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Paper 14
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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 IPR2016-00163
Patent 6,842,502 B2

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

KIM, *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. 1201, “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.

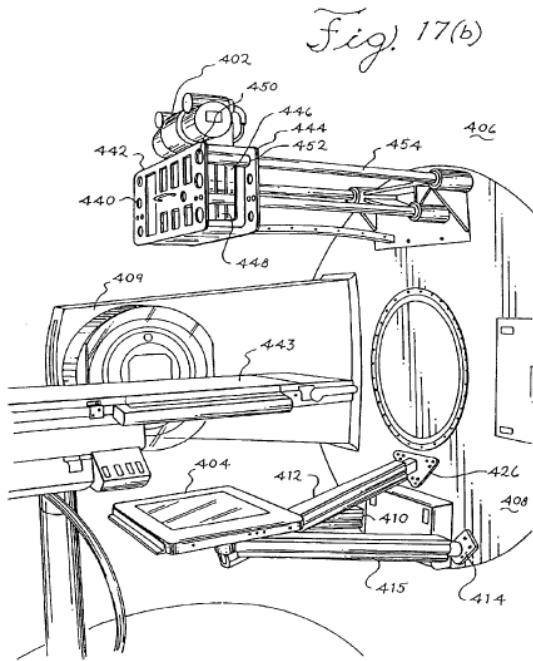
B. *Related Proceedings*

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, IPR2016-00166, and IPR2016-00169. 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, 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. 1201, 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. 1201, 6:53–56.



or pyramid. Ex. 1201, 19:67–20:2. Flat-panel imager 404 employs amorphous silicon detectors. Ex. 1201, 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 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 a radiation therapy treatment plan involving said radiation source based on said image.

E. Asserted Grounds of Unpatentability

Petitioner challenges claims 43–46, 48–55, 57, 59–66, and 68 on the following grounds.

Reference(s)	Basis	Challenged Claims
Jaffray 1999 SPIE, ¹ Jaffray 1999 JRO, ² Adler, ³ and Depp ⁴	§ 103(a)	43–46, 48–55, 57, 59
Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, Depp, and Yan ⁵	§ 103(a)	60–66, 68

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. 1205, “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. 1206, “Jaffray 1999 JRO”).

³ U.S. Patent No. 5,207,223, issued May 4, 1993 (Ex. 1203).

⁴ U.S. Patent No. 5,427,097, issued June 27, 1995 (Ex. 1204).

⁵ D. Yan et al., *The Use of Adaptive Radiation Therapy to Reduce Setup Error: A Prospective Clinical Study*, Int’l J. Radiation Oncology Biol. Phys., 41:715–20 (1998) (Ex. 1207, “Yan”).

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 term requires construction.

“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. 14 (citing Ex. 1201, 3:40–43; Ex. 1202 ¶ 37). Patent Owner disagrees, and asserts that “three-dimensional information” should be construed more narrowly as “volumetric data.” Prelim. Resp. 28–32 (citing Ex. 1201, 2:42–48, 3:30–43, 9:62–64, 10:3–5, 11:9–12, 16:27–63, 31:17–21, Fig. 14; Ex. 1202 ¶¶ 66, 75; Ex. 1203, 9:12–16; Ex. 1210). 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.”

B. Whether Jaffray 1999 SPIE and Jaffray 1999 JRO are Prior Art to Claims 43–46, 48–55, 57, 59–66, and 68

Petitioner challenges two sets of claims: independent claim 43, and its dependent claims 44, 45, 48–55, 57, and 59; and independent claim 60, and its dependent claims 61–66 and 68. For each set of claims, Petitioner asserts that (1) the claims 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);⁶ 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. 14–16 (citing Exs. 1201, 1202, 1210). Patent Owner counters that (1) each set of challenged claims is 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

⁶ All references to 35 U.S.C. §§ 102, 103 herein will be pre-AIA.

35 U.S.C. § 102(a), because the authors of those references are the named-inventors of the '502 Patent. Prelim. Resp. 15–26 (citing Exs. 1201, 1202, 1205, 1206, 1210). We examine each of these contentions in turn.

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 to claims 43–46, 48–55, 57, and 59 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 43 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. 14–18. Specifically, Petitioner asserts that because the ’590 Application does not provide sufficient written description support for “controlling said path of said radiation source based on said image,” as recited in independent claim 43, the effective date of independent claim 43 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 16, 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 43 is entitled to the benefit of priority of the '590 Application because the '590 Application provides sufficient written description support for “controlling said path of said radiation source based on said image,” as recited in independent claim 43. Prelim. Resp. 15–23 (citing *Polaris Wireless, Inc. v. TruePosition, Inc.*, Case No. IPR2013-00323, 2013 WL 8563953, at *17 (PTAB Nov. 15, 2013) (Paper 9) (“[T]he Patent Owner has to make a sufficient showing of entitlement to earlier filing date or dates, 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 43.

Patent Owner principally identifies the following two portions: “[t]his imaging system can be installed on a conventional radiotherapy linear accelerator for application to image-guided radiation therapy” (Ex. 1210, 6:13–15); and “[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. 1210, 30:2–6). We are persuaded, on this record, that the '590 Application provides sufficient description support for “controlling said path of said radiation source based on said image.” 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 controlling a path that is “navigated” for that therapy.

Accordingly, we determine that Patent Owner has met its burden of production, and, thus, all burdens⁷ concerning this issue are on Petitioner. We determine that Petitioner has not shown sufficiently, on this record, that both Jaffray 1999 SPIE and Jaffray 1999 JRO are prior art to independent claim 43 under 35 U.S.C. § 102(b).

3. Whether Jaffray 1999 SPIE and Jaffray 1999 JRO are Prior Art to claims 60–66, and 68 under 35 U.S.C. § 102(b)

The relevant limitation for independent claim 60 is “controlling a radiation therapy treatment plan involving said radiation source based on said image.” For the same reasons as set forth in the previous section, we determine that Petitioner has met its initial burden of production by asserting that independent claim 60 is 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). Accordingly, we advance to Patent Owner’s assertions.

Patent Owner identifies again principally the following two portions of the ’590 Application as providing written description support for “controlling a radiation therapy treatment plan involving said radiation source based on said image”: “[t]his imaging system can be installed on a conventional radiotherapy linear accelerator for application to image-guided radiation therapy” (Ex. 1210, 6:13–15); and “[i]maging systems based on this technology can be constructed to address specific imaging problems,

⁷ Both the burden of production and the burden of persuasion.

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. 1210, 30:2–6). Again, we are persuaded that they provide sufficient description support. Specifically, the relevant limitation of independent claim 60 uses the broad word “involved” to link the recited “image” and the recited “radiation therapy treatment plan involving said radiation source,” indicating that all the ’590 Application is required to disclose, essentially, is any relationship between an image and a treatment plan. We are persuaded that the aforementioned portions of the ’590 Application disclose that relationship, as tenuous as that relationship may appear to be.

Accordingly, we determine that Patent Owner has met its burden of production, and, thus, all burdens 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 to independent claim 60 under 35 U.S.C. § 102(b).

4. Whether Jaffray 1999 SPIE, Jaffray 1999 JRO are Prior Art to claims 43–46, 48–55, 57, 59–66 and 68 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 to independent claims 43 and 60 under 35 U.S.C. § 102(a). Pet. 17–18 (“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 to independent claims 43 and 60 under 35 U.S.C. § 102(a), because they are not the work “of another.” Prelim. Resp. 23–26. 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 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.

Prelim. Resp. 25–26. 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. Siewerdesen, 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. Claims 43–46, 48–55, 57, and 59 as Unpatentable 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 43–46, 48–55, 57, and 59. Pet. 17–46 (citing Exs. 1202–1206). Patent Owner disagrees. Prelim. Resp. 28–36, 45–52 (citing Exs. 1202–1206).

1. Jaffray 1999 SPIE

Jaffray 1999 SPIE discloses 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. 1205, 17. More specifically, Jaffray 1999 SPIE discloses that while radiotherapy has proved successful in managing various types and stages of cancer, potential exists for increased tumor control through increased dose. Ex. 1205, 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. 1205, 16–17. According to Jaffray 1999 SPIE, a strong candidate is CBCT. Ex. 1205, 17. A single CBCT scan is

obtained by acquiring 300 projection images over 360 degrees of rotation.
Ex. 1205, 19, 25.

2. *Jaffray 1999 JRO*

Jaffray 1999 JRO discloses an on-line kV imaging system that has been integrated with a medical linear accelerator for localizing a patient and verifying beam placement. Ex. 1206, 18. Under the heading “Optimization of imaging parameters for localization,” Jaffray 1999 JRO discloses 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. 1206, 15.

3. *Adler*

Adler discloses 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. 1203, 1:6–10. Specifically, Adler discloses that a 3-dimensional mapping of a mapping region of at least a portion of a living organism is prepared. Ex. 1203, 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. 1203, 4:5–10. Adler then discloses 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. 1203, 4:41–46. Adler discloses 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. 1203, 7:17–23.

4. *Depp*

Depp discloses an apparatus for and method of carrying out stereotactic 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. 1204, 1:6–12. Depp further discloses 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. 1204, 11:46–61.

5. *Analysis*

Petitioner asserts that a combination of Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp renders obvious claims 43–46, 48–55, 57, and 59. Pet. 17–46 (citing Exs. 1202–1206). 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 disclosing beaming apparatus 20 performing stereotactic surgery

using an x-ray linear accelerator. Independent claim 43 recites also “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 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. Independent claim 43 recites further “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 that “an entire volumetric image is acquired through a single rotation of the source and detector.” Independent claim 43 recites additionally “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. 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 33–37 of the Petition. Petitioner performs a similar analysis for dependent claims 44–46, 48–55, 57, and 59.

Patent Owner asserts that Adler does not disclose “controlling said path of said radiation source based on said image,” “wherein said image contains at least three dimensional information of said object,” as recited in independent claim 43, because Adler’s imager only creates two flat, two-

dimensional pictures that contain no volumetric data. 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),” and not “volumetric data.” Moreover, Patent Owner’s assertions are misplaced, as Petitioner has essentially replaced 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. 1202, ¶ 76.) 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. 1202, ¶ 76.) 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.*, ¶ 76.)

Pet. 36–37. 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 discloses 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. 33. 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 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. 1203, 7:17–23.

Patent Owner asserts additionally that Petitioner’s representations concerning Adler and Depp are inconsistent with Petitioner’s own conduct during prosecution of Petitioner’s own patents. 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. Patent Owner represents that such a format is a violation of Board rules, and that the Petition should be denied on that basis. 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 discloses comparing two flat, two-dimensional pictures to its 3-dimensional mapping in order to control a path of the radiation source, 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. 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 1214–1237 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 104–138. 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 43–46, 48–55, 57, and 59 are obvious over a combination of Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp.

D. *Claims 60–66 and 69 as Unpatentable over Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, Depp, and Yan*

Petitioner asserts that a combination of Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, Depp, and Yan renders obvious claims 60–66 and 68. Pet. 17–49 (citing Exs. 1202–1207). Patent Owner disagrees. Prelim. Resp. 28–52 (citing Exs. 1202–1207).

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. 1207, 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. Ex. 1207, 8. Daily portal images were taken and used to identify errors in the treatment plan. Ex. 1207, 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. Ex. 1207, 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. Ex. 1207, 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. 17–49 (citing Exs. 1202–1207). 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. 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 49 of the

Petition. Petitioner performs a similar analysis for dependent claims 61–66 and 68.

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. 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. 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 Jaffray 1999 SPIE 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. 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. 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. 45 (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 Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, Depp, and Yan.

C. 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 claims 43–46, 48–55, 57, 59–66, and 68 of the '502 Patent on the following grounds:

- claims 43–46, 48–55, 57, and 59 as unpatentable under 35 U.S.C. § 103(a) over a combination of Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp; and
- claims 60–66 and 68 as unpatentable under 35 U.S.C. § 103(a) over a combination of Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, Depp, and Yan;

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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