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Paper 14
Entered: May 6, 2016

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 IPR2016-00160
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 1–14, 16–29, 33, and 35–38 of U.S. Patent No. 6,842,502 B2 (Ex. 1001, "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 1–14, 16–29, 33, and 35–38 are unpatentable.

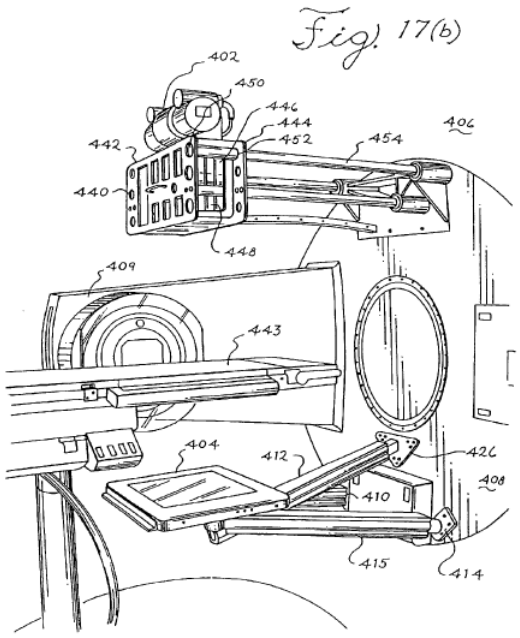
B. Related Proceedings

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: IPR2016-00162, IPR2016-00163, and IPR2016-00166. 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. 1001, 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. 1001, 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. 1001, 19:64–67. X-ray tube 402 generates beam of x-rays 407 in a form of a cone or pyramid. Ex. 1001, 19:67–20:2. Flat-panel imager 404 employs amorphous silicon detectors. Ex. 1001, 20:6–7.

D. Illustrative Claim

Petitioner challenges claims 1–14, 16–29, 33, and 35–38 of the '502 Patent. Claim 1 is the only independent claim, and is reproduced below:

> 1. A radiation therapy system comprising:
>
> a radiation source that moves about a path and directs a beam of radiation towards an object;
>
> a cone-beam computed tomography system comprising:
>
> an x-ray source that emits an x-ray beam in a cone-beam form towards said object;
>
> a flat-panel imager receiving x-rays after they pass through the object, said imager providing an image of said object, 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
>
> a computer connected to said radiation source and said cone beam computed tomography system, wherein said computer receives said image of said object and based on said image sends a signal to said radiation source that controls said path of said radiation source.

E. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–14, 16–29, 33, and 35–38 under 35 U.S.C. § 103(a) as obvious over a combination of Jaffray 1999 SPIE,[1] Jaffray 1999 JRO,[2] Adler,[3] and Depp[4].

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[1] D.A. Jaffray et al., *Performance of a Volumetric CT Scanner Based Upon a Flat-Panel Imager*, SPIE, 3659:204–14 (Feb. 1999) (Ex. 1005, "Jaffray 1999 SPIE").
[2] D.A. Jaffray et al., *A Radiographic and Tomographic Imaging System Integrated into a Medical Linear Accelerator for Localization of Bone and Soft-Tissue Targets*, Int. J. Radiation Oncology Biol. Phys., 45:773–89 (Oct. 1999) (Ex. 1006, "Jaffray 1999 JRO").
[3] U.S. Patent No. 5,207,223, issued May 4, 1993 (Ex. 1003).
[4] U.S. Patent No. 5,427,097, issued June 27, 1995 (Ex. 1004).

II. ANALYSIS

A. 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 claim 1 recites "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. 1001, 3:40–43; Ex. 1002 ¶ 37). Patent Owner disagrees, and asserts that "three-dimensional information" should be construed more narrowly as "volumetric data." Prelim. Resp. 36–40 (citing Ex. 1001, 2:42–48, 3:30–43, 9:62–64, 10:3–5, 11:9–12, 16:27–63, 31:17–21, Fig. 14; Ex. 1002 ¶¶ 66, 75; Ex. 1003, 9:12–16; Ex. 1009). 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 '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."

2. "a computer . . . that controls said path of said radiation source."

Independent claim 1 recites "a computer connected to said radiation source and said cone beam computed tomography system, wherein said computer receives said image of said object and based on said image sends a signal to said radiation source that controls said path of said radiation source." Petitioner asserts that this is a means-plus-function limitation that should be construed in accordance with § 112, ¶ 6. Pet. 14. Petitioner contends that the term is indefinite because the '502 Patent does not disclose an algorithm for programming the general purpose computer to perform the claimed function. *Id.* at 14–16. Petitioner contends, in the alternative, that the structure for performing the recited function is a computer performing the algorithm described at column 4, lines 57–62, column 27, lines 15–23, column 27, line 40 to col. 28, line 19, and depicted in Figures 24 and 26. *Id.* at 16.

Patent Owner argues that the limitation does *not* invoke § 112, ¶ 6. Prelim. Resp. 13–14. Patent Owner contends that the claim language appropriately "describes how the 'computer' operates in the context of the invention, including its connections to and interactions with other components," (*id.* at 15), and argues that a "computer" is sufficient structure,

at least for the purposes of § 112, ¶ 6. *Id.* at 15–16. Patent Owner argues, in the alternative, that even if the limitation is construed under § 112, ¶ 6, the '502 Patent discloses an algorithm for performing the recited function. *Id.* at 16–18.

On this record, we are not persuaded that this is a means-plus-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 [that § 112 ¶ 6 does not apply] 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. 14. 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" has been construed as a means-plus-function limitation. *See id.* In the absence of such analysis,

evidence, or testimony by Petitioner, we agree with Patent Owner for the reasons set forth in the Preliminary Response.

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.

B. Whether Jaffray 1999 SPIE and Jaffray 1999 JRO are Prior Art to Claims 1–14, 16–29, 33, and 35–38

Petitioner asserts that (1) claims 1–14, 16–29, 33, and 35–38 are not entitled to the benefit of priority of the February 18, 2000 filing date of provisional application no. 60/183,590 ("the '590 Application"), and, thus, Jaffray 1999 SPIE and Jaffray 1999 JRO are prior art under 35 U.S.C. § 102(b);[5] and (2) even if the claims are entitled to the benefit of the February 18, 2000, filing date of the '590 Application, Jaffray 1999 SPIE and Jaffray 1999 JRO are still prior art under 35 U.S.C. § 102(a). Pet. 16–20 (citing Exs. 1001, 1002, 1010). Patent Owner counters that (1) the challenged claims are entitled to the benefit of priority of the February 18, 2000, filing date of the '590 Application, and, thus, Jaffray 1999 SPIE and Jaffray 1999 JRO are not prior art under 35 U.S.C. § 102(b); and (2) Jaffray 1999 SPIE and Jaffray 1999 JRO are not prior art under 35 U.S.C. § 102(a), because the authors of those references are the named inventors of the '502 Patent. Prelim. Resp. 20–31 (citing Exs. 1001, 1002, 1005, 1006, 1010). We examine each of these contentions in turn.

[5] All references to 35 U.S.C. §§ 102, 103 herein will be pre-AIA.

1. Principles of Law

Petitioner has the burden of persuasion to prove unpatentability by a preponderance of the evidence. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015). Petitioner also has the initial burden of production to show that a reference is prior art to certain claims under a relevant section of 35 U.S.C. § 102. *Id.* Once Petitioner has met that initial burden, the burden of production shifts to Patent Owner to argue or produce evidence that the asserted reference is not prior art to certain claims, for example, because those claims are entitled to the benefit of priority of an earlier-filed application. *Id.* at 1380. Once Patent Owner has met that burden of production, the burden is on Petitioner to show that the claims at issue are not entitled to the benefit of priority of the earlier filed application. *Id.*

Section 102(a) recites "[a] person shall be entitled to a patent unless . . . (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." "[O]ne's own work is not prior art under [§] 102(a) even though it has been disclosed to the public in a manner or form which otherwise would fall under [§ 102(a)]." *In re Katz*, 687 F.2d 450, 454 (Fed. Cir. 1982). Generally, "[a] patent is 'to another' when the 'inventive entities' are different." *In re Fong*, 378 F.2d 977, 980 (CCPA 1967); *see also In re Land*, 368 F.2d 866, 877 (CCPA 1966) ("There appears to be no dispute as to the law that A is not 'another' as to A, B is not 'another' as to B, or even that A & B are not 'another' as to A & B. But that is not this case, which involves . . . , the question whether either A or B is 'another' as to A & B as joint inventors under section

102(e).").

> What we have in this case is ambiguity created by the printed publication. The article does not tell us anything specific about inventorship, and appellant is only one of three authors who are reporting on scientific work in which they have all been engaged in some capacity at the Harvard Medical School. It was incumbent, therefore, on appellant to provide a satisfactory showing which would lead to a reasonable conclusion that he is the sole inventor.

In re Katz, 687 F.2d at 455 (footnote omitted).

2. Whether Jaffray 1999 SPIE and Jaffray 1999 JRO are Prior Art under 35 U.S.C. § 102(b)

Applying the framework from *Dynamic Drinkware*, we determine that Petitioner has met its initial burden of production by asserting that independent claim 1 was not entitled to the benefit of priority of the '590 Application, and, thus, that both Jaffray 1999 SPIE and Jaffray 1999 JRO are prior art under 35 U.S.C. § 102(b). Pet. 16–20. Specifically, Petitioner asserts that because the '590 Application does not provide sufficient written description support for "said computer receives said image of said object and based on said image sends a signal to said radiation source that controls said path of said radiation source," as recited in independent claim 1, the effective date of independent claim 1 is February 16, 2001, the filing date of U.S. Application No. 09/788,335, which issued as the '502 Patent. And as each of Jaffray 1999 SPIE and Jaffray 1999 JRO has a publication date earlier than February 18, 2000, they are each prior art under 35 U.S.C. § 102(b).

The burden of production having shifted to Patent Owner, Patent Owner asserts that independent claim 1 is entitled to the benefit of priority of the '590 Application because the '590 Application provides sufficient

written description support for the disputed limitation in independent claim 1. Prelim. Resp. 20–27 (citing *Polaris Wireless, Inc. v. TruePosition, Inc.*, Case No. IPR2013-00323, 2013 WL 8563953, at *17 (PTAB Nov. 15, 2013) (Paper 9) ("Patent Owner need only show its entitlement to the filing date of the provisional, 'in a manner that is commensurate in scope with the specific points and contentions raised by Petitioner.'")). More specifically, Patent Owner identifies several portions of the '590 Application that allegedly provide written description support for the aforementioned limitation of independent claim 1.

Patent Owner principally identifies the following portions: "[t]his imaging system can be installed on a conventional radiotherapy linear accelerator for application to image-guided radiation therapy" (Ex. 1009, 6:13–15); "[i]maging systems based on this technology can be constructed to address specific imaging problems, including non-destructive testing (at kilovoltage or megavoltage energies), early detection and monitoring of specific medical conditions, and, of course, navigational imaging for therapies" (Ex. 1009, 30:2–6); "an FPI-based kilovoltage CBCT scanner for guiding radiation therapy on a medical linear accelerator" (Ex. 1009, 31:6–7); "produced under computer control" (Ex. 1009, 8:6–7); "[t]he values are transferred . . . to a hardware buffer in the host computer" (Ex. 1009, 9:7–8), and "the host computer advances the motorized rotation stage" (Ex. 1009, 11:6). We are persuaded, on this record, that the '590 Application provides sufficient description support for "said computer receives said image of said object and based on said image sends a signal to said radiation source that controls said path of said radiation source." Specifically, we discern that the aforementioned portions of the '590 Application disclose a relationship

between an imaging system and "navigational imaging for therapies." We discern further that "navigational imaging for therapies" involves using images to navigate a therapy, which we determine would involve a computer controlling a path that is "navigated" for that therapy.

Accordingly, we determine that Patent Owner has met its burden of production, and, thus, all burdens[6] concerning this issue are on Petitioner. We determine also that Petitioner has not shown sufficiently, on this record, that both Jaffray 1999 SPIE and Jaffray 1999 JRO are prior art under 35 U.S.C. § 102(b).

3. Whether Jaffray 1999 SPIE, Jaffray 1999 JRO are Prior Art under 35 U.S.C. § 102(a)

Again applying the framework from *Dynamic Drinkware*, we determine that Petitioner has met its initial burden of production by asserting that each of Jaffray 1999 SPIE and Jaffray 1999 JRO are prior art under 35 U.S.C. § 102(a). Pet. 19 ("at a minimum, the Jaffray 1999 references are prior art under § 102(a) (pre-AIA) because each published before February 18, 2000, the filing date of the earliest application appearing on the face of the '502 Patent").

The burden of production having shifted to Patent Owner, Patent Owner asserts that Jaffray 1999 SPIE and Jaffray 1999 JRO are not prior art under 35 U.S.C. § 102(a), because they are not the work "of another." Prelim. Resp. 28–31. Specifically, Patent Owner asserts the following:

> Here, the co-authors were all co-workers at William Beaumont Hospital operating under a grant for which named inventor Jaffray was the lead investigator. (Ex. 2008, DARPA.) The system described in the 1999 Jaffray publications is the same one

[6] Both the burden of production and the burden of persuasion.

> that is depicted and claimed in the patent and shown in DARPA. (*See id.* at Fig. 4.) In this circumstance, it is clear that all of the articles disclose the inventors' work.

Id. at 30. On this basis, we determine that Patent Owner has met its burden of production, and, thus, all burdens concerning this issue are on Petitioner.

Even with Petitioner having all burdens concerning this issue, however, we are persuaded that the record shows sufficiently that Jaffray 1999 SPIE and Jaffray 1999 JRO are the work "of another." Specifically, the listed inventors of the '502 Patent are David A. Jaffray, John B. Wong, and Jeffrey H. Siewerdesen, whereas the listed authors of Jaffray 1999 SPIE are D.A. Jaffray, J.H. Siewerdsen, and D.G. Drake, and the listed authors of Jaffray 1999 JRO are David A. Jaffray, Douglas G. Drake, Michel Moreau, Alvaro A. Martinez, and John W. Wong. Generally, "a patent is 'to another' when the 'inventive entities' are different." *In re Fong*, 378 F.2d at 980; *see also In re Land*, 368 F.2d at 877. While Jaffray 1999 SPIE and Jaffray 1999 JRO are articles, and not patents, nevertheless, Petitioner has shown sufficiently at this stage of the proceedings that the different inventive and authoring entities evidence that the articles are by "another" for purposes of 35 U.S.C. § 102(a). Upon institution, Patent Owner will have the opportunity to submit argument and evidence to show otherwise. *See In re Katz*, 687 F.2d at 455.

Accordingly, we determine that Petitioner has shown sufficiently, on this record, that both Jaffray 1999 SPIE and Jaffray 1999 JRO are prior art to independent claims 43 and 60, and the challenged claims that depend therefrom, under 35 U.S.C. § 102(a).

C. The Challenged Claims – Obviousness over Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp

Petitioner asserts that a combination of Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp renders obvious claims 1–14, 16–29, 33, and 35–38. Pet. 18–58. Patent Owner disagrees. Prelim. Resp. 32–51.

1. Jaffray 1999 SPIE

Jaffray 1999 SPIE teaches a cone-beam computed tomography ("CBCT") system for radiotherapy guidance on a treatment-by-treatment basis using CT data obtained with a kV x-ray source and a large area, indirect detection flat-panel imager ("FPI"). Ex. 1005, 17. More specifically, Jaffray 1999 SPIE teaches that while radiotherapy has proved successful in managing various types and stages of cancer, potential exists for increased tumor control through increased dose. Ex. 1005, 16. In order to more effectively deliver that increased dose to the target organ, while limiting collateral exposure, however, an online imaging and guidance system capable of detecting the organ and surrounding structures with high spatial accuracy is desired. Ex. 1005, 16–17. According to Jaffray 1999 SPIE, a strong candidate is CBCT. Ex. 1005, 17. A single CBCT scan is obtained by acquiring 300 projection images over 360 degrees of rotation. Ex. 1005, 19, 25.

2. Jaffray 1999 JRO

Jaffray 1999 JRO teaches an on-line kV imaging system that has been integrated with a medical linear accelerator for localizing a patient and verifying beam placement. Ex. 1006, 18. Under the heading "Optimization of imaging parameters for localization," Jaffray 1999 JRO teaches the following:

> There is significant room for additional optimization of the system: investigating the impact of x-ray scatter, reducing veiling glare in the optical housing, and exploring the use of flat-panel imagers for increased detective quantum efficiency.

Ex. 1006, 15.

3. 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. 1003, 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. 1003, 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. 1003, 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. 1003, 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. 1003, 7:37–40.

4. 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. 1004, 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. 1004, 11:46–61.

5. Analysis

Petitioner asserts that a combination of Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp renders obvious claims 1–14, 16–29, 33, and 35–38. Pet. 18–58. For example, independent claim 1 recites "a radiation source that moves about a path and directs a beam of radiation towards an object." Petitioner cites Adler for disclosing beaming apparatus 20 performing stereotaxic surgery using an x-ray linear accelerator, and cites Jaffray 1999 SPIE for disclosing an Elekta SL-20 linear accelerator that produces MV photon beams. Pet. 28–29. Independent claim 1 also recites

> a cone-beam computed tomography system comprising:
>
> an x-ray source that emits an x-ray beam in a cone-beam form towards said object;
>
> a flat-panel imager receiving x-rays after they pass through the object, said imager providing an image of said object

Petitioner cites Jaffray 1999 SPIE for disclosing a CBCT x-ray system with an x-ray tube, a rotation stage, and a flat-panel imager, where a single CBCT scan of an organ is obtained by acquiring 300 projection images over 360 degrees of rotation, and cites Jaffray 1999 JRO for suggesting use of a flat-panel imager. Pet. 29–31. Independent claim 1 also recites "wherein said image contains at least three dimensional information of said object based on one rotation of said x-ray source around said object." Petitioner cites Jaffray 1999 SPIE for disclosing, *inter alia*, that "an entire volumetric image is acquired through a single rotation of the source and detector." Pet. 31–32. Independent claim 1 also recites "a computer connected to said radiation source and said cone beam computed tomography system, wherein said computer receives said image of said object and based on said image sends a signal to said radiation source that controls said path of said radiation source." 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. For a rationale to modify Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp in view of each other, Petitioner sets forth such a rationale on pages 35–40 of the Petition. Petitioner performs a similar analysis for dependent claims 2–14, 16–29, 33, and 35–38.

Patent Owner asserts that Adler does not disclose a "a computer that receives an image that 'contains at least three dimensional information' and 'based on said image sends a signal to said radiation source that controls said path of said radiation source,'" (Prelim. Resp. 36) because Adler's imager "creates two flat, two-dimensional pictures that contain no volumetric data" (*id.* at 40). 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 Jaffray 1999 SPIE. Specifically, Petitioner asserts the following:

> One of skill in the art would be motivated to combine the Jaffray 1999 references with Adler/Depp because all three references are in the same field of medical imaging in conjunction with radiation therapy and all three 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; Jaffray SPIE 1999, at 16–17; *see also* Ex. 1002, ¶ 81.) As explained by Dr. Balter, the combination of the CBCT-FPI methodology of the Jaffray 1999 references with the radiotherapy control apparatus of Adler and Depp, as done by the '502 applicants, was also obvious because it combined the known methods of CBCT with an FPI to improve the diagnostic imaging and real-time adjustment of radiotherapy described in Adler and Depp. (*See* Ex. 1002, ¶ 81.) In this field, 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 Jaffray 1999 references with the radiotherapy systems of Adler/Depp. (*See id.*)

Pet. 39. 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 3-dimensional mapping, and we are persuaded that comparing that 3-dimensional mapping with another 3-dimensional mapping, as disclosed in Jaffray 1999 SPIE, 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. 41. Patent Owner's assertions are misplaced, as the relevant limitation of independent claim 1 is not so narrowly directed to "shift correction," instead reciting "said computer . . . based on said image sends a signal to said radiation source that controls said path of said radiation source." To that end, Adler teaches "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. 1003, 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. 43–44. 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. 44–47. 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, two-dimensional 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 Jaffray 1999 SPIE. 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. 49–50. 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 1013–1037 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 122–157. Prelim. Resp. 50–51. 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.

6. Conclusion

On this record, we are persuaded that Petitioner has shown a reasonable likelihood that claims 1–14, 16–29, 33, and 35–38 are obvious over a combination of Jaffray 1999 SPIE, Jaffray 1999 JRO, 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 1–14, 16–29, 33, and 35–38 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 claims 1–14, 16–29, 33, and 35–38 of the '502 Patent

as unpatentable under 35 U.S.C. § 103(a) over a combination of Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp; 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.

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