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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VARIAN MEDICAL SYSTEMS, INC., Petitioner,

v.

WILLIAM BEAUMONT HOSPITAL, Patent Owner.

> Case IPR2016-00170 Patent 7,471,765 B2

Before MICHAEL W. KIM, KALYAN K. DESHPANDE, and MATTHEW R. CLEMENTS, *Administrative Patent Judges*.

DESHPANDE, Administrative Patent Judge.

DECISION Decision Instituting *Inter Partes* Review 37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Varian Medical Systems, Inc. ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1–13 and 20–31 of U.S. Patent No. 7,471,765 B2 (Ex. 1101, "the '765 patent"). Paper 1 ("Pet."). William Beaumont Hospital ("Patent Owner") filed a Preliminary Response. Paper 11 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted unless the information presented in the Petition shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the Petition and Preliminary Response, we are persuaded that Petitioner has met its burden of showing a reasonable likelihood that it would prevail in showing that claims 1–13 and 20–31 are unpatentable.

B. Related Proceedings

Petitioner and Patent Owner identify the following district court proceedings concerning the '765 patent: *Elekta Ltd. and William Beaumont Hospital v. Varian Medical Systems, Inc.*, Case No. 2:15-cv-12169-AC-MKM (E.D. Mich.). Pet. 1; Paper 9, 1. Petitioner and Patent Owner identify further the following *inter partes* reviews also directed to the '765 patent: IPR2016-00169 and IPR2016-00171. Pet. 1; Paper 9, 1–2. Petitioner and Patent Owner identify further the following *inter partes* reviews also directed to the U.S. Patent 6,842,502 B2 ("the '502 patent"): IPR2016-00160, IPR2016-00162, IPR2016-00163, and IPR2016-00166. Pet. 1; Paper 9, 1–2. Patent Owner identifies also the following *inter partes* review directed to U.S. Patent No. 7,826,592 B2, which claims priority to the '502 Patent: IPR2016-00187. Paper 9, 2–3.

C. The '765 Patent

The '765 patent discloses that it is directed to a cone-beam computed tomography system that employs an amorphous silicon flat-panel imager for use in radiotherapy applications where images of a patient are acquired with the patient in a treatment position on a treatment table. Ex. 1101, 1:16–21. Figure 17(b) (below) depicts a diagrammatic view of one orientation of an exemplary wall-mounted cone beam computerized tomography system employing a flat-panel imager. *Id.* at 6:48–52.



Specifically, Figure 17(b) above shows wall-mounted cone beam computerized tomography system 400 includes an x-ray source, such as x-ray tube 402, and flatpanel imager 404 mounted on gantry 406. *Id.* at 19:41–43. X-ray tube 402 generates beam of x-rays 407 in a form of a cone or pyramid. *Id.* at 19:43–56. Flat-panel imager 404 employs amorphous silicon detectors. *Id.* at 19:46–47.

D. Illustrative Claim

Petitioner challenges claims 1–13 and 20–31 of the '765 patent. Claims 1 and 20 are the only independent claims at issue, and claim 1 is reproduced below:

1. A radiation therapy system comprising:

a radiation source that moves about an object and directs a beam of radiation towards said object;

a cone-beam computed tomography system comprising:

an x-ray source that moves about said object and emits toward said object from multiple positions around said object xray beams in a cone-beam form;

a flat-panel imager positioned to receive x-rays after at least a portion of said x-ray beams pass through said object, said imager providing an image that contains three-dimensional information concerning said object based on a plurality of twodimensional projection images; and

a computer coupled to said cone-beam computed tomography system, wherein said computer receives said threedimensional information and based on said three dimensional information received controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object, wherein said receiving said x-rays by said flat panel imager is performed substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.

Ex. 1101, 28:2–24.

E. Asserted Ground of Unpatentability

Petitioner challenges claims 1–13 and 20–31 on the following ground:

References	Basis	Challenged Claims
Cho, ¹ Antonuk, ² Jaffray 1997, ³ Adler, ⁴ and Depp ⁵	§ 103(a)	1–13 and 20–31

Pet. 3.

II. ANALYSIS

A. 35 U.S.C. § 325(d)

Patent Owner argues that we should deny this Petition under § 325(d) because "the asserted ground relies on 'substantially the same' art and arguments as were cited during prosecution." Prelim. Resp. 45–47. This argument is not persuasive because the references asserted here are not the same as those cited by the Examiner during prosecution, and the Patent Owner has not shown that the references asserted here are substantially the same as the references cited by the Examiner during prosecution. Patent Owner acknowledges that the art cited before the Examiner is Roos and Swerdloff, and argues that "Petitioner's art is even more remote from the art before the Examiner." *Id.* It follows that an alleged ground of unpatentability based on Cho, Antonuk, Jaffray 1997, Adler, and Depp was not

¹ Paul S. Cho et al., *Cone-beam CT for radiotherapy applications, Physics in Medicine & Biology*, 1863–1883 (Nov. 1995) (Ex. 1105) ("Cho").

² Larry E. Antonuk et al., *Thin-film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging*, IEEE Transactions on Medical Imaging, 482–490 (Sept. 1994) (Ex. 1106) ("Antonuk").

³ D.A. Jaffray et al., "*Target Of The Day*" Strategies for A Medical Linear Accelerator With Conebeam-CT Scanning Capability, XII International Conference on the Use of Computers in Radiation Therapy, 172–174 (May 1997) (Ex. 1107) ("Jaffray 1997").

⁴ U.S. Patent No. 5,207,223, issued May 4, 1993 (Ex. 1103) ("Adler").

⁵ U.S. Patent No. 5,427,097, issued June 27, 1995 (Ex. 1104) ("Depp").

presented before the Examiner. *See id.* Patent Owner's argument that Petitioner's art is more remote is insufficient to demonstrate that the "substantially the same" art and arguments were presented before the Office. Accordingly, we decline to deny this Petition under § 325(d).

B. Claim Construction

As a step in our analysis for determining whether to institute a review, we determine the meaning of the claims for purposes of this Decision. In an *inter* partes review, a claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); see also In re Cuozzo Speed Techs., LLC, 793 F.3d 1268, 1278 (Fed. Cir. 2015) ("We conclude that Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA."), cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 890 (mem.) (2016). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. In re Translogic Tech., Inc., 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994). We must be careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. In re Van Geuns, 988 F.2d 1181, 1184 (Fed. Cir. 1993). Only terms which are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc.* v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999).

For the purposes of this Decision, the following terms requires construction.

1. "substantially at a time"

Independent claims 1, 7, 20, and 26 each recite the limitation "substantially at a time." Petitioner first asserts that "substantially at a time" is "vague in itself because it is a term of degree, and no standard for determining the scope of the claimed degree is given by the patent specification." Pet. 15. Petitioner argues that Patent Owner attempted to amend the claims, which originally recited a "small probability," with "substantially at a time" in order to provide clarity to the limitation, but rather just replaced a vague term with another vague term. *Id.* at 15–16. Patent Owner argues that the limitation "substantially at a time" informs "with reasonable certainty those skilled in the art about the scope of the invention,' when viewed in light of the specification and prosecution history." Prelim. Resp. 14–15 (quoting *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014)). Patent Owner argues that the term "substantially" does not render patent claims so unclear as to render the claims indefinite. *Id.* at 15–16.

We agree with Patent Owner. A person with ordinary skill in the art would have understood the scope of the "substantially at a time," regardless of the limitation's use of the relative term. Specifically, we are persuaded that a person of ordinary skill in the art of x-ray technology and radiation therapy would understand the metes and bounds required by "substantially at a time" based on the claim language itself. Independent claims 1, 7, 20, and 26 recite that "receiving said x-rays" occurs "substantially at a time of occurrence" of "controlling" the path of radiation. We are persuaded that a person with ordinary skill in the art would understand how close in time the "receiving" of x-rays would need to be to the "controlling" of the radiation path. Accordingly, we are not persuaded by Petitioner that the limitation "substantially at a time" would render the claims indefinite under 35 U.S.C. § 112 ¶ 2.

Petitioner argues that if "substantially at a time" does not render the claims indefinite, then "substantially at a time" should be construed to mean "substantially at the same time." Pet. 16–17. Petitioner argues, based on the Declaration of Dr. Balter, that a person of ordinary skill in the art would understand the term based on the intrinsic record. *Id.* (citing Ex. 1102 ¶ 38). Patent Owner argues that "substantially at a time," when read in light of the specification, should be construed as "the time when the patient is on the treatment table for treatment." Prelim. Resp. 18 (citing Ex. 1109, 13–14; Ex. 1101, 23:26–29). Patent Owner argues that the claims are directed to "online" image acquisition, which occurs while the patent is on the treatment. *Id.*

We are persuaded by Petitioner that "substantially at a time" should be construed to mean "substantially at the same time" based on the intrinsic evidence, and decline to restrict this limitation to being anytime when a "patient is on the treatment table for treatment," as proffered by Patent Owner. Specifically, as discussed above, independent claims 1, 7, 20, and 26 recite that "receiving said xrays" occurs "substantially at a time of occurrence" of "controlling" the path of radiation. That is, the x-rays are received at "substantially at a time" that the path of radiation is controlled. Furthermore, the '765 patent specification supports such a construction. The '765 patent discloses that "the cone beam computerized tomography image is preferably acquired with the patient on the treatment table ... immediately prior to treatment delivery." Ex. 1101, 23:26–29. The '765 patent specification further discloses that "the process is both 1) 'on-line' since the patient is on the treatment table during the process and 2) '*real-time*' since the image is acciuired [sic] substantially at the time of the treatment delivery." Id. at 23:29-33 (emphasis added). Therefore, the '765 patent specification distinguishes between "on-line," which is the patient is on the treatment table, and "real-time," which is

substantially at the time of the treatment delivery, i.e. the controlling of the radiation path. Accordingly, on this record, we are persuaded by Petitioner that "substantially at a time" should be construed to mean "substantially at the same time," where the "receiving" of the x-rays is substantially at the same time of the "controlling" of the radiation path.

2. "three-dimensional information"

Independent claims 1, 7, 20, and 26 each recite "three-dimensional information." Petitioner asserts that "three-dimensional information" should be construed as "information concerning three dimensions of an object (such as length, width, and depth)." Pet. 17 (citing Ex. 1101, 3:41–44; Ex. 1102 ¶ 39). Patent Owner disagrees, and asserts that "three-dimensional information" should be construed more narrowly as "volumetric data." Prelim. Resp. 31–35 (citing Ex. 1101, 2:44–50, 3:29–44, 9:54–56, 9:62–63, 10:66–11:2, 16:7–12, 16:24–28, 16:39–42, Fig. 14; Ex. 1102 ¶¶ 90, 135; Ex. 1103, 9:12–16). We agree with Petitioner.

We begin first with the claim language, and note that "three-dimensional information" appears facially to be co-extensive with any information relevant to three-dimensions. We discern that "length, width, and depth" are just such information. We have considered Patent Owner's above-cited portions of the '765 patent, but are unpersuaded that it narrows "three-dimensional information" with sufficient "reasonable clarity, deliberateness, and precision" such that one of ordinary skill would have understood "three-dimensional information" as co-extensive with Patent Owner's proffered construction. *In re Paulsen*, 30 F.3d at 1480. For example, column 3, lines 41–44 mentions "three-dimensional (3-D) images," which we agree would appear to require "volumetric data," however, the claim limitation at issue is the broader term "three-dimensional information." In

another example, column 9, line 62 through column 10, line 5 clearly refers to "volumetric data," but does not indicate its relation to "three-dimensional information." In a further example, column 16, lines 29–66 do not recite "threedimensional information," instead disclosing "3-D structure" and "3-D nature" in relation generally to "volumetric data," but, again, not in a manner sufficient to indicate a particular relationship. Finally, in regards to Dr. Balter's Declaration, we discern that while Dr. Balter's testimony supports the proposition that "volume data sets" and "volumetric image" clearly are "three-dimensional information," we are unpersuaded that it follows that "three-dimensional information" is limited to "volume data sets" and "volumetric image."

3. "computer" (claim 1), "controller" (claim 7), "structure" (claim 20), "support table" (claim 26)

Independent claims 1, 7, 20, and 26 recite a "computer," a "controller," a "structure," and a "support table," respectively, that "control[s] a path of said beam of radiation." Petitioner asserts that these are means-plus-function limitations that should be construed in accordance with § 112 ¶ 6. Pet. 17–24. Petitioner contends that the terms are indefinite because the '765 patent does not disclose an algorithm for programming the general purpose computer to perform the claimed function. *Id.* Petitioner contends, in the alternative, that the structure for performing the recited function is a computer performing the algorithm described at column 4, lines 56–61, column 26, lines 59–67, column 27, lines 16–57, and depicted in Figures 24 and 26. *Id.*

Patent Owner argues that the limitations of claims 1, 7, and 26 do *not* invoke § 112 ¶ 6. Prelim. Resp. 19–23. Patent Owner contends that claims 1 and 7 describe a computer or controller and its connections with other components. *Id.* at 20–21. Patent Owner also argues that claim 26 describes a support table. *Id.* at 21. Patent Owner argues that these claims have sufficient structure. *Id.* at 20–23.

Patent Owner argues, in the alternative, that even if the limitation is construed under § 112 ¶ 6, the '765 patent discloses an algorithm for performing the recited function. *Id.* at 22–23.

On this record, we are not persuaded that claims 1, 7 and 26 recite a meansplus-function limitation that should be construed in accordance with § 112 ¶ 6. "The standard is whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (citing *Greenberg v. Ethicon Endo-Surgery, Inc*, 91 F.3d, 1580, 1583 (Fed. Cir. 1996)); *Greenberg*, 91 F.3d at 1583 ("What is important is . . . that the term, as the name for structure, has a reasonably well understood meaning in the art."). When, as here, a claim term lacks the word "means," "the presumption can be overcome and § 112 [¶] 6 will apply if the challenger demonstrates that the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function."" *Williamson*, 792 F.3d at 1349 (citing *Watts v. XL Sys., Inc.,* 232 F.3d 877, 880 (Fed. Cir. 2000)).

Petitioner asserts that "[t]his purely functional computer term is not a description of structure, and no structure for performing the claimed function is recited elsewhere in the claim." Pet. 17–23. Petitioner does not, however, provide any further analysis, evidence, or testimony to support its assertion, or even cite a case in which the term "computer," "controller," and "support table" have been construed as a means-plus-function limitation. *Id*.

On this record, and for purposes of this Decision, we are not persuaded that the term "computer" fails to recite sufficiently definite structure. As a result, we decline to construe this limitation as a means-plus-function limitation in accordance with § $112 \$ 6.

Claim 20 recites a "structure." Petitioner argues that there is "insufficient structure . . . provided for performing the claimed function of beam control [relative to the patient] based on the 3-D information obtained from the CBCT system." Pet. 21–22. Petitioner argues, in the alternative, that "should the Board conclude the term is not indefinite under § 112(6), then this 'structure for controlling' element should be construed as a means-plus-element, whose structure includes an algorithm based on the meager functional restatements provided in the specification." *Id.* at 22. (citing Ex. 1101, 4:56–61, 26:59–67, 27:16–57, Figs. 24, 26). Patent Owner does not dispute that claim 20 invokes § 112 ¶ 6. Patent Owner argues that the '765 patent specification provides the corresponding structure for the alleged functions and further provides such an algorithm. Prelim. Resp. 22–23 (citing Ex. 1101, 2:25–31, 16:66–17:3, 26:59–67, 27:16–57).

We disagree with Petitioner that claim 20 is indefinite, but rather agree with both Petitioner and Patent Owner that the '765 patent specification adequately provides support for the claimed "structure." The '765 patent specification provides a computer for performing the recited function steps. *See* Ex. 1101, Fig. 4 (element 328), 8:27–40. As noted by both Petitioner and Patent Owner, the '765 patent further provides an algorithm for performing the functional steps recited. *See id.* at 26:59–67, 27:16–57. Accordingly, we do not agree with Petitioner that claim 20 is indefinite.

C. Claims 1–13 and 20–31 – Obviousness over Cho, Antonuk, Jaffray 1997, Adler, and Depp

Petitioner asserts that a combination of Cho, Antonuk, Jaffray 1997, Adler, and Depp renders obvious claims 1–13 and 20–31. Pet. 31–59. Patent Owner disagrees. Prelim. Resp. 26–45.

1. Cho

Cho describes a cone-beam CT system for radiotherapy applications and an algorithm used therein to permit an increased reconstruction volume to be imaged using a detector of a given size. Ex. 1105, Abstract. The system described in Cho is a digital spot imager (*id.* at 6), but Cho also describes the use of a flat panel detector for real-time diagnostic X-ray imaging (*id.* at 24 (citing Antonuk)). Cho describes generating a 3-D image "by rotating the gantry over 360° at approximately 1° increments." *Id.* at 15; *id.* at 9, 16–17.

2. Antonuk

Antonuk describes "Thin-Film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging." Ex. 1106, Title. Specifically, Antonuk describes how "[t]he recent development of large-area, flat-panel a-Si:H imaging arrays is generally expected to lead to real-time diagnostic and megavoltage x-ray projection imagers with film-cassette-like profiles." *Id.* at Abstract. According to Antonuk, "[t]he construction, operation, and properties of the arrays have been extensively reported." *Id.* at 3. "It is widely perceived that part of the solution is to obtain imaging information with the portal beam immediately prior to and/or during the treatment." *Id.* at 5. "Toward this aim of patient verification, a variety of real-time megavoltage imaging devices, including our a-Si:H imager, have been developed over the last decade." *Id.* "This composite imager would be positioned behind the patient in the middle of the megavoltage radiation field during imaging." *Id.* at 6, Fig. 5. In an alternative configuration, "[s]everal a-Si:H x-ray detectors rotate with an x-ray tube collecting conebeam projection data inside the bore of a PET machine." *Id.* at 8.

3. Jaffray 1997

Jaffray 1997 describes "a conebeam-computed tomography (CB-CT) scanner for installation on our medical linear accelerator." Ex. 1107, 4. A schematic of the dual-beam imaging system is shown in Figure 1 below of Jaffray 1997.



Id. at 5. As shown in Figure 1, "[t]wo fluoroscopic imaging systems are attached to a Philips SL-20 medical linear accelerator; one detects the megavoltage image, the other a kV image produced with a kV beam projected at 90° to the treatment beam axis." *Id.* at 4. Jaffray 1997 states that the "gantry is rotated continuously" in order to generate a "conebeam imaging sequence consist[ing] of ~100 exposures over 194° of rotation." *Id.* at 5.

4. Adler

Adler teaches an apparatus and method for extending a surgical instrumentality to a target region in a patient, for example, for performing stereotaxic surgery using an x-ray linear accelerator. Ex. 1103, 1:6–10. Specifically, Adler teaches that a 3-dimensional mapping of a mapping region of at least a portion of a living organism is prepared. *Id.* at 3:64–68. First and second

diagnostic beams are then passed through the mapping region, and are used to produce respective first and second images of respective first and second projections within the mapping region. *Id.* at 4:5–10. Adler then teaches that the 3-dimensional mapping and the first and second images are compared to derive therefrom data representative of a real-time location of a target portion of the mapping region. *Id.* at 4:41–46. Adler teaches further "adjusting the relative position of the beaming apparatus 20 and the patient 14 as needed in response to data which is representative of the real time location of the target region 18." *Id.* at 7:37–40 (emphasis omitted).

5. Depp

Depp teaches an apparatus for and method of carrying out stereotaxic radiosurgery and/or radiotherapy on a particular target region within a patient utilizing previously obtained reference data indicating the position of the target region with respect to its surrounding area which also contains certain nearby reference points. Ex. 1104, 1:6–12. Depp further teaches the following:

The apparatus also utilizes a pair of diagnostic beams of radiation or target locating beams, as they will be referred to in this discussion. These beams are passed through the surrounding area containing the target region and reference points and, after passing through the surrounding area, contain data indicating the positions of the reference points within the surrounding area. This position data is collected by cooperating detectors, as described previously, and delivered to the multiprocessor computer where the latter compares it with previously obtained reference data for determining the position of the target region with respect to each of the reference points during each such comparison. The radiosurgical beam is accurately directed into the target region in substantially real time based on this information.

Id. at 11:46–61.

6. Analysis

Petitioner asserts that a combination of Cho, Antonuk, Jaffray 1997, Adler, and Depp renders obvious claims 1–13 and 20–31. Pet. 31–59. For example, claim 1 recites "[a] radiation therapy system." Petitioner argues that Adler and Depp disclose a system for radiotherapy that is configured for selectively irradiating a target within a patient. *Id.* at 31–32 (citing Ex. 1103, Abstract, 3:62– 68; Ex. 1104, Abstract, 1:6–12, 1:18–26; Ex. 1102 ¶¶ 64–65). Petitioner further argues that Antonuk and Jaffray 1997 also disclose radiotherapy systems using a medical linear accelerator device. *Id.* at 32.

Claim 1 further recites "a radiation source that moves about an object and directs a beam of radiation towards said object." Petitioner argues that Adler/Depp discloses that the beaming apparatus can be adjusted such that the collimated beam is continuously focused on the target region. *Id.* at 32–33 (citing Ex. 1103, 7:52–58; Ex. 1104, 5:25–31). Petitioner further argues that Jaffray 1997 and Antonuk disclose the use of a radiation source. *Id.* at 33 (citing Ex. 1107, 4; Ex. 1106, 3, 5).

Claim 1 also recites "a cone-beam computed tomography system comprising: an x-ray source that moves about said object and emits toward said object from multiple positions around said object x-ray beams in a cone-beam form." Petitioner argues that Cho discloses a cone-beam computed tomography ("CBCT") system that generates a 3-D image by rotating an x-ray source around an object. *Id.* at 33–34 (citing Ex. 1105, 15). Petitioner further argues that Jaffray 1997 discloses a cone beam CT apparatus that uses a linear accelerator that obtains 3-D information from a plurality of 2-D projection images by rotating the gantry around a patient. *Id.* at 34 (citing Ex. 1107, 4–5). Petitioner further argues, applying the testimony of Dr. Balter, that Antonuk discloses an x-ray source that

emits beams in a con-beam geometry. Pet. 34–35 (citing Ex. 1106, Fig. 5; Ex. 1102 \P 72).

Claim 1 additionally recites "a flat-panel imager positioned to receive x-rays after at least a portion of said x-ray beams pass through said object, said imager providing an image that contains three-dimensional information concerning said object based on a plurality of two-dimensional projection images." Petitioner argues that Cho discloses an amorphous silicon flat panel imager ("FPI") that detects cone-beam x-ray projection images, and Cho specifically references to Antonuk for its FPI. Id. at 35 (citing Ex. 1105, 24). Petitioner then argues that Antonuk discloses flat panel imagers as diagnostic x-ray detectors mounted on a linear accelerator for imaging during radiotherapy. Id. (citing Ex. 1106, 3). Petitioner argues, as explained by Dr. Balter, the FPI devices detect multiple x-ray beams that pass through an object being imaged, and each FPI receives a plurality of 2-D x-rays. Id. at 35–36 (citing Ex. 1106, Fig. 5; Ex. 1102 ¶¶ 58, 73–74). Petitioner argues that Adler/Depp disclose obtaining two x-ray images at a known angle relative to one another, and, therefore, providing three-dimensional information about the imaged object. Id. at 36–37 (citing 1103, 7:6–12, 7:17–23; Ex. 1102 ¶ 75).

Claim 1 further recites:

a computer coupled to said cone-beam computed tomography system, wherein said computer receives said three-dimensional information and based on said three dimensional information received controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object, wherein said receiving said x-rays by said flat panel imager is performed substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.

Petitioner argues that Adler discloses a computer, coupled to the x-ray system, that receives three-dimensional information, as discussed above, and adjusts the

position of the radiation beam in response to the real-time three-dimensional location information of the target. Pet. 37–38 (citing Ex. 1103, 7:37–40). Petitioner argues that the radiation source is adjusted in the gantry or by moving the patient table. *Id.* at 38 (citing Ex. 1103, 7:42–58). Petitioner further argues that Depp discloses the use of diagnostic beams that pass through target region and surrounding area, and then contain data indicating the position of the target. *Id.* at 39 (citing Ex. 1104, 11:46–61). The substantially real time position data is used to direct the radio surgical beam to the target region. *Id.* (citing Ex. 1104, 11:46–61).

For a rationale to modify Cho, Antonuk, Jaffray 1997, Adler, and Depp in view of each other, Petitioner sets forth such a rationale on pages 46–50 of the Petition. Petitioner performs a similar analysis for dependent claims 2–6, 8–13, 21–25, and 27–31. *Id.* at 50–59.

Patent Owner argues that "Cho employs a digital spot detector imager (not a flat panel imager)." Prelim. Resp. 28–30. Petitioner, however, relies upon not only Cho, but also Antonuk, which explicitly teaches a flat-panel imager. *See* Pet. 35–37.

Patent Owner also argues that "Cho does not disclose use of a flat panel imager imaging system *on a linear accelerator for online image guided radiation therapy*" (Prelim. Resp. 28) (emphasis added) because the CBCT system in Cho is being used with "a radiotherapy simulator (not a linear accelerator) to perform cone beam CT for treatment planning (not for image guided radiation therapy)" *(id.).* Patent Owner's arguments are not commensurate with the scope of the claims, which do not recite a linear accelerator for image guided radiation therapy. To the extent Patent Owner is arguing that Cho does not disclose the "radiation therapy system" recited in the preamble or the "radiation source" recited in claim

1, that argument is not persuasive because Petitioner relies upon Adler, Depp, Antonuk, and Jaffray 1997, not Cho, to teach those limitations. *See* Pet. 31–32.

Patent Owner also argues that "Antonuk does not use cone beam computed tomography in any context," and "does not disclose capturing any 3-D images; he only discloses using 2-D images for guiding treatment." Prelim. Resp. 29. Again, Patent Owner's arguments are not persuasive because Petitioner relies upon Cho and Jaffray 1997, not Antonuk, for teaching those limitations. *See* Pet. 36–37.

Patent Owner also argues that Jaffray 1997 "likewise provides no disclosure of a flat panel imager for image guided radiation therapy." Prelim. Resp. 30. Again, Patent Owner's arguments are not persuasive because Petitioner relies upon Cho and Antonuk, not Jaffray 1997, for teaching the flat panel imager, and upon Adler and Depp, not Jaffray 1997, for teaching a radiation therapy system. *See* Pet. 35–37.

Patent Owner asserts that Petitioner has not shown that the cited references disclose "control[ling] a path of said beam of radiation . . . by controlling a relative position" either "based on" (claims 1 and 20) or "in response to" (claims 7 and 26) "three dimensional information," because Adler/Depp's imager "creates two flat, two-dimensional pictures that contain no volumetric data." Prelim. Resp. 35–39. As an initial matter, we note that we construed "three dimensional information" as "information concerning three dimensions of an object (such as length, width, and depth)," not as "volumetric data." Moreover, Patent Owner's assertions are unpersuasive because Petitioner is proposing a combination that replaces the two flat, two-dimensional pictures of Adler with the volumetric image of Cho and Jaffray 1997. Specifically, Petitioner asserts the following:

One of skill in the art would be motivated to combine the Cho, Antonuk, and Jaffray 1997 references with Adler/Depp because all the references are in the same field of medical imaging in conjunction with radiation

therapy and all are concerned with the problem of obtaining accurate 3-D information about the internal structure of objects like patients. (*See* Adler, 1:6-18; Depp, 1:6-18; Cho, at 5; Antonuk, at 3, 5; Jaffray 1997, at 4; *see also* Ex. 1102, ¶ 91.) As explained by Dr. Balter, the results obtained by the inventors (obtaining 3-D image information concerning target lesions in patients for the purpose of targeting the radiation beam) were the predictable work of combining the CBCT-FPI system of the Cho and Antonuk references with the radiotherapy systems of Adler/Depp. (*See* Ex. 1102, ¶¶ 86-91.)

Pet. 49–50. We have considered Petitioner's proffered rationale in light of Patent Owner's assertions, and, on this record, determine they are persuasive. In particular, Adler teaches a 3-dimensional mapping, and we are persuaded that comparing that 3-dimensional mapping with another 3-dimensional mapping, as disclosed in Cho and Jaffray 1997, would be preferable to the two flat, twodimensional pictures of Adler.

Patent Owner asserts further that Adler does not disclose "adjusting a patient's position to correct for any shift in the target's location relative to surrounding tissues after treatment planning images are acquired." Prelim. Resp. 36–39. Patent Owner's assertions are misplaced, as the relevant limitation of independent claim 1 is not so narrow, instead reciting "said computer . . . based on said three dimensional information received controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object." To that end, Petitioner argues that Adler teaches "adjusting the relative positions of the beaming apparatus 20 and the patient 14 as needed in response to data which is representative of the real time location of the target region 18." Pet. 37–38 (citing Ex. 1103, 7:37–40) (emphasis omitted). Petitioner also argues that Depp discloses the use of diagnostic beams that pass through target region and surrounding area, and then contain data indicating the position of the target. *Id.* at 39 (citing Ex. 1104, 11:46–61).

Patent Owner asserts additionally that Petitioner's representations concerning Adler and Depp are inconsistent with Petitioner's conduct during prosecution of Petitioner's patents. Prelim. Resp. 38–39. Patent Owner's assertions are misplaced, as our focus here is not on Petitioner's conduct in other proceedings, but what the references themselves disclose or suggest relative to the challenged claims of the '765 patent.

Patent Owner asserts also that the Petition should be denied because Petitioner confusingly cites multiple references for the same claim limitation, without explaining explicitly how those multiple references are to be modified in view of each other, as required to make a showing of obviousness. *Id.* at 40–42. Patent Owner represents that such a format is a violation of Board rules, and that the Petition should be denied on that basis. *Id.* Although we agree with Patent Owner that Petitioner's citation format is not a best practice, on this record, we are unpersuaded that it is so incomprehensible or confusing as to warrant a denial of institution on that basis. To be sure, if the citation of multiple references for a particular claim limitation causes such confusion that it is unclear whether that claim limitation is met, such confusion should be held against Petitioner. On this record, however, Patent Owner has not identified, and we are unable to ascertain independently, any particular claim limitation for which such confusion exists.

In essence, we discern that Petitioner has taken the general structural framework of Adler and, where Adler teaches comparing two flat, twodimensional pictures to its 3-dimensional mapping in order to control a path of the radiation source, Petitioner has replaced those two flat, two-dimensional pictures with the volumetric images from Cho and Jaffray 1997. On this record, we are persuaded that Petitioner has made that proposed combination with adequate clarity.

Patent Owner further argues that "Petitioner also articulates no rational basis for why it would have been obvious to combine any particular elements of the cited references to achieve the claimed invention with all its limitations." Prelim. Resp. 42–45. We are not persuaded by Patent Owner. Petitioner argues that all of the references are in the field of medical imaging in conjunction with radiation therapy, and are all concerned with obtaining accurate 3-D information about the internal structure of objects. Pet. 47–50. Petitioner argues that the combination of the references results in the benefit of obtaining precise and accurate location of targeted areas for radiation. *Id.* Petitioner also argues that Dr. Balter explains that the results of the combination of these references was predictable. *Id.* (citing Ex. 1102 ¶¶ 86–91). On this record, we are not persuaded by Patent Owner that Petitioner has not provided a sufficient basis with a rational underpinning for combining the cited prior art.

Patent Owner asserts that Dr. Balter's Declaration largely parrots conclusory statements made in the Petition and should be afforded little or no weight. Prelim. Resp. 47–48. We disagree. To the extent that Dr. Balter does repeat *verbatim* a specific conclusory assertion set forth in the Petition that does not have sufficient underlying facts or rational underpinnings, we agree that assertion should be given little or no weight. We decline, however, to conclusorily extend that determination to the entirety of Dr. Balter's Declaration. Furthermore, we have reviewed certain portions of Dr. Balter's Declaration that were deemed relevant to our analysis herein, and are unpersuaded that they are so conclusory or lacking in support or analysis as to be accorded no weight. Patent Owner will certainly have further opportunities to challenge portions of Dr. Balter's Declaration as lacking adequate support, to cross-examine Dr. Balter, and to present its own contrary evidence and assertions, upon institution of trial.

Patent Owner asserts further that Petitioner presents numerous other Exhibits 1114–1135 that are not referenced in the Petition, and which Petitioner only presents in a section of Dr. Balter's Declaration labelled "additional exhibits (Exs. 1112-1135)" to "Dr. Balter's declaration," and spanning paragraphs 115–143 of Dr. Balter's Declaration. Prelim. Resp. 48–49. Patent Owner asserts that Petitioner should not be permitted to rely on these references in this proceeding. *Id.* We agree. Insofar as Petitioner may attempt to use any of these references to *fill in* any *gap* in the Petition that has been or will be identified by Patent Owner, we determine that Petitioner is prohibited expressly from doing so.

7. *Conclusion*

On this record, we are persuaded that Petitioner has shown a reasonable likelihood that claims 1–13 and 20–31 are obvious over a combination of Cho, Antonuk, Jaffray 1997, Adler, and Depp.

D. Conclusion

For the foregoing reasons, we are persuaded that Petitioner has met its burden of showing a reasonable likelihood that claims 1–13 and 20–31 of the '765 patent are unpatentable.

III. ORDER

After due consideration of the record before us, and for the foregoing reasons, it is:

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted as to the proposed ground of obviousness of claims 1–13 and 20– 31 over Cho, Antonuk, Jaffray 1997, Adler, and Depp.

FURTHER ORDERED that no other grounds are instituted; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '765 patent is hereby instituted commencing on the entry date of this

Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

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