

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLINK AB,
Petitioner,

v.

ORGANOVO, INC.,
Patent Owner.

IPR2021-01050
Patent 9,855,369 B2

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

ROESEL, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. *Background and Summary*

Cellink AB (“Petitioner”) filed a Petition (Paper 2, “Pet.”) seeking an *inter partes* review of claims 1–15 (the “challenged claims”) of U.S. Patent No. 9,855,369 B2 (Ex. 1001, “the ’369 Patent”). Organovo, Inc. (“Patent Owner”) filed a Preliminary Response. 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) (2021). An *inter partes* review may not be instituted “unless . . . 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(a). After considering the parties’ arguments and evidence, we determine that the reasonable likelihood standard is not met. Accordingly, we deny institution of *inter partes* review.

B. *Related Matters*

Patent Owner indicates that the ’369 Patent is at issue in the following district court action: *Cellink AB v. Organovo, Inc.*, No. 21-cv-00832 (D. Del.). Paper 5, 1.

C. *The ’369 Patent (Ex. 1001)*

The ’369 Patent discloses a bioprinter for fabricating three-dimensional (“3D”) tissues and organs. Ex. 1001, code (57), 1:56–58, 6:9–15, 7:22–28, 12:42–44, 18:34–35. The bioprinter includes a printer head for receiving and holding at least one cartridge containing “bio-ink” or 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.

Id. at code (57), 1:59–65, 6:16–24, 12:44–53. “[B]io-ink” is a “liquid, semi-solid, or solid composition comprising a plurality of cells.” *Id.* at 7:14–15, 20:24–25. 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.” *Id.* at 2:16–19, 4:16–21, 13:19–23. 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.” *Id.* at 2:9–14, 4:16–21, 13:10–15. The position of the cartridge may be calibrated along the x-axis, the y-axis, and/or the z-axis. *Id.* at 2:48–54, 4:11–16, 6:32–37.

The ’369 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, 4:29–48, 6:38–47, 18:58–67. A “computer module” is “a software component (including a section of code) that interacts with a larger computer system.” *Id.* at 7:32–34, 19:22–24. 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. *Id.* at 12:4–7, 14:62–65, 18:50–54. According to the ’369 Patent, in some embodiments, “computer code specifies the positioning of a printer head to configure printer head height above a receiving surface.” *Id.* at 14:65–67. “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.” *Id.* at 14:67–15:3.

The ’369 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, 15:8–11, 16:65–17:1.

D. Illustrative Claim

Petitioner challenges claims 1–15 of the ’369 Patent. Pet. 1, 5.
Claims 1 and 4 are independent claims. Claim 1 is reproduced below.

1. A method of printing a three-dimensional (3D) structure, the method comprising:

(a) providing a 3D printer, the printer comprising:

- i. one or more printer heads, wherein a printer head comprises a means for receiving and holding at least one cartridge, wherein the cartridge comprises at least one deposition orifice and contents comprising a bio-ink, wherein the bio-ink comprises cell solutions, cells suspensions, or cell concentrations;
- ii. a means for dispensing the contents of at least one cartridge;
- iii. a receiving surface for receiving a first layer of the materials dispensed from the at least one cartridge;
- iv. a programmable computer processor communicatively connected to the means for dispensing, the programmable computer processor for positioning the one or more printer heads in three dimensions and regulating the dispensing of the contents of the at least one cartridge; and
- v. a means for calibrating the position of the at least one cartridge or the at least one deposition orifice;

(b) providing the materials to be dispensed;

(c) encoding the printer with a 3D structure to be printed, wherein the 3D structure is a tissue construct;

(d) dispensing from the deposition orifice the materials to be dispensed, wherein the materials to be dispensed comprise cell solutions, cells suspensions, or cell concentrations, wherein the dispensing is by extrusion;

(e) depositing a first layer of the dispensed materials on the receiving surface; and

(f) repeating the depositing step by depositing subsequent dispensed material on the first and any subsequent layers of deposited material, thereby depositing layer upon layer of dispensed materials in a geometric arrangement according to the 3D structure.

Ex. 1001, 38:30–64.

Claim 4 is identical to claim 1, except that claim 4 does not recite “v. a means for calibrating the position of the at least one cartridge or the at least one deposition orifice.” *Compare* Ex. 1001, 38:30–64 (claim 1), *with id.* at 39:6–40:7 (claim 4).

E. Asserted Grounds and Evidence

Petitioner asserts the following grounds of unpatentability under 35 U.S.C. § 103(a):¹

Claim(s) Challenged	Reference(s)
1, 2, 4–15	Lipson ²
3	Lipson, Pasciak ³

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 ’369 Patent has an effective filing date before this date, the pre-AIA version of § 103 applies. Ex. 1001, code (63).

² Ex. 1004, Lipson et al., US 2006/0156978 A1, published July 20, 2006.

³ Ex. 1009, Pasciak, US 4,808,000, issued February 28, 1989.

Claim(s) Challenged	Reference(s)
1, 2, 4–9, 11–15	Warren ⁴
3	Warren, Pasciak
10	Warren, Lipson

Pet. 5. Petitioner relies on the Declaration of Dr. William Cimino to support its challenges. Ex. 1002.

II. ANALYSIS

A. Legal Standards

“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 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

⁴ Ex. 1005, Warren et al., US 2004/0253365 A1, published December 16, 2004.

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

Relying on Dr. Cimino’s testimony, Petitioner contends that a person of ordinary skill in the art (“POSA”) would have had “a minimum of a bachelor’s degree in mechanical engineering, electrical engineering, biomedical engineering, or a related field, and approximately [five] years of relevant experience or equivalent study in electromechanical systems, regenerative medicine, tissue/organ engineering, and/or biologic and medical research.” Pet. 13 (citing Ex. 1002 ¶¶ 10–12). Petitioner asserts that “[a]dditional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education.” *Id.*

For purposes of the Preliminary Response, Patent Owner does not dispute Petitioner's definition of a POSA. Prelim. Resp. 3.

We find that Petitioner's definition of a POSA is consistent with the scope and content of the '369 Patent and the asserted prior art, and we apply this definition for purposes of this Decision.

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. 14–17. 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. Petitioner's Lipson-Led Grounds

Petitioner contends that claims 1, 2, and 4–15 are unpatentable as obvious in view of Lipson and that claim 3 is unpatentable as obvious in view of Lipson and Pasciak. Pet. 17–45. Patent Owner opposes these challenges. Prelim. Resp. 5–32. We provide an overview of Lipson before turning to the parties' contentions and our analysis.

1. Lipson (Ex. 1004)

Lipson discloses a method and system for fabricating a living three-dimensional structure. Ex. 1004, code (57), ¶ 10. Lipson depicts its system in Figure 2, reproduced below.

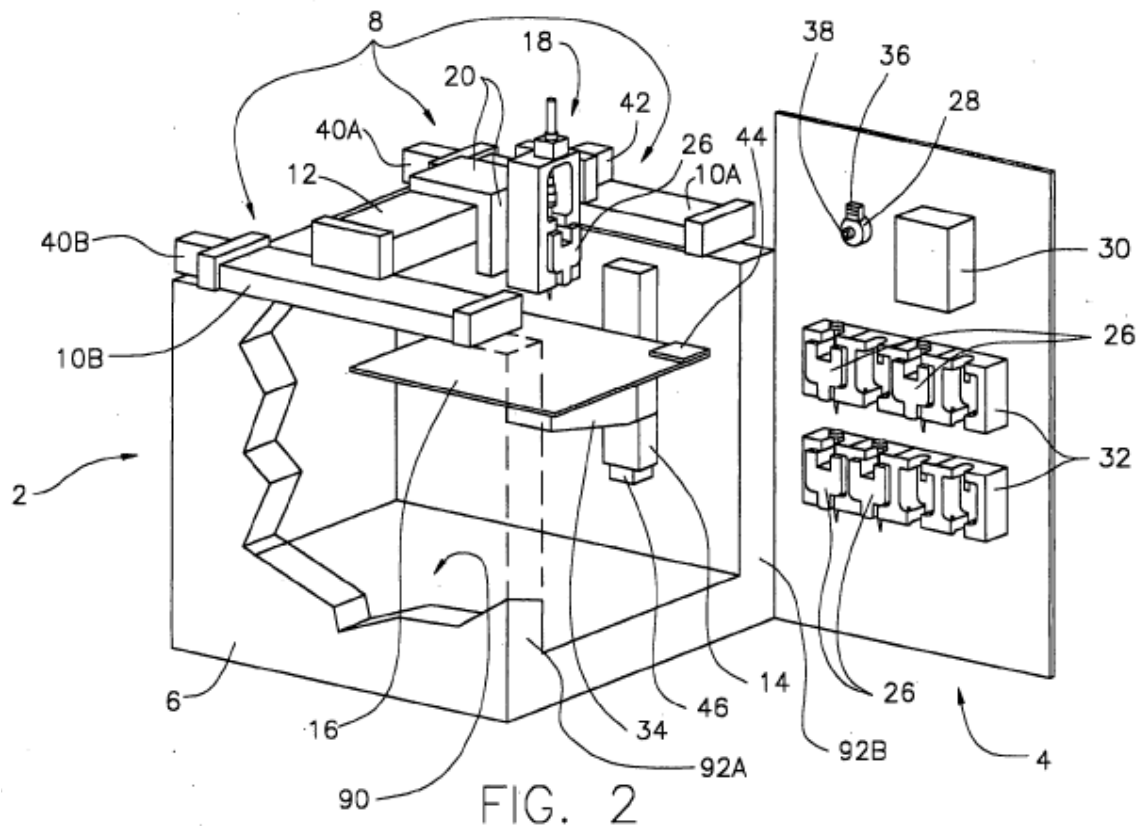


Figure 2 shows a perspective view of Lipson's material deposition device 2 and tool rack 4, wherein material deposition device 2 includes machine

base 6, positioning system 8, substrate 16, and tool interface 20. Ex. 1004 ¶¶ 48, 54. Material deposition tool 18 is mounted on tool interface 20 and holds material cartridge 26. *Id.* ¶¶ 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.” *Id.* ¶ 54. Lipson also discloses a system controller “operably connected to the material deposition device to control operation of the material deposition device.” *Id.* ¶ 8.

2. Independent claims 1 and 4

Our analysis focuses on the portion of independent claims 1 and 4 that recites: “a 3D printer, the printer comprising: . . . a programmable computer processor . . . the programmable computer processor for positioning the one or more printer heads in three dimensions.” Ex. 1001, 38:32–43 (claim 1), 39:8–21 (claim 4).⁵

Petitioner contends that Lipson discloses a programmable computer (system controller) and that the system controller is for positioning Lipson’s printer head in three dimensions. Pet. 26–28. In the alternative, Petitioner contends that three-dimensional positioning of the printer head would have been obvious. Pet. 28. Petitioner provides an additional contention to cover the contingency that the term “programmable computer processor” is interpreted under § 112 ¶ 6. Pet. 28–29.

⁵ For the Lipson-led ground, Petitioner relies on the same contentions for claim 4 as it presents for claim 1 (Pet. 34–37), and our analysis of Petitioner’s contentions is the same for both claims.

Patent Owner argues that Petitioner fails to demonstrate that Lipson discloses “a 3D printer . . . comprising . . . a programmable computer processor,” as claims 1 and 4 require. Prelim. Resp. 6–8. According to Patent Owner, the Petition fails to show that Lipson’s system controller (the alleged “programmable computer processor”) “is included in the arrangement shown in FIG. 1 of Lipson,” which Petitioner identifies as the claimed “3D printer.” *Id.* at 6–7 (emphasis omitted). In addition, Patent Owner argues that Lipson does not disclose “a programmable computer processor . . . for positioning the one or more printer heads in three dimensions” and that Petitioner’s obviousness analysis for this claim requirement is insufficient. *Id.* at 10–16.

After considering the parties’ arguments and evidence, we agree with Patent Owner that Petitioner has not demonstrated sufficiently that Lipson discloses or suggests a 3D printer ***comprising*** a programmable computer processor, as claims 1 and 4 require. In addition, Petitioner has not demonstrated sufficiently that Lipson discloses a programmable computer processor ***for positioning one or more printer heads in three dimensions*** or that it would have been obvious to modify Lipson to meet this claim requirement. We address each of these claim requirements in turn below.

a) a 3D printer comprising a programmable computer processor

Petitioner contends that “Lipson discloses a programmable computer processor (system controller).” Pet. 26 (emphasis omitted). As support for that contention, Petitioner relies on the following two sentences from Lipson: “System controller 104 is operated by fabrication system software that automatically converts design data into a manufacturing plan.” *Id.* (quoting Ex. 1004 ¶ 95). “The pattern is established by the system

controller, which operates according to an electronic data file so that changes to the product only require changes to the design data of the system controller.” Pet. 27 (quoting Ex. 1004 ¶ 94).

Petitioner does not adequately address whether Lipson discloses a 3D printer *comprising* a programmable computer processor. We find that Lipson paragraphs 94 and 95 are not sufficient to support Petitioner’s argument. At best, these paragraphs provide some support for Petitioner’s contention that Lipson’s system controller *is* a programmable computer processor. But these paragraphs do not address whether Lipson’s 3D printer *comprises* a programmable computer processor, as claims 1 and 4 require.

Petitioner contends that Lipson discloses a 3D printer and directs us to Lipson Figure 1, which shows a “fabrication system.” Pet. 20; Ex. 1004 ¶ 17. Petitioner does not assert that Lipson’s fabrication system comprises a system controller. By way of contrast, Petitioner explicitly maps the other four elements of the claimed 3D printer to components of Lipson’s fabrication system. Pet. 20–26, 29–30 (addressing the claimed printer heads, means for dispensing, receiving surface, and means for calibrating).

More specifically, Petitioner maps the claimed “printer heads” to Lipson’s material deposition tool 18 illustrated in Lipson Figures 1 and 2, which show the fabrication system, and Lipson Figures 4 and 6, which show the material deposition tool in more detail. Pet. 21–24; Ex. 1004 ¶¶ 47, 48, 51, 72, 76. Petitioner maps the claimed “means for dispensing” to Lipson’s piston 70 and plunger 62, which force material out of cartridge 26, as illustrated in Lipson Figure 8, which shows material deposition tool 18 of the fabrication system. Pet. 24–25; Ex. 1004 ¶¶ 51, 76, 78. Petitioner maps the claimed “receiving surface” to Lipson’s receptacle 306 of module 300 shown in Figure 15, which attaches to substrate 16 of the fabrication system,

as shown in Figure 18. Pet. 25–26; Ex. 1004 ¶¶ 34, 111, 112, 125, Fig. 18. Petitioner maps the claimed “means for calibrating” to Lipson’s calibration sensor, including optical emitter/detector pairs 200A, B and 202A, B illustrated in Lipson Figure 13, which shows calibration sensor device 44 mounted on substrate 16 of the fabrication system. Pet. 29–30; Ex. 1004 ¶¶ 29, 108, Figs. 2, 13.

In contrast, however, Petitioner maps the claimed “programmable computer processor” to Lipson’s system controller 104 (Pet. 26), which Lipson illustrates and describes as an “external computer,” not a component of the fabrication system. Ex. 1004 ¶¶ 26, 90, 91, 93, Fig. 10. More specifically, Lipson Figure 10 depicts system controller 104 as a laptop computer that is separate from the fabrication system that Petitioner identifies as a 3D printer. *Id.* Fig. 10. Lipson describes the system controller as an external computer in the following passages.

FIG. 10 is a perspective view of a fabrication system in accordance with the present invention Also shown is the electronic wiring of a fabrication system that connects to ***an external computer***.

Id. ¶ 26 (emphasis added).

Operation of the system of the present invention is controlled by a ***system controller*** operably connected to the material deposition device and the transfer device. . . . Figure 10 illustrates the system of the present invention with electrical connections to ***system controller 104, which is an external computer***.

Id. ¶ 90 (emphasis added); *see also id.* ¶¶ 91, 93 (discussing external computer 104).

Petitioner ignores the foregoing disclosures and fails to address Lipson’s repeated description and illustration of the system controller as an

external computer. Particularly in view of Lipson's express disclosure that the system controller (programmable computer processor) is *external* to the fabrication system (3D printer), Petitioner had a duty to provide evidence and argument, as part of its case-in-chief, sufficient to make a threshold showing that Lipson discloses a 3D printer *comprising* a programmable computer processor. Because Petitioner does not explain how or why Lipson discloses or suggests this claim limitation, the Petition is deficient.

Although Petitioner relies on paragraphs 95–101 of Dr. Cimino's testimony as support for its contentions regarding a programmable computer processor (Pet. 29), the cited testimony suffers from the same deficiencies as the Petition. Dr. Cimino fails to explain how Lipson's disclosure of a system controller external to the fabrication system would have taught or suggested a 3D printer comprising a programmable computer processor, as claimed. Ex. 1002 ¶¶ 95–101.

Petitioner's alternative contention based on a § 112 ¶ 6 construction for "programmable computer processor" (Pet. 28–29) does nothing to remedy the deficiencies in Petitioner's showing that Lipson discloses or suggests a 3D printer comprising a programmable computer processor.

b) *"the programmable computer processor for positioning the one or more printer heads in three dimensions"*

Petitioner contends that Lipson's system controller "is for positioning the one or more printer heads (commanding positioning system 8 to move material deposition tool 18 and the substrate)." Pet. 27 (citing Ex. 1004 ¶¶ 9, 14, 83). Petitioner further contends that "Lipson discloses that the printer head is positioned in three dimensions," asserting that the printer head is "moved in the X-Y plane" and "positioned in the Z-axis direction by

moving the receiving surface relative to the printer head.” Pet. 28 (citing Ex. 1004 ¶¶ 51, 53).

We agree with Patent Owner (Prelim. Resp. 10–11) that Petitioner does not show sufficiently that Lipson discloses a programmable computer processor “for positioning the one or more printer heads in three dimensions,” as recited in claims 1 and 4. Petitioner maps the claimed “one or more printer heads” to Lipson’s material deposition tool 18. Pet 20–21. Petitioner does not, however, make a sufficient threshold showing that Lipson’s material deposition tool 18 is positioned in three dimensions. Petitioner asserts that Lipson discloses a printer head that moves in an X-Y plane and a receiving surface that moves in the Z-axis direction. Pet. 28 (citing Ex. 1004 ¶¶ 51, 53). Petitioner contends that the claims do not require moving the printer head relative to the receiving surface in all three dimensions instead of moving the receiving surface (Pet. 19), but presents no claim construction analysis or other reasoning to support that contention. Petitioner does not show sufficiently for purposes of institution that “positioning the one or more printer heads in three dimensions,” as recited in claims 1 and 4, is broad enough to encompass positioning a printer head in two dimensions and positioning a receiving surface in a third dimension.

Alternatively, Petitioner contends that “it would have been an obvious design choice to move the printer head in the Z-axis direction instead of moving the receiving surface.” Pet. 28. As an obviousness rationale, Petitioner asserts “there were only two options (moving the printer head or moving the receiving surface), both of which would have been obvious.” *Id.*; *see also* Ex. 1002 ¶ 100 (same). Petitioner and Dr. Cimino provide no further explanation or evidentiary support for their assertion.

We agree with Patent Owner that Petitioner's obviousness analysis is conclusory and insufficiently supported. Prelim. Resp. 12–16. Essentially, Petitioner and Dr. Cimino assert that “there were only two options,” one of which is disclosed in the prior art, but not claimed, and the other of which is claimed, but not disclosed in the prior art. Pet. 28; Ex. 1002 ¶ 100. That naked assertion is inherently based on a hindsight view of the claims of the challenged patent. Petitioner and Dr. Cimino provide no analysis supporting their assertion that “moving the printer head or moving the receiving surface” were the only two options. Pet. 28; Ex. 1002 ¶ 100. Petitioner and Dr. Cimino fail to consider that there are three directions, namely the X-, Y-, and Z-axis directions, in which the printer head or the receiving surface could be moved.⁶ Under these circumstances, Petitioner's and Dr. Cimino's “only two options” rationale does not meet the standard of “articulated reasoning with some rational underpinning” sufficient to support institution based on obviousness. *In re Kahn*, 441 F.3d at 988.

Furthermore, Petitioner and Dr. Cimino fail to explain sufficiently how or why a POSA would have considered modifying Lipson's system controller to position material deposition tool 18 in the Z-axis direction

⁶ Assuming only one of these components moves in each direction, this leads to eight possible combinations: (1) the printer head moves in the X-, Y-, and Z- directions; (2) the receiving surface moves in the X-, Y-, and Z- directions; (3) the printer head moves in the X-direction, and the receiving surface moves in the Y- and Z-directions; (4) the receiving surface moves in the X-direction, and the printer head moves in the Y- and Z-directions; (5) the printer head moves in the Y-direction, and the receiving surface moves in the X- and Z-directions; (6) the receiving surface moves in the Y-direction, and the printer head moves in the X- and Z-directions; (7) the printer head moves in the Z-direction, and the receiving surface moves in the X- and Y-directions; (8) the receiving surface moves in the Z-direction, and the printer head moves in the X- and Y-directions.

instead of positioning substrate 16 in the Z-axis direction, as Lipson discloses. Ex. 1004 ¶ 53. Petitioner and Dr. Cimino also fail to explain sufficiently how or why a POSA would have modified Lipson’s fabrication system to accomplish positioning material deposition tool 18 in three dimensions as opposed to two, as Lipson discloses. *Id.*

Petitioner’s alternative contention based on a § 112 ¶ 6 construction for “programmable computer processor” (Pet. 28–29) does nothing to remedy the deficiencies in Petitioner’s showing that Lipson discloses or suggests a “programmable computer processor for positioning the one or more printer heads in three dimensions,” as recited in claims 1 and 4.

3. Dependent claims 2, 3, and 5–15

Claims 2 and 3 each depend directly or indirectly from claim 1, and claims 5–15 each depend directly or indirectly from claim 4. Ex. 1001, 38:65–39:5, 40:8–32. Petitioner contends that claims 2 and 5–15 would have been obvious in view of Lipson and that claim 3 would have been obvious in view of Lipson and Pasciak. Pet. 34, 37–45. We find that Petitioner’s arguments and evidence for dependent claims 2, 3, and 5–15 fail to remedy the deficiencies in Petitioner’s arguments and evidence for independent claims 1 and 4.

E. Petitioner’s Warren-Led Grounds

Petitioner contends that claims 1, 2, 4–9, and 11–15 are unpatentable as obvious in view of Warren, that claim 3 is unpatentable as obvious in view of Warren and Pasciak, and that claim 10 is unpatentable as obvious in view of Warren and Lipson. Pet. 45–72. Patent Owner opposes these challenges. Prelim. Resp. 32–60. We provide an overview of Warren before turning to the parties’ contentions and our analysis.

1. *Warren (Ex. 1005)*

Warren discloses “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.” *Id.* ¶ 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).” *Id.* ¶¶ 10, 11. According to Warren, the disclosed apparatus can be used for “in vivo procedures” or for “in vitro applications in a tabletop setting.” *Id.* ¶¶ 11, 12, 58–60, Figs. 1, 2.

Warren discloses 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).” *Id.*; *see also id.* ¶¶ 320–323 (describing embodiments of the biological HAT dispensing system for tissue engineering).

Warren discloses the DWDT/HAT includes 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 id.* ¶¶ 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 (*id.* ¶¶ 284–319, Figs. 18–22), methods for depositing tissue engineering material at a selected position on a substrate in vitro (*id.* ¶¶ 379–383), and methods for depositing tissue engineering material at a target area within a subject’s body (*id.* ¶¶ 384–472).

2. *Independent claims 1 and 4*

Our analysis focuses on the portion of independent claims 1 and 4 that recites: “a programmable computer processor communicatively connected to the means for dispensing.” Ex. 1001, 38:43–44 (claim 1), 39:21–22 (claim 4).⁷

Petitioner contends that Warren “discloses a programmable computer processor (Windows based PC)” that is “communicatively connected to the means for dispensing for regulating the dispensing of the contents of the at least one cartridge (providing fine control over material dispensing by operating the control valve on a pneumatic air cylinder).” Pet. 55. Petitioner provides an additional contention to cover the contingency that “programmable computer processor” is interpreted under § 112 ¶ 6. Pet. 56–57.

Patent Owner argues that Petitioner fails to demonstrate that Warren discloses a “programmable computer processor” as the challenged claims require. Prelim. Resp. 33–38. 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* (mapped to the claimed “programmable computer processor”) . . . is “communicatively connected to” the

⁷ For the Warren-led grounds, Petitioner relies on the same contentions for claim 4 as it presents for claim 1 (Pet. 62–65), and our analysis of Petitioner’s contentions is the same for both claims.

“air pressure” aspects of *Warren* (which Petitioner maps to the claimed “means for dispensing”)]

Prelim. Resp. 37.

After considering the 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 connected to the means for dispensing,” as recited in claims 1 and 4.

Petitioner contends that Warren “discloses a means for dispensing the contents of the cartridge (air pressure).” Pet. 54 (citing Ex. 1005 ¶¶ 280, 296). Petitioner further contends that “Warren discloses a programmable computer processor (Windows based PC)” that is “communicatively connected to the means for dispensing for regulating the dispensing.” Pet. 55–56 (citing Ex. 1005 ¶¶ 227–229, 280, 413, 422). Petitioner does not, however, show sufficiently that Warren’s “Windows based PC,” which Petitioner identifies as the recited “programmable computer processor” (Pet. 55) is communicatively connected to any mechanism for controlling air pressure, which Petitioner identifies as the recited “means for dispensing the contents of at least one cartridge” (Pet. 53–54).

To establish a communicative connection, Petitioner asserts that Warren discloses “providing fine control over material dispensing by operating the control valve on a pneumatic air cylinder.” Pet. 55. As further discussed below, Petitioner’s assertion misstates Warren’s disclosure by merging two unrelated snippets from Warren, the first related to a through-nozzle dispenser and the second related to a capillary-based dispenser.

Petitioner’s first snippet, “providing fine control over material dispensing,” is from Warren’s disclosure 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. “[T]he 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.” *Id.* ¶ 225, Fig. 11. Valve 130 controls the flow of material through the dispenser. *Id.* Contrary to Petitioner’s assertion, however, Warren’s valve 130 is not a “control valve on a pneumatic air cylinder,” and actuator 144 does not operate a control valve on a pneumatic air cylinder. Pet. 55.

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.

Petitioner’s second snippet, “by operating the control valve on a pneumatic air cylinder,” is from Warren’s disclosure 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.” *Id.* ¶ 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.” *Id.*

By selectively quoting from Warren, Petitioner tries to suggest that a control valve on a pneumatic air cylinder controls air pressure for dispensing the contents of a cartridge. Pet. 54, 56. Warren does not support that suggestion. Warren discloses “a pneumatic air cylinder with a proportional control valve [for] controlling extension and retraction speeds.” Ex. 1005 ¶ 280. The control valve controls extension and retraction of the capillary dispenser, not the dispensing of material from the dispenser. *Id.* ¶¶ 279, 280.

Despite Petitioner’s assertion that Warren provides “fine control over material dispensing by operating the control valve on a pneumatic air cylinder” (Pet. 55), Petitioner does not direct us to any disclosure or suggestion in Warren of a control valve for controlling air pressure for material dispensing. Nor does Petitioner direct us to any disclosure or suggestion in Warren that the “Windows based PC,” which Petitioner identifies as the recited “programmable computer processor” (Pet. 55) is communicatively connected to any mechanism for controlling air pressure, which Petitioner identifies as the recited “means for dispensing the contents of at least one cartridge” (Pet. 53–54).

For a through-nozzle dispenser, Warren discloses a communicative connection between the Windows based PC and a valve for controlling the flow of material from the dispenser. Ex. 1005 ¶¶ 54, 227–229, 232, 235, 236, Fig. 36. Petitioner does not, however, rely on Warren’s through-nozzle dispenser or valve as teaching the “means for dispensing the contents of the at least one cartridge.” Pet. 53–54. Instead, Petitioner relies on Warren’s teachings related to capillary-based dispenser. *Id.* (citing Ex. 1005 ¶¶ 280,

296).⁸ For the capillary-based dispenser, Petitioner does not direct us to any communicative connection between the Windows based PC and air pressure, which Petitioner relies upon as teaching a “means for dispensing the contents of the cartridge.” *Id.*

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 ¶ 171 (citing Ex. 1005 ¶ 196). When addressing the “programmable computer processor” limitation (*id.* ¶¶ 176–181), however, Dr. Cimino does not identify any disclosure or suggestion in Warren that any processor is communicatively connected with “the application of pressure” that “causes the contents of the cartridge . . . to be dispensed” (*id.* ¶ 171). Instead, Dr. Cimino echoes the same unsupported characterization of Warren’s disclosure as set forth in the Petition. *Compare* Pet. 55 (asserting that Warren discloses “providing fine control over material dispensing by operating the control valve on a pneumatic air cylinder”), *with* Ex. 1002 ¶ 178 (same). For the reasons discussed above, Warren does not support this characterization.

Petitioner’s alternative contention based on a § 112 ¶ 6 construction for “programmable computer processor” (Pet. 56–57) does nothing to remedy the deficiencies in Petitioner’s showing that Warren discloses or suggests “a programmable computer processor communicatively connected to the means for dispensing,” as recited in claims 1 and 4.

⁸ Petitioner’s citation to Warren paragraphs 224 and 380 without explanation (Pet. 54) is not enough to convey that Petitioner relies on Warren’s through-nozzle dispenser or valve as teaching the “means for dispensing the contents of the at least one cartridge.”

3. *Dependent claims 2, 3, and 5–15*

Petitioner contends that claims 2, 5–9, and 11–15 would have been obvious in view of Warren, that claim 3 would have been obvious in view of Warren and Pasciak, and that claim 10 would have been obvious in view of Warren and Lipson. Pet. 61–62, 65–72. After reviewing Petitioner’s contentions, we find that Petitioner’s arguments and evidence for dependent claims 2, 3, and 5–15 fail to remedy the deficiencies in Petitioner’s arguments and evidence for independent claims 1 and 4.

F. *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. 60–62. 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.

III. CONCLUSION

For the above reasons, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing that claims 1–15 of the ’369 Patent are unpatentable on the grounds asserted in the Petition.

IV. ORDER

It is

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

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