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 IPR2016-00166 Patent 6,842,502 B2

> > _____

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

CLEMENTS, 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 43–46, 48–55, 57, 59–66, and 68 of U.S. Patent No. 6,842,502 B2 (Ex. 1301, "the '502 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 43–46, 48–55, 57, 59–66, and 68 are unpatentable.

B. Related Proceedings

Petitioner and Patent Owner identify the following district court proceedings concerning the '502 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 '502 Patent: IPR2016-00160, IPR2016-00162, and IPR2016-00163. Pet. 1; Paper 9, 2. Patent Owner identifies additionally the following *inter partes* reviews directed to U.S. Patent No. 7,471,765 B2, which claims priority to the '502 Patent: IPR2015-00169, IPR2016-00170, and IPR2016-00171. Paper 9, 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, 3.

C. The '502 Patent

The '502 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. 1301, 1:11–17. 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. Ex. 1301, 6:53–56.



Specifically, Figure 17(b) depicts wall-mounted cone beam computerized tomography system 400 includes an x-ray source, such as x-ray tube 402, and flat-panel imager 404 mounted on gantry 406. Ex. 1301, 19:64–67. X-ray tube 402 generates beam of x-rays 407 in a form of a cone or pyramid. Ex. 1301, 19:67–20:2. Flat-panel imager 404 employs amorphous silicon detectors. Ex. 1301, 20:6–7.

D. Illustrative Claims

Petitioner challenges claims 43–46, 48–55, 57, 59–66, and 68 of the '502 Patent. Claims 43 and 60 are the only independent claims at issue, and are reproduced below:

43. A method of treating an object with radiation, comprising:

move a radiation source about a path;

direct a beam of radiation from said radiation source towards an object;

emitting an x-ray beam in a cone beam form towards an object;

detecting x-rays that pass through said object due to said emitting an x-ray beam with a flat-panel imager;

generating an image of said object from said detected x-rays,

wherein said generating comprises forming a computed tomography image of said object based on said detected x-rays,

wherein said image contains at least three dimensional information of said object based on one rotation of said x-ray source around said object; and

controlling said path of said radiation source based on said image.

60. A method of treating an object with radiation, comprising:

move a radiation source about a path;

direct a beam of radiation from said radiation source towards an object;

emitting an x-ray beam in a cone beam form towards an object;

detecting x-rays that pass through said object due to said emitting an x-ray beam with a flat-panel imager; generating an image of said object from said detected xrays,

wherein said generating comprises forming a computed tomography image of said object based on said detected x-rays,

wherein said image contains at least three dimensional information of said object based on one rotation of said x-ray source around said object; and

controlling a radiation therapy treatment plan involving said radiation source based on said image.

E. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–14, 16–29, 33, and 35–38 on the

following grounds.

Reference (s)	Basis	Challenged Claims
Cho, ¹ Antonuk, ² Jaffray 1997, ³ Adler, ⁴ and Depp ⁵	§ 103(a)	43–46, 48–55, 57, and 59

¹ P.S. Cho et al., *Cone-beam CT for radiotherapy applications*, Phys. Med. Biol., 40:1863-83 (1995) (Ex. 1305, "Cho").

² L.E. Antonuk et al., *Thin-Film, Flat-Panel, Composite Imagers for Projection and Tomographic Imaging*, IEEE Transactions on Medical Imaging, 13:482-90 (1994) (Ex. 1306, "Antonuk").

³ D.A. Jaffray et al., *Exploring "Target Of The Day" Strategies for A Medical Linear Accelerator With Conebeam-CT Scanning Capability*, Proceedings of the 12th International Conference on the Use of Computers in Radiation Therapy, Medical Physics Publishing, pp. 172-75 (1997) (Ex. 1307, "Jaffray 1997")

⁴ U.S. Patent No. 5,207,223, issued May 4, 1993 (Ex. 1303, "Adler").

⁵ U.S. Patent No. 5,427,097, issued June 27, 1995 (Ex. 1304, "Depp").

Reference(s)	Basis	Challenged Claims
Cho, Antonuk, Jaffray 1997, Adler, and Depp, and Yan ⁶	§ 103(a)	60–66 and 68

II. ANALYSIS

A. § 325(d)

Patent Owner argues that we should deny this Petition under § 325(d) because "the asserted grounds rely on 'substantially the same' art and arguments as were cited during prosecution." Prelim. Resp. 43. 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 also argues that "this Petition is the second of two Petitioner filed on the same day challenging the same claims of the '502 patent." Prelim. Resp. 45. This Petition, however, is based upon a combination of Cho, Antonuk, Jaffray 1997, Adler, and Depp, whereas the ground asserted in the other petition is based upon a combination of Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp. Patent Owner has not shown sufficiently that the teachings of Cho, Antonuk, and Jaffray 1997 are "substantially the same" as the teachings of Jaffray 1999 SPIE and Jaffray 1999 JRO. Moreover, Cho, Antonuk, and Jaffray 1997 are prior art under 35 U.S.C. § 102(b), whereas the prior art status of Jaffray 1999 SPIE and Jaffray 1999 JRO is in dispute

⁶ A.L. Boyer, *Laser "cross-hair" sidelight*, Med. Phys., 5:58-60 (1978) (Ex. 1308, "Boyer")

in the other proceeding. For all of the foregoing reasons, 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 that 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, only the following terms require construction.

1. "three-dimensional information"

Independent claims 43 and 60 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. 13–14 (citing Ex. 1301, 3:40–43; Ex. 1302 ¶ 37). Patent Owner disagrees, and asserts that "three-dimensional information" should be construed more narrowly as "volumetric data." Prelim. Resp. 19–23 (citing Ex. 1301, 2:42–48, 3:30–43, 9:62–64, 10:3–5, 11:9–12, 16:27–63, 31:17–21, Fig. 14; Ex. 1302 ¶¶ 59–61; Ex. 1303, 9:12–16; Ex. 1311). We agree with Petitioner.

We begin first with the claim language, and note that "threedimensional 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 '502 Patent, but are unpersuaded that those portions narrow "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 40–43, 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 27– 63, does not recite "three-dimensional 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."

C. Claims 43–46, 48–55, 57, and 59 – 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 43–46, 48–55, 57, and 59. Pet. 15– 47. Patent Owner disagrees. Prelim. Resp. 15–47.

1. Cho

Cho describes a cone-beam CT system for radiotherapy applications, and algorithm used therein to permit an increased reconstruction volume to be imaged using a detector of a given size. Ex. 1305, 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. 1306, 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 mega voltage 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 mega voltage 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. 1307, 4. A schematic of the dual-beam imaging system is shown in Figure 1 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. 1303, 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. Ex. 1303, 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. Ex. 1303, 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. Ex. 1303, 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." Ex. 1303, 7:37–40.

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. 1304, 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.

Ex. 1304, 11:46-61.

6. Analysis

Petitioner asserts that a combination of Cho, Antonuk, Jaffray 1997, Adler, and Depp renders obvious claims 43–46, 48–55, 57, and 59. Pet. 15– 47. For example, independent claim 43 recites "move a radiation source about a path; [and] direct a beam of radiation from said radiation source towards an object." Petitioner cites Adler for teaching beaming apparatus 20 performing stereotaxic surgery using an x-ray linear accelerator, and cites Antonuk and Jaffray 1997 for teaching medical linear accelerators. Pet. 25– 26. Independent claim 43 also recites "emitting an x-ray beam in a cone beam form towards an object; detecting x-rays that pass through said object due to said emitting an x-ray beam with a flat-panel imager; [and] generating an image of said object from said detected x-rays, wherein said generating

comprises forming a computed tomography image of said object based on said detected x-rays." Petitioner cites Cho and Jaffray 1997 for disclosing CBCT x-ray systems, cites Cho and Antonuk for teaching a flat panel imager for receiving diagnostic x-rays, and cites Cho and Jaffray 1997 for generating a 3-D image CT images based on the detected x-rays. Pet. 26-29. Independent claim 1 also recites "wherein said image contains at least three dimensional information of said object based on one rotation of said xray source around said object." Petitioner cites Cho for disclosing that "[t]he projection data were obtained by rotating the gantry over 360° at approximately 1° increments," and for disclosing a modified Feldkamp algorithm for reconstructing the projection data into a 3-D image Pet. 29–30 (quoting Ex. 1305, 15); Ex. 1305, 22 ("data were available through a full 360° rotation."). Finally, independent claim 43 recites "controlling said path of said radiation source based on said image." Petitioner cites Adler for disclosing the comparing of a previously obtained 3-dimensional mapping with newly acquired first and second images, and then adjusting patient treatment based on that comparison. Pet. 30–33. 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 33–37 of the Petition. Petitioner performs a similar analysis for dependent claims 44–46, 48–55, 57, and 59.

Patent Owner argues that "Cho employs a digital spot detector imager (not a flat panel imager)." Prelim. Resp. 15–16. Petitioner, however, relies upon not only Cho, but also Antonuk, which explicitly teaches a flat-panel imager. *See* Pet. 28–29.

Patent Owner also argues that "Cho does not disclose use of a flat panel imager *on a linear accelerator for image guided radiation therapy*" (Prelim. Resp. 16) (emphasis added) because the CBCT system in Cho is being used with "a radiotheraphy 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 source" recited in claim 1, that argument is not persuasive because Petitioner relies upon Adler and Depp, not Cho, to teach that limitation. *See* Pet. 25.

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. 16–17. Again, Patent Owner's arguments are not persuasive because Petitioner relies upon Cho and Jaffray 1997, not Antonuk, for teaching these limitations. *See* Pet. 30–31.

Patent Owner also argues that Jaffray 1997 "likewise provides no disclosure of a flat panel imager for image guided radiation therapy." Prelim. Resp. 17. Again, Patent Owner's arguments are not persuasive because Petitioner relies upon Antonuk, not Jaffray 1997, for teaching the flat panel imager (*see* Pet. 28–29), and upon Adler and Depp, not Jaffray 1997, for teaching a radiation therapy system (*see id.* at 23–24).

Patent Owner asserts that "Petitioner has not shown that the cited references disclose controlling the path of the radiation source 'based on' an image that 'contains three dimensional information,'" (Prelim. Resp. 19)

because Adler's imager "creates two flat, two-dimensional pictures that contain no volumetric data" (*id.* at 23). 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, twodimensional 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.) 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 source) 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. 1302, ¶¶ 65–68.)

Pet. 36. We have considered Petitioner's proffered rationale in light of Patent Owner's assertions, and, on this record, determine Petitioner's proffered rationale is persuasive. In particular, Adler teaches a 3dimensional mapping, and we are persuaded that comparing that 3dimensional mapping with another 3-dimensional mapping, as disclosed in Cho and Jaffray 1997, would be preferable to the two flat, two-dimensional 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. 24. Patent Owner's assertions are misplaced, as the relevant limitation of independent claim 43 is not so narrowly directed to "shift correction," instead reciting "controlling said path of said radiation source based on said image." To that end, Adler discloses "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." Ex. 1303, 7:37–40.

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. 26–27. 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 '502 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. Prelim. Resp. 36–38. 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, twodimensional 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 asserts that Dr. Balter's Declaration largely parrots conclusory statements made in the Petition and should be afforded little or no weight. Prelim. Resp. 45–46. 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 1315–1335 that are not referenced in the Petition, and which

Petitioner only presents in a section of Dr. Balter's Declaration labelled "Additional Prior Art Demonstrating Obviousness of the Claims," and spanning paragraphs 98–125. Prelim. Resp. 47. Patent Owner asserts that Petitioner should not be permitted to rely on these references in this proceeding. 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 43–46, 48–55, 57, and 59 are obvious over a combination of Cho, Antonuk, Jaffray 1997, Adler, and Depp. Patent Owner disagrees. Prelim. Resp. 28–52

D. Claims 60–66 and 68 – Obviousness over Obviousness over Cho, Antonuk, Jaffray 1997, Adler, Depp, and Yan

Petitioner asserts that a combination of Cho, Antonuk, Jaffray 1997, Adler, Depp, and Yan renders obvious claims 60–66 and 68. Pet. 47–50. Patent Owner disagrees. Prelim. Resp. 27–36.

1. Yan

Yan discloses its purpose as the following:

Adaptive Radiation Therapy (ART) is a feedback treatment process that optimizes a patient's treatment according to the patient specific information measured during the course of treatment. Utilizing an electronic portal imaging device (EPID) and a computer-controlled multileaf collimator (MLC), the ART process is currently being implemented in our clinic to improve the treatment accuracy by compensating for the treatment setup error. Ex. 1308, 7. Yan discloses treating patients using conventional external beam therapy, which was planned using either a two-dimensional (2D) or a three-dimensional (3D) planning system. *Id.* at 8. Daily portal images were taken and used to identify errors in the treatment plan. *Id.* at 9. Yan discloses further using a closed-loop treatment process to apply patient specific information measured during a treatment course to reevaluate and reoptimize the treatment plan. *Id.* at 11. According to Yan, an optimal way to implement this feedback process integrates new technologies such as a 3D treatment planning system, an on-line imaging device, and MLC through an information and control network. *Id.* at 11.

2. Analysis

Petitioner asserts that a combination of Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, Depp, and Yan renders obvious claims 60–66 and 68. Pet. 47–50. Specifically, Petitioner relies on its analysis of independent claim 43, as set forth *supra*, for the bulk of its analysis of independent claim 60, and then identifies the only substantive difference between independent claim 43 and independent claim 60 as the recitation of the following limitation in independent claim 60: "controlling a radiation therapy treatment plan involving said radiation source based on said image." For that limitation, Petitioner cites Yan for disclosing reevaluating and reoptimizing a treatment plan based on feedback data, for example, from errors identified using analysis of daily portal images. Pet. 48–49. For a rationale to modify Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, Depp, and Yan in view of each other, Petitioner sets forth such a rationale on pages 33–37 and 50 of the Petition. Petitioner performs a similar analysis for dependent claims 61–66 and 68. Pet. 49.

Patent Owner asserts that Yan does not disclose "controlling a radiation therapy treatment plan involving said radiation source based on said image," "wherein said image contains at least three dimensional information of said object," as recited in independent claim 60, because Yan uses only two-dimensional daily portal images that contain no volumetric data. Prelim. Resp. 28–31. Our analysis here is analogous to that set forth above with respect to similar assertion made by Patent Owner concerning Adler, and need not be repeated here.

Patent Owner asserts further that Yan does not disclose both "a beam of radiation" and "an x-ray beam," as recited in independent claim 60. Prelim. Resp. 31–32. Patent Owner's assertions are misplaced, as beaming apparatus 20 of Adler is cited as corresponding to the recited "beam of radiation," and the CBCT x-ray system of Cho and Jaffray 1997 is cited as corresponding to the recited "x-ray beam."

Patent Owner asserts additionally that Yan does not teach "wherein said object is located at a single position during said emitting and said detecting and remains at said position during said controlling," as recited in independent claim 68. Prelim. Resp. 32–34. Patent Owner's assertions are misplaced, as Adler is cited as disclosing this claim limitation.

Furthermore, with respect to dependent claim 68, Patent Owner asserts that Petitioner's proffered combination of Yan and Adler/Depp is insufficient to meet this claim limitation because Petitioner has not set forth a sufficient rationale for modifying Yan and Adler/Depp with regards to the exact limitation recited in dependent claim 68, as opposed to the combination of Yan and Adler/Depp generally. Prelim. Resp. 35–36. Specifically, according to Patent Owner, Yan alone is cited for the recited

treatment plan, and Adler alone is cited for the recited single position, and, thus, Petitioner must account explicitly for the connection between these two disclosures in order to meet dependent claim 68. While Patent Owner's assertion has some merit, on this record, we are persuaded that Petitioner has articulated a sufficient rationale. In particular, with regards to similarly worded dependent claims 55 and 57, which Petitioner cited to in addressing dependent claims 66 and 68, Petitioner cites Adler for disclosing that "[g]enerally, it is preferable to keep the patient 14 relatively stationary and to move the gantry 40." Pet. 46 (Ex. 1203, 7:59–61). Although this citation is more directed to cautioning against moving the patient during imaging, on this record, we are unpersuaded that one of ordinary skill would not have made the same realization for treatment. Insofar as Patent Owner is asserting that Yan does not disclose the reevaluating and reoptimizing being done in real-time, Patent Owner's assertions are misplaced, as Petitioner cites Adler and Depp for that aspect.

All other assertions made by Patent Owner concerning this ground of unpatentability have been addressed *supra* with respect to the other asserted ground of unpatentability, and need not be repeated here.

3. Conclusion

On this record, we are persuaded that Petitioner has shown a reasonable likelihood that claims 60–66 and 68 are obvious over a combination of Cho, Antonuk, Jaffray 1997, Adler, Depp, and Yan.

E. Conclusion

For the foregoing reasons, we are persuaded that Petitioner has met its burden of showing a reasonable likelihood that claims 43–46, 48–55, 57, 59–66, and 68 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 following grounds:

- Claims 43–46, 48–55, 57, and 59 of the '502 Patent as unpatentable under 35 U.S.C. § 103(a) over a combination of Cho, Antonuk, Jaffray 1997, Adler, and Depp;
- Claims 60–66 and 68 of the '502 Patent as unpatentable under 35 U.S.C. § 103(a) over a combination of Cho, Antonuk, Jaffray 1997, Adler, Depp, and Yan; and

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 '502 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.

PETITIONER:

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