

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Cellink AB,
Petitioner,

v.

Organovo, Inc.,
Patent Owner.

IPR2021-01049
Patent 9,149,952 B2

Before JEFFREY W. ABRAHAM, ELIZABETH M. ROESEL, and
MICHELLE N. ANKENBRAND, *Administrative Patent Judges*.

ABRAHAM, *Administrative Patent Judge*.

DECISION

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

I. INTRODUCTION

Cellink AB (“Petitioner”) filed a Petition requesting *inter partes* review of claims 1–11 of U.S. Patent No. 9,149,952 (“the ’952 patent,” Ex. 1001). Paper 2 (“Pet.”). Organovo, Inc. (“Patent Owner”) filed a Patent Owner Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2020). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted “unless the Director determines . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

For the reasons set forth below, upon considering the Petition, Preliminary Response, and evidence of record, we determine the information presented in the Petition fails to establish a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, we deny the Petition, and do not institute an *inter partes* review.

II. BACKGROUND

A. *Related Matters*

Patent Owner states that the ’952 patent is at issue in *Cellink AB v. Organovo, Inc.*, No. 21-cv-00832 (D. Del.), filed on June 7, 2021. Paper 5, 1.

B. *The ’952 Patent*

The ’952 patent discloses a bioprinter for fabricating tissues and organs. Ex. 1001, code (57), 1:48–50, 5:66–6:5, 7:12–18. The bioprinter includes one or more printer heads, wherein a printer head comprises a

means for receiving and holding at least one cartridge containing “bio-ink” and support material; a means for calibrating the position of at least one cartridge; and a means for dispensing the contents of at least one cartridge. Ex. 1001, code (57), 1:51–57, 6:6–13, 12:22–32. “Bio-ink” is a “liquid, semi-solid, or solid composition comprising a plurality of cells.” Ex. 1001, 7:4–5. The “means for dispensing the contents of at least one cartridge” may be “application of a piston, application of pressure, application of compressed gas, hydraulics, or a combination thereof.” Ex. 1001, 2:7–11. The “means for calibrating the position of at least one cartridge” may be “laser alignment, optical alignment, mechanical alignment, piezoelectric alignment, magnetic alignment, electrical field or capacitance alignment, ultrasound alignment, or a combination thereof.” Ex. 1001, 2:1–5. The position of the cartridge may be calibrated along the x-axis, the y-axis, and/or the z-axis. Ex. 1001, 2:39–44.

The ’952 patent discloses a method for fabricating tissue constructs wherein a “computer module” receives input of a visual representation of a desired tissue construct and provides a series of commands to a bioprinter, and the bioprinter deposits bio-ink and support material according to the commands to form a construct with a defined geometry. Ex. 1001, 4:19–27. A “computer module” is “a software component (including a section of code) that interacts with a larger computer system.” Ex. 1001, 7:22–24. Examples of bioprinting parameters that are defined by user input and translated into computer code include print height, pump speed, robot speed, and/or control of variable dispensing orifices. Ex. 1001, 11:49–54. According to the ’952 patent, in some embodiments, “computer code specifies the positioning of a printer head to configure printer head height above a receiving surface.” Ex. 1001, 14:39–44. “In further embodiments,

computer code specifies the direction and speed of the motion of a printer head to configure dispensing characteristics for bio-ink and/or support material.” Ex. 1001, 14:44–47.

The ’952 patent discloses that “the bioprinter dispenses bio-ink or support material in a specific pattern and at specific positions in order to form a specific cellular construct, tissue, or organ.” Ex. 1001, 14:52–55.

C. Challenged Claims

Petitioner challenges claims 1–11 of the ’952 patent. Claim 1 is the only independent claim, and is reproduced below.

1. A bioprinter comprising:

- a) one or more printer heads, wherein each printer head comprises a means for receiving and holding at least one cartridge, and wherein each cartridge comprises a deposition orifice and a bio-ink, the bio-ink comprising a solid or semi-solid composition comprising living cells;
- b) a means for dispensing the bio-ink of a selected cartridge by application of pressure to extrude the bio-ink of the selected cartridge through the deposition orifice;
- c) a means for determining a position of the selected cartridge in space; and
- d) a programmable computer processor for regulating the dispensing of the bio-ink communicatively coupled to the means for determining a position of the selected cartridge and the means for dispensing the bio-ink.

Ex. 1001, 37:56–38:12.

D. Asserted Challenges

Petitioner asserts that claims 1–11 would have been unpatentable based on the following challenges:

Claim(s) Challenged	35 U.S.C. § ¹	Reference(s)/Basis
1–11	103	Lipson ²
1–8, 10, 11	103	Warren ³
9	103	Warren, Lipson
1–8, 10, 11	103	Smith ⁴
9	103	Smith, Lipson

Petitioner also relies on the declaration of William Cimino, Ph.D.
(Ex. 1002).

III. ANALYSIS

A. Principles of Law

“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) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)); *see also* 37 C.F.R. § 42.104(b) (requiring a petition for *inter partes* review to identify how the challenged claim is to be construed and where each element of the claim is found in the prior art patents or printed publications relied upon).

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that

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 ’952 patent issued was filed before this date, the pre-AIA version of § 103 applies.

² US 2006/0156978 A1, published July 20, 2006 (Ex. 1004).

³ US 2004/0253365 A1, published Dec. 16, 2004 (Ex. 1005).

⁴ Smith, et al., *Three-Dimensional BioAssembly Tool for Generating Viable Tissue-Engineered Constructs*, Tissue Engineering, Vol. 10, No. 9/10 (2004).

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 based on 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 ordinary skill in the art; and (4) when presented, objective evidence of nonobviousness, i.e., secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Additionally, the obviousness inquiry typically requires an analysis of “whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”)). Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements,” but “must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

B. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art would have had “a minimum of a bachelor’s degree in mechanical engineering, electrical engineering, biomedical engineering, or a related field, and approximately 5 years of relevant experience or equivalent study in electro mechanical systems, regenerative medicine, tissue/organ engineering, and/or biologic and medical research.” Pet. 13 (citing Ex. 1002 ¶¶ 10–12). Patent Owner states that for purposes of its Preliminary Response, it “does not

address” Petitioner’s definition, but also states that it “does not agree or acquiesce” to Petitioner’s purported definition. Prelim. Resp. 3.

In light of the record now before us, for purposes of this Decision, we accept Petitioner’s definition of a person of ordinary skill in the art. Additionally, we note that the level of ordinary skill in the art is reflected by the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

C. Claim Construction

In an *inter partes* review, we apply the same claim construction standard as would be used by a district court to construe a claim in a civil action involving the validity or infringement of a patent. 37 C.F.R. § 42.100(b). Under that standard, claim terms are given their ordinary and customary meaning, as would have been understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc); *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365–66 (Fed. Cir. 2012).

Petitioner provides proposed constructions for several claim terms, including the means-plus-function claim terms. Pet. 13–17. For purposes of the Preliminary Response, Patent Owner applies Petitioner’s constructions. Prelim. Resp. 3.

We determine that we do not need to resolve any claim construction disputes for purposes of this Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean*

Motor Co., 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of *inter partes* review).

D. Challenge based on Lipson alone

Petitioner contends claims 1–11 are unpatentable as obvious in view of Lipson. Pet. 18–36. Patent Owner challenges Petitioner’s arguments. Prelim. Resp. 5–11.

1. Lipson (Ex. 1004)

Lipson discloses a method and system for fabricating a living three-dimensional structure. Ex. 1004, Abstract, ¶ 10. Lipson depicts its system in Figure 2, reproduced below.

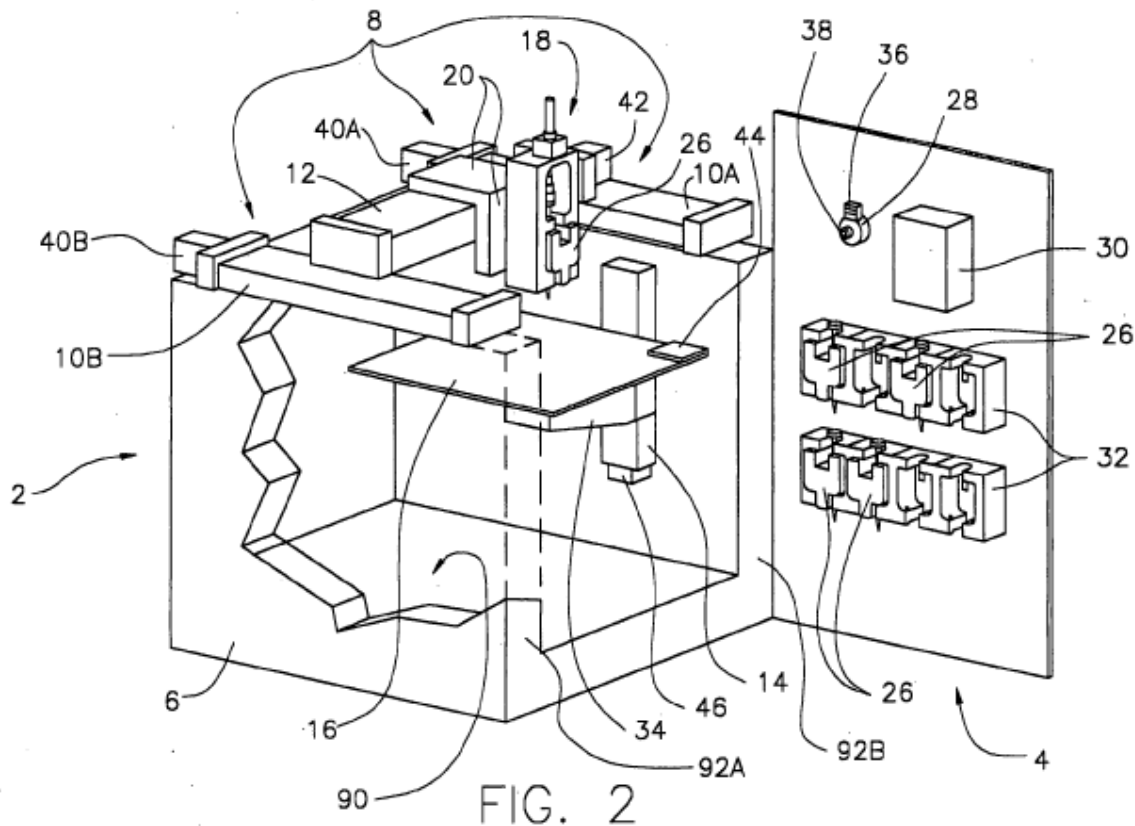


Figure 2 shows a perspective view of Lipson’s material deposition device 2 and tool rack 4, wherein material deposition device 2 includes machine base

6, positioning system 8, substrate 16, and tool interface 20. Ex. 1004 ¶¶ 48, 54. Material deposition tool 18, which holds material cartridge 26, is mounted on tool interface 20. Ex. 1004 ¶¶ 8, 51. Lipson teaches that “[i]n operation, material deposition device 2 fabricates a product as positioning system 8 moves material deposition tool 18 in a pathway along substrate 16 and material deposition tool 18 deposits material onto substrate 16 along the pathway.” Ex. 1004 ¶ 54. Lipson also discloses a system controller “operably connected to the material deposition device to control operation of the material deposition device.” Ex. 1004 ¶ 8.

2. Analysis

Claim 1 recites a bioprinter comprising several components, including, *inter alia*, “a programmable computer processor for regulating the dispensing of the bio-ink.”⁵ Ex. 1001, 38:8–12.

Petitioner contends the “fabrication system” shown in Lipson Figure 1 corresponds to the claimed bioprinter. Pet. 20–21. Petitioner further contends that “Lipson discloses a programmable computer (system controller),” and directs us to paragraphs 94 and 95 of Lipson, which state, respectively, that “the system controller . . . operates according to an electronic data file,” and “[s]ystem controller 104 is operated by fabrication system software.” Pet. 28 (quoting Ex. 1004 ¶¶ 94, 95) (emphasis omitted).

Patent Owner argues that Petitioner fails to explain how Lipson discloses a “bioprinter comprising” a programmable computer processor, as claim 1 requires. Prelim. Resp. 6–7. According to Patent Owner, the “cited paragraphs of *Lipson* merely identify a ‘system controller’, but do not

⁵ Petitioner asserts, and Patent Owner does not dispute, that “‘programmable computer processor’ is a recognized structure in the art and §112 ¶ 6 does not apply.” Pet. 16; Prelim. Resp. 3.

describe that the controller is included in the ‘system’ that Petitioner maps to the bioprinter” of claim 1. Prelim. Resp. 6. Additionally, Patent Owner asserts that Lipson’s “system controller” is not included in the “bioprinter” because Lipson refers to the “system controller” as “external computer 104” and depicts “system controller 104” as an externally connected laptop in Figure 10. Prelim. Resp. 7–8 (citing Ex. 1004 ¶ 90, Fig. 10). Patent Owner also contrasts Lipson’s configuration with the example shown in Figure 7 of the ’952 patent, which depicts a computer processor included in the bioprinter, not as an “externally attached” component. Prelim. Resp. 8–9 (citing Ex. 1001, Fig. 7, 5:59–62).

We agree with Patent Owner that Petitioner has failed to demonstrate sufficiently that Lipson discloses a bioprinter comprising a programmable computer processor, as claim 1 requires.

As support for its statement that “Lipson discloses a programmable computer processor (system controller),” Petitioner presents two paragraphs in Lipson describing that Lipson’s system controller operates according to “fabrication system software” and “an electronic data file.” Pet. 28 (quoting Ex. 1004 ¶¶ 95 and 94, respectively).⁶ At best, paragraphs 94 and 95 of Lipson indicate that Lipson’s system controller is a programmable computer processor. These paragraphs in Lipson do not address whether Lipson’s bioprinter *comprises the system controller* (the programmable computer

⁶ Petitioner includes a citation to paragraphs 97–101 of the Cimino declaration at the end of the section of its claim chart addressing this limitation. Pet. 29. But, in paragraphs 97 and 98 of his declaration, Dr. Cimino simply mirrors the language in the Petition. Ex. 1002 ¶¶ 97, 98. And paragraphs 99–101 relate to different limitations recited in claim 1 and Petitioner’s alternative arguments based on a § 112 ¶ 6 construction for “programmable computer processor.” Ex. 1002 ¶¶ 99–101.

processor), as claim 1 requires. Petitioner and Dr. Cimino likewise fail to address whether Lipson's bioprinter comprises the system controller when discussing these paragraphs. By way of contrast, we note that for other components the bioprinter comprises, such as one or more printer heads recited in claim 1, Petitioner explicitly maps the component to the "fabrication system" depicted in Lipson Figure 1. Pet. 21–22. Petitioner, however, does not provide a similar analysis for Lipson's system controller.

Petitioner's failure to do so here is particularly problematic in view of Lipson's express disclosure that the system controller is an "external computer" and Lipson's depiction of system controller 104 as a laptop computer that is separate from the bioprinter in Figure 10. Ex. 1004 ¶¶ 26, 90, Fig. 10. As such, there is evidence of record suggesting that Lipson's fabrication system, which according to Petitioner corresponds to the bioprinter of claim 1, does not comprise the system controller.⁷ Ex. 1004 ¶ 90, Fig. 10.

Petitioner bears the burden of demonstrating that Lipson discloses or suggests a bioprinter comprising a computer programmable processor. In view of Petitioner's reliance solely on general descriptions of Lipson's system controller and Petitioner's failure to address specifically the relationship between the system controller and bioprinter in Lipson, we are

⁷ Petitioner argues that, to the extent § 112 ¶ 6 applies to the term "programmable computer processor," the function is "regulating the dispensing of the bio-ink," and the corresponding structure is software. Pet. 16–17. Petitioner contends that Lipson discloses software for performing the claimed function in paragraphs 95, 96, and 99. Pet. 29. These paragraphs in Lipson, however, describe the software *in system controller 104*, and, therefore, do not remedy Petitioner's failure to demonstrate Lipson's *bioprinter* comprises a "programmable computer processor."

not persuaded Petitioner has presented sufficient evidence to satisfy its burden. As a result, we determine that Petitioner has not demonstrated adequately that Lipson teaches or suggests all limitations of claim 1, and, therefore, that Petitioner has not shown a reasonable likelihood that it would prevail with respect to its argument that claim 1 is unpatentable as obvious in view of Lipson.

Claims 2–11 each depend from claim 1, and, therefore, include all of the limitations of claim 1. In view of our determination that Petitioner fails to establish a reasonable likelihood that claim 1 is unpatentable as obvious in view of Lipson, we reach the same result for claims 2–11.

E. Challenges based on Warren

Petitioner contends that claims 1–8, 10, and 11 are unpatentable as obvious in view of Warren, and that claim 9 is unpatentable as obvious in view of Warren and Lipson. Pet. 36–56. Patent Owner opposes these challenges. Prelim. Resp. 11–23.

1. Warren (Ex. 1005)

Warren is directed to “tools and methods for depositing materials accurately on a selected substrate,” including “a tool for in vitro or in vivo use in biological, tissue-engineering, and medical processes.” Ex. 1005 ¶¶ 3, 58. As one embodiment, Warren discloses “a direct-write patterning system suitable for either fine-pattern microdispensing and/or fine-focused laser-beam writing over flat or conformal surfaces.” Ex. 1005 ¶ 10. Warren discloses an integrated tool for “direct-write deposition” of material, i.e., an additive process, which Warren refers to as “‘direct-write deposition technology’ (DWDT).” Ex. 1005 ¶¶ 10, 11. According to Warren, the disclosed apparatus can be used for “in vivo procedures” or for “in vitro applications in a tabletop setting.” Ex. 1005 ¶¶ 11, 12, 58–60, Figs. 1, 2.

Warren states that, “[f]or biological, medical, bioengineering, and tissue-engineering embodiments of the DWDT, the apparatus may be referred to herein as the ‘human architecture tool’ (HAT).” Ex. 1005 ¶ 14. According to Warren, “[t]he in vitro and/or in vivo HAT technology . . . can allow the user to ‘print’ biocompatible scaffolds, cells, growth factors, therapeutics, enzymes, extracellular matrix (ECM) proteins, and the like inside the human body using a microscale dispensing orifice (e.g., a dispenser or stylus).” Ex. 1005 ¶ 14; *see also* Ex. 1005 ¶¶ 320–323 (describing embodiments of the biological HAT dispensing system for tissue engineering).

Warren teaches that its DWDT/HAT may include material dispenser 100 for performing additive procedures by which 3D engineered tissue constructs are fabricated from biological, organic, or inorganic components. Ex. 1005 ¶¶ 62, 94; *see also* Ex. 1005 ¶¶ 221–283, Figs. 5–7, 11–13, 23 (describing and illustrating various embodiments of material dispenser 100). Warren also discloses a system and method for controlling the position of one or more elements of a dispensing system using force feedback (Ex. 1005 ¶¶ 284–319, Figs. 18–22), methods for depositing tissue engineering material at a selected position on a substrate in vitro (Ex. 1005 ¶¶ 379–383), and methods for depositing tissue engineering material at a target area within a subject’s body (Ex. 1005 ¶¶ 384–472).

2. Analysis

Our analysis begins with the limitation of independent claim 1 that recites: “a programmable computer processor for regulating the dispensing of the bio-ink communicatively coupled to the means for determining a position of the selected cartridge and the means for dispensing the bio-ink.” Ex. 1001, 38:8–11.

Petitioner contends that Warren discloses this limitation because “Warren discloses that a programmable computer processor (Windows based PC) regulates the dispensing of the bio-ink (for providing fine control over material dispensing by operating the control valve on a pneumatic air cylinder). Dispensing material in accordance with a design, as disclosed by **Warren**, is ‘regulating.’” Pet. 49. As support for this contention, Petitioner cites to paragraphs 228, 229, and 280 of Warren. Pet. 49 (citing Ex. 1005 ¶¶ 228, 229, 280, 413, 422).⁸

Patent Owner argues that Petitioner fails to demonstrate that Warren discloses a “programmable computer processor” as required by the challenged claims. Prelim. Resp. 12–17. Among other things, Patent Owner argues:

Petitioner’s assertions and cited portions of *Warren* do not demonstrate how and where *Warren* discloses that the Windows based PC in *Warren* (which Petitioner maps to the claimed ‘programmable computer processor’) . . . is ‘communicatively coupled to’ . . . the ‘air pressure’ aspects of *Warren* (which Petitioner maps to the claimed ‘means for dispensing’ . . .).”

Prelim. Resp. 16.

Patent Owner also argues that Petitioner fails to explain how Warren discloses a programmable computer processor that is “communicatively coupled to the means for determining a position of the selected cartridge.” Prelim. Resp. 15. In particular, Patent Owner asserts that Petitioner’s

⁸ Petitioner provides an additional contention to cover the contingency that we interpret “programmable computer processor” under § 112 ¶ 6. Pet. 50. To show that Warren discloses the recited function, Petitioner relies on the same showing as it presents under a non-means-plus-function interpretation. Pet. 50. In addition, Petitioner contends that “Warren discloses software for performing the function.” Pet. 50 (citing Ex. 1005 ¶¶ 409–415, 429–430, 455).

allegation that Warren discloses “means for determining a position of the selected cartridge” (Pet. 47 (referring to an ultrasonic pinger and piezomembrane)), is inconsistent with Petitioner’s allegation that the claimed programmable computer processor is communicatively coupled to means for determining the position of a cartridge (Pet. 49 (referring to the Windows PC “synchronizing the location control device with an actuator”)). Prelim. Resp. 15–16.

After considering both parties’ arguments and evidence, we agree with Patent Owner that Petitioner has not adequately established that Warren discloses or suggests a “programmable computer processor communicatively coupled to . . . to the means for dispensing the bio-ink,” as claim 1 requires. More specifically, Petitioner does not show sufficiently that Warren’s “Windows based PC,” which Petitioner identifies as the recited “programmable computer processor” (Pet. 48), is communicatively coupled to any mechanism for “operating the control valve on a pneumatic air cylinder” (Pet. 49).

To establish the required communicative coupling, Petitioner asserts that Warren discloses “providing fine control over material dispensing by operating the control valve on a pneumatic air cylinder.” Pet. 49. Petitioner’s assertion misstates Warren’s disclosure by merging two unrelated teachings from Warren relating to different types of dispensers.

The first teaching Petitioner relies on, “providing fine control over material dispensing,” is from Warren’s disclosure related to a through-nozzle dispenser. Ex. 1005 ¶ 228; Pet. 49. In that context, Warren states that “material dispenser 100 also include[s] a means for selectively synchronizing the location control device 800 with the actuator, to provide fine control over material dispensing.” Ex. 1005 ¶ 228. In this paragraph,

“the actuator” is a reference to actuator 144, which “is operatively coupled to the valve 130 for selectively moving the valve between the open position and the closed position.” Ex. 1005 ¶ 225, Fig. 11. Valve 130 controls the flow of material through the dispenser, as material is permitted to flow when valve 130 is in the open position, and material is not permitted to flow when valve 130 is in the closed position. Ex. 1005 ¶ 225, Fig. 11. Contrary to Petitioner’s assertion, however, this portion of Warren does not describe valve 130 as a “control valve on a pneumatic air cylinder,” or disclose that actuator 144 operates a control valve on a pneumatic air cylinder. Pet. 49.

Warren discloses that location control device 800 “can selectively position the material dispenser 100 in xyz space (i.e., in three dimensions)” and is synchronized with valve actuator 144, so that “the valving mechanism may be synchronized with the xyz motion of the dispenser.” Ex. 1005 ¶¶ 227–229, 232, 235, 236; *see id.* ¶ 54, Fig. 36 (schematically illustrating “devices and methods for controlling and synchronizing the position of the material dispenser and the position of the valve within the material dispenser”). Petitioner does not, however, direct us to any disclosure or suggestion in Warren that location control device 800 is synchronized with a control valve on a pneumatic air cylinder or with any other mechanism for controlling air pressure for dispensing the contents of a cartridge.

The second teaching Petitioner relies upon, “by operating the control valve on a pneumatic air cylinder,” is from Warren’s disclosure regarding a capillary-based dispenser. Pet. 49; Ex. 1005 ¶ 280. In that context, Warren states that “[t]he capillary dispensers in the illustrated embodiment may be extended via a pneumatic air cylinder with a proportional control valve controlling extension and retraction speeds.” Ex. 1005 ¶ 280. “[T]he illustrated embodiment” is a reference to Figure 23, which shows “four

material dispensers, one through-nozzle dispenser and three capillary-based dispensers.” Ex. 1005 ¶ 279. Warren discloses that “[t]he dispensers in the illustrated embodiment have been designed to extend and retract, so that only one dispenser is writing at a time.” Ex. 1005 ¶ 279.

By selectively quoting from different portions of Warren, Petitioner tries to suggest that a control valve on a pneumatic air cylinder controls air pressure for regulating the dispensing of bio-ink. Pet. 49. Warren does not support that suggestion. Instead, Warren discloses “a pneumatic air cylinder with a proportional control valve [for] controlling extension and retraction speeds.” Ex. 1005 ¶ 280. In other words, the control valve Petitioner directs us to for this limitation controls extension and retraction of the capillary dispenser itself, not the dispensing of bio-ink from the dispenser. Ex. 1005 ¶¶ 279, 280.

Thus, although Petitioner asserts that the “Windows based PC,” which Petitioner identifies as the recited “programmable computer processor” (Pet. 48), provides control over material dispensing by operating the control valve on a pneumatic air cylinder, Petitioner does not direct us to any disclosure or suggestion in Warren of actually regulating the dispensing of bio-ink by operating a control valve on a pneumatic air cylinder. Petitioner’s citation to portions of Warren that purportedly disclose a communicative coupling between the Windows based PC and a valve for controlling the flow of material from *a through-nozzle dispenser* do not support Petitioner’s arguments regarding the control valve on a pneumatic air cylinder of a *capillary-based dispenser*. Pet. 48–49; Ex. 1005 ¶¶ 54, 227–229, 232, 235, 236, 280, Fig. 36.

Notably, when addressing the separate limitation of “means for dispensing the bio-ink” in claim 1, Petitioner cites to paragraph 296 of

Warren, which discusses applying air pressure to the top side of a plunger. Pet. 46. Petitioner, however, does not cite to paragraph 296 of Warren when addressing the limitation requiring the programmable computer processor to be communicatively coupled to the means for dispensing the bio-ink. Pet. 48–50. Nor does Petitioner direct us to any discussion of a “control valve on a pneumatic air cylinder” in connection with paragraph 296 of Warren. See Pet. 46.

Similarly, Dr. Cimino testifies that, in Warren, “the application of pressure causes the contents of the cartridge (the hydrogel or paste in reservoir 3850) to be dispensed through the deposition orifice (tip 3840).” Ex. 1002 ¶ 137. When addressing the “programmable computer processor” limitation, however, Dr. Cimino does not identify any disclosure or suggestion in Warren that any processor is communicatively coupled with “the application of pressure” that “causes the contents of the cartridge . . . to be dispensed.” Ex. 1002 ¶ 137. Instead, Dr. Cimino echoes the same unsupported characterization of Warren’s disclosure as set forth in the Petition. *Compare* Pet. 49 (asserting that Warren discloses “providing fine control over material dispensing by operating the control valve on a pneumatic air cylinder”), *with* Ex. 1002 ¶ 146 (same). For the reasons discussed above, Warren does not support this characterization.

For these reasons, Petitioner has not shown sufficiently that Warren teaches or suggests a programmable computer processor that is communicatively coupled to means for dispensing the bio-ink, as claim 1 requires.

Petitioner’s arguments regarding claim 1 suffer from an additional flaw. For the limitation of independent claim 1 that recites “a means for determining a position of the selected cartridge in space,” Petitioner argues

that Warren “discloses an ultrasonic pinger that allows tracking of the tip of the device” and “using a piezomembrane with vibration transducer to detect a feedback signal to control the position of the dispenser.” Pet. 47–48 (citing Ex. 1005 ¶¶ 132, 296, 297, 303, Fig. 19). For the limitation in claim 1 that recites “a programmable computer processor . . . communicatively coupled to the means for determining a position of the selected cartridge,” Petitioner focuses on “location control device 800” and argues that “the Windows PC is used to synchronize the location control device with the actuator that controls dispensing.” Pet. 49–50 (citing Ex. 1005 ¶¶ 228, 229, 232, 380); Prelim. Resp. 15–16.

Petitioner, however, does not explain adequately why it directs us to an “ultrasonic pinger” and a “piezomembrane” in Warren as allegedly disclosing the claimed “means for determining a position of the selected cartridge,” but directs us to what appears to be something different, namely “location control device 800,” when asserting Warren discloses a programmable computer processor that is communicatively coupled to the means for determining a position of the selected cartridge. Nor does Dr. Cimino, who again echoes the information provided in the Petition, provide an adequate explanation. *See* Ex. 1002 ¶¶ 140–148. Absent additional information regarding how the various cited features of Warren collectively teach or suggest “a means for determining a position of the selected cartridge in space,” and “a programmable computer processor . . . communicatively coupled to the means for determining a position of the selected cartridge,” we are not persuaded that Petitioner’s evidence and arguments are sufficient to show, for purposes of institution, that Warren discloses these limitations of claim 1

For all of the foregoing reasons, Petitioner has failed to establish a reasonable likelihood of demonstrating claim 1 is unpatentable as obvious in view of Warren.

Claims 2–11 each depend from claim 1, and, therefore, include all of the limitations of claim 1. In view of our determination that Petitioner fails to establish a reasonable likelihood that claim 1 is unpatentable as obvious in view of Warren, we reach the same result for claims 2–11.

F. Challenges based on Smith

Petitioner contends that claims 1–8, 10, and 11 are unpatentable as obvious in view of Smith, and that claim 9 is unpatentable as obvious in view of Smith and Lipson. Pet. 56–72. Patent Owner opposes these challenges. Prelim. Resp. 23–44.

1. Smith (Ex. 1006)

Smith is a journal article that describes a BioAssembly Tool (“BAT”) for “fabrication of constructs for the replacement of nonfunctional tissue.” Ex. 1006, Abstract. According to Smith, its BAT “is a multihead, through-nozzle deposition machine deemed to conformably deposit biomaterials, cells, and cofactors on various supporting surfaces to create surrogate tissues and tentative platforms for experiments in cell biology and tissue

engineering.” Ex. 1006, 1567. Smith includes a picture of its BAT in Figure 1, reproduced below.

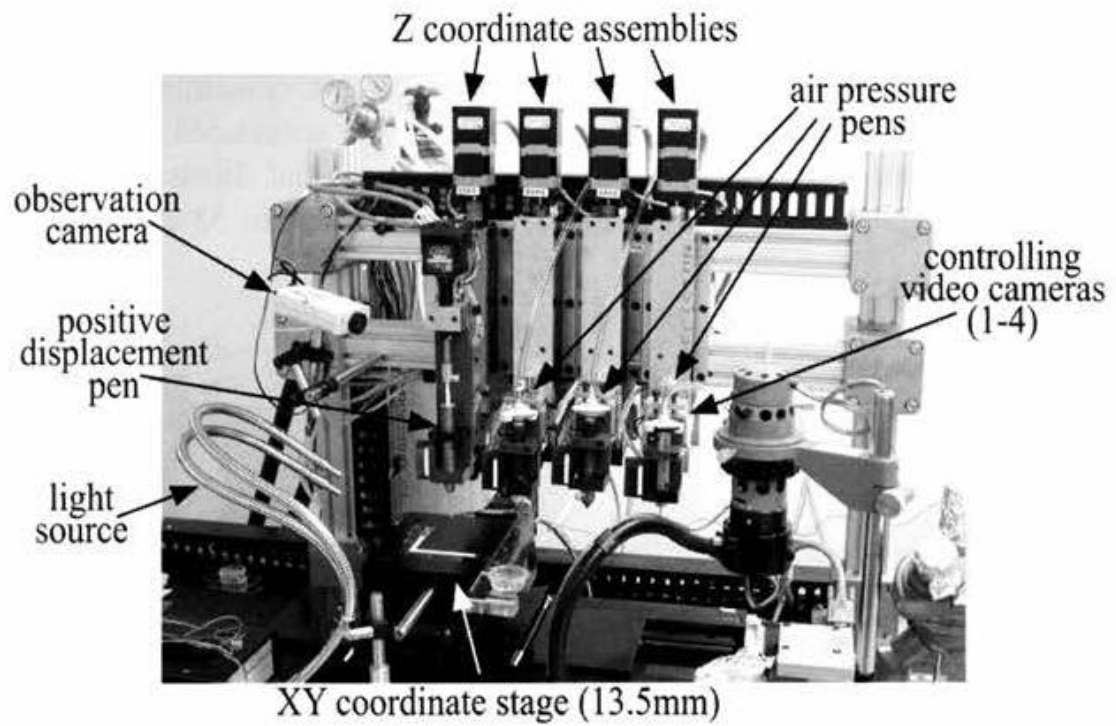


Figure 1 of Smith shows a three-dimensional, direct-write system having multiple deposition heads that hold microdispense pens, which can be filled with a variety of different solutions comprising cells. Ex. 1006, 1567, Fig. 1. The BAT also includes an observation camera, light source, and controlling video cameras. Ex. 1006, 1567, Fig. 1. Smith explains that its BAT has an XY coordinate system with a stage and a number of Z-traveling deposition heads. Ex. 1006, 1567.

2. Analysis

Claim 1 requires a bioprinter comprising, *inter alia*, a printer head for holding at least one cartridge, and “means for determining the position of the selected cartridge in space.” Ex. 1001, 38:7–8. Petitioner contends that Smith discloses this element because Smith “discloses using reciprocal sp[at]ial calibration of individual nozzles, which is a means for determining

a position of the selected cartridge in space. Smith further discloses determining position using piezoelectric and optical sensors.” Pet. 64 (citing Ex. 1006, 1567). Petitioner relies on the same disclosure in Smith for an alternative analysis, “to the extent this term is interpreted under § 112 ¶ 6.” Pet. 65 (arguing that Smith discloses the recited function “as shown above,” and that “[p]iezoelectric sensors and optical sensors are a structural equivalent to the claimed means for determining [a position]”).

Patent Owner argues that the cited portions of Smith do not support Petitioner’s argument that Smith discloses means for determining a position of the selected cartridge in space. Prelim. Resp. 41–44. In particular, Patent Owner argues that Smith’s disclosure of “reciprocal calibration of individual nozzles” does not demonstrate how Smith discloses the function of “determining a position of the selected cartridge in space” or the “means” for performing that function. Prelim. Resp. 42 (arguing that Petitioner fails to explain or point to anything that is included within a bioprinter that allegedly performs the claimed function). Patent Owner also argues that Petitioner fails to explain how Smith’s “piezoelectric and optical sensors” and “their ability to allow curved surface deposition provides determining a ‘position’ of anything.” Prelim. Resp. 43.

After considering both parties’ arguments and evidence, we agree with Patent Owner that Petitioner has not adequately established that Smith discloses or suggests a “means for determining a position of the selected cartridge in space” as claim 1 requires.

Smith states that “[r]eciprocal spatial calibration of the individual nozzles allows for the inline replacement of one nozzle for another one with the same 5- μ m accuracy.” Ex. 1006, 1567. Petitioner simply concludes, without any explanation, that “reciprocal spatial calibration of individual

nozzles” discloses “a means for determining a position of the selected cartridge in space.” Pet. 64–65. For example, Petitioner and Dr. Cimino do not adequately explain how a person of ordinary skill in the art would have understood the meaning of the phrase “reciprocal spatial calibration” in the context of Smith. Nor do they explain adequately how Smith’s disclosure of “reciprocal spatial calibration,” which Smith describes as allowing for the replacement of one nozzle with another (Ex. 1006, 1567), would have disclosed or suggested a “means for determining a position,” as claim 1 recites. Additionally, as Patent Owner points out, Petitioner never directs us to any corresponding structure in Smith that performs the “reciprocal spatial calibration.” Pet. 64–65; Prelim. Resp. 42. Absent additional information regarding Smith’s disclosure, Petitioner’s mere conclusory statement is insufficient to satisfy its burden to make a threshold showing of obviousness. *See Magnum Oil*, 829 F.2d at 1380.

Smith also states that “[p]iezoelectric and optical sensors allow for conformable deposition on curved surfaces.” Ex. 1006, 1567. Based on this statement, Petitioner and Dr. Cimino conclude that Smith teaches or suggests “means for determining a position of the selected cartridge.” Pet. 64–65. Neither Petitioner nor Dr. Cimino, however, explains adequately how “allow[ing] for conformable deposition on curved surfaces” corresponds to “determining a position of the selected cartridge.” Petitioner appears to rely on the fact that Smith, like the ’952 patent, discloses the use of piezoelectric and optical sensors. Pet. 65. But absent additional evidence or information from Petitioner or Dr. Cimino, we are not persuaded that Petitioner has shown sufficiently that Smith’s use of common sensors to allow for the deposition of material on a curved surface would have

disclosed or suggested the use of those sensors to “determin[e] a position of the selected cartridge in space,” as claim 1 requires.

Petitioner’s alternative contention based on a § 112 ¶ 6 construction does nothing to remedy the deficiencies in Petitioner’s showing that Smith discloses or suggests “determining a position of the selected cartridge in space” as claim 1 requires.

For these reasons, Petitioner has not shown sufficiently that Smith teaches or suggests “means for determining a position of the selected cartridge in space.”

Petitioner’s arguments regarding claim 1 are deficient for an additional reason. As noted above, claim 1 recites a bioprinter comprising several components, including, *inter alia*, “a programmable computer processor for regulating the dispensing of the bio-ink.” Ex. 1001, 38:8–12.

Petitioner contends that Smith teaches or suggests this limitation because “Smith discloses executing software such as scripts, which a [person of ordinary skill in the art] would have understood are executed on a programmable computer processor.” Pet. 65 (citing Ex. 1006, 1567, 1569).

Patent Owner argues that, even accepting Petitioner’s statement as true, Petitioner fails to demonstrate how Smith discloses that a processor is included in the bioprinter. Prelim. Resp. 34. In particular, Patent Owner contends that “*Smith* states that ‘the process of deposition is controlled by specified software’ but makes no mention as to what executes that software, and more specifically, that whatever does so is included in the ‘system’ that Petitioner maps to the bioprinter.” Prelim. Resp. 35. According to Patent Owner, Smith does not mention a computer processor when describing what its device contains. Prelim. Resp. 35–36 (citing Ex. 1006, 1567).

We agree with Patent Owner that Smith does not expressly disclose that its bioprinter comprises a programmable computer processor. Prelim. Resp. 35–36; Ex. 1006, 1567, 1569. And even though Smith states that “[t]he process of deposition is controlled by specified software,” Patent Owner is correct that Petitioner has not shown sufficiently that the software is executed by a processor that is included in Smith’s bioprinter. *See* Pet. 65. Petitioner bears the burden of demonstrating that Smith discloses or suggests a bioprinter comprising a programmable computer processor. In view of Petitioner’s reliance solely on general descriptions of software in Smith, and Petitioner’s failure to address specifically the relationship between anything that executes the software and the bioprinter in Smith, we are not persuaded Petitioner has presented sufficient evidence to satisfy its burden for purposes of institution.

For all of the foregoing reasons, we determine that Petitioner has not demonstrated adequately that Smith teaches or suggests all limitations of claim 1, and, therefore, that Petitioner has not shown a reasonable likelihood that it would prevail with respect to its argument that claim 1 is unpatentable as obvious in view of Smith.⁹

Claims 2–11 each depend from claim 1, and, therefore, include all of the limitations of claim 1. In view of our determination that Petitioner fails to establish a reasonable likelihood that claim 1 is unpatentable as obvious in view of Smith, we reach the same result for claims 2–11.

⁹ In view of this determination, we do not address Patent Owner’s argument that Smith fails to qualify as prior art. Prelim. Resp. 23–33.

G. Discretion under 35 U.S.C. § 325(d)

Patent Owner argues that the Board should exercise its discretion to deny the Petition under 35 U.S.C. § 325(d). Prelim. Resp. 44–46. In view of our determination that Petitioner has not met the threshold for instituting review on the merits, we need not consider Patent Owner’s arguments for a discretionary denial of institution.

IV. CONCLUSION

For the above reasons, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing that claims 1–11 of the ’952 patent are unpatentable on the grounds asserted in the Petition.

V. ORDER

It is

ORDERED that, the Petition is *denied*, and no trial is instituted.

IPR2021-01049
Patent 9,149,952 B2

FOR PETITIONER:

Scott A. McKeown
James L. Davis, Jr.
Christopher M. Bonny
ROPES & GRAY LLP
scott.mckeown@ropesgray.com
james.l.davis@ropesgray.com
christopher.bonny@ropesgray.com

FOR PATENT OWNER:

Naveen Modi
Joseph E. Palys
Elizabeth L. Brann
PAUL HASTINGS LLP
naveenmodi@paulhastings.com
josephpalys@paulhastings.com
elizabethbrann@paulhastings.com