson falls short because there is no sufficient guidance for what components would be combined, given the lack of detailed teaching as to the character of Marcus' control ports and their

function, and the failure of Marcus to provide a reason to seek reservoirs that operate as claimed. *Id.* at 72–73 (citing Ex. 2001 ¶¶ 167–168).

3. Analysis

On this record, Petitioner fails to sufficiently establish that it would have been obvious to modify Marcus with the teachings of Anderson as would be required to meet the claims. As highlighted by Patent Owner, there is insufficient basis set forth forth by Petitioner for Marcus to reasonably constitute disclosure of a "first reservoir . . . adapted for dampening or absorbing a pressure pulse propagated across the flow channel." Rather, as Patent Owner contends, control ports 3 and 4 in Marcus are only identified as ports to provide flow into the flow channel, and Petitioner's argument that one of the two opposed control ports must dampen or absorb a pressure pulse simply because it is disposed opposite the actuated port is deficient. Prelim. Resp. 71–72 (citing Pet. 54–59; Ex. 2001 ¶ 166).

To the extent that Petitioner relies on the testimony of Dr. Weigl (*see* Pet. 56–58 (citing Ex. 1002 ¶¶ 210–216)), we find it conclusory, largely unsupported as applied to Marcus, and entitled to little weight. Dr. Weigl contends that the orientation of opposing microchannels across from one another indicates that one, or both, of them function as a reservoir that is adapted to dampen or absorb a pressure pulse, and then points to differing structure in other references that are not shown to be similar or to have the same function as support. Ex. 1002 ¶¶ 210–216. This is not adequate support for his contentions, particularly where there is inadequate explanation provided as to why what Dr. Weigl contends is disclosed in the further "background references" is what is also present in Marcus' disclosed

structure, or what would follow based on its function. *See generally* Pet.; Ex. 1002.

Again, as in the combination with Wada, Anderson does not remedy the deficiency in Marcus because there is no particular reason to use actuators and micropumps from Anderson that would dampen or absorb a pressure pulse for control ports 3 and/or 4, particularly as opposed to any of the other actuators and micropumps in Anderson that would not dampen or absorb a pressure pulse.

In sum, as above, Petitioner sets forth merely what the skilled artisan could have made, and not a sufficient basis for what they would have been motivated to make. *See Belden Inc.*, 805 F.3d at 1073. Also as above, there is an insufficient showing that the ground set forth by Petitioner is not grounded on hindsight reconstruction. *See Grain Processing*, 840 F.2d at 907.

Petitioner fails, accordingly, to meet its burden for instituting *inter* partes review on the basis of Marcus and Anderson. *Harmonic Inc.*, 815 F.3d at 1363.

CONCLUSION

Based on the arguments and evidence of record, we determine that Petitioner has not established a reasonable likelihood of prevailing on any of its assertions that claims 1–3, 9, 17, and 18 of the '295 patent are unpatentable. Because of this, we need not reach the other issues raised by the parties, including the exercise of discretion under 35 U.S.C. § 314(a).

ORDER

For the reasons given, it is:

ORDERED that the Petition is denied as to all challenged claims of the '295 patent and no trial is instituted.

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