Trials@uspto.gov
Tel: 571-272-7822

Paper 14
Entered: May 5, 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 IPR2016-00169
Patent 7,471,765 B2

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

DESHPANDE, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Varian Medical Systems, Inc. ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1–13 and 20–31 of U.S. Patent No. 7,471,765 B2 (Ex. 1001, "the '765 patent"). Paper 1 ("Pet."). William Beaumont Hospital ("Patent Owner") filed a Preliminary Response. Paper 11 ("Prelim. Resp.").

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

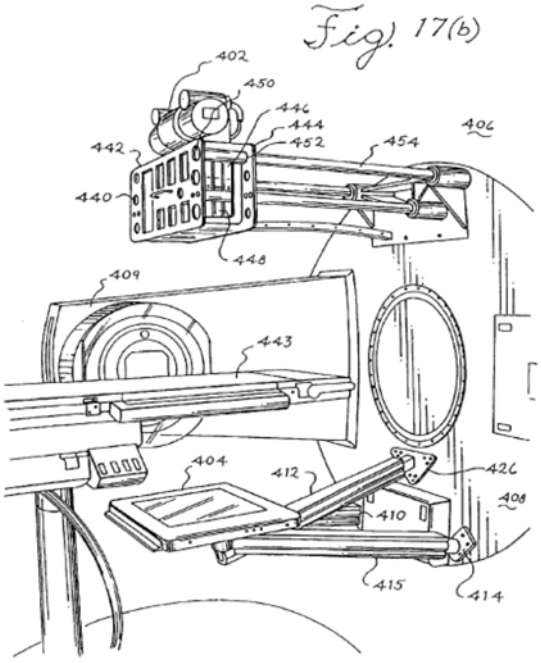
B. Related Proceedings

Petitioner and Patent Owner identify the following district court proceedings concerning the '765 patent: *Elekta Ltd. and William Beaumont Hospital v. Varian Medical Systems, Inc.*, Case No. 2:15-cv-12169-AC-MKM (E.D. Mich.). Pet. 1; Paper 9, 1. Petitioner and Patent Owner identify further the following *inter partes* reviews also directed to the '765 patent: IPR2016-00170 and IPR2016-00171. Pet. 1; Paper 9, 1–2. Petitioner and Patent Owner identify further the following *inter partes* reviews also directed to the U.S. Patent 6,842,502 B2 ("the '502 patent"), which the '765 patent claims priority to: IPR2016-00160, IPR2016-00162, IPR2016-00163, and IPR2016-00166. Pet. 1; Paper 9, 1–2. Patent Owner identifies also the

following *inter partes* review directed to U.S. Patent No. 7,826,592 B2, which also claims priority to the '502 patent: IPR2016-00187. Paper 9, 2–3.

C. The '765 Patent

The '765 patent discloses that it is directed to a cone-beam computed tomography system that employs an amorphous silicon flat-panel imager for use in radiotherapy applications where images of a patient are acquired with the patient in a treatment position on a treatment table. Ex. 1001, 1:16–21. Figure 17(b) (below) depicts a diagrammatic view of one orientation of an exemplary wall-mounted cone beam computerized tomography system employing a flat-panel imager. *Id.* at 6:48–52.



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

or pyramid. *Id.* at 19:43–56. Flat-panel imager 404 employs amorphous silicon detectors. *Id.* at 19:46–47.

D. Illustrative Claim

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

> 1. A radiation therapy system comprising:
>
> a radiation source that moves about an object and directs a beam of radiation towards said object;
>
> a cone-beam computed tomography system comprising:
>
> an x-ray source that moves about said object and emits toward said object from multiple positions around said object x-ray beams in a cone-beam form;
>
> a flat-panel imager positioned to receive x-rays after at least a portion of said x-ray beams pass through said object, said imager providing an image that contains three-dimensional information concerning said object based on a plurality of two-dimensional projection images; and
>
> a computer coupled to said cone-beam computed tomography system, wherein said computer receives said three-dimensional information and based on said three dimensional information received controls a path of said beam of radiation through said object by controlling a relative position between said radiation source and said object, wherein said receiving said x-rays by said flat panel imager is performed substantially at a time of occurrence of said controlling said path of said beam of radiation through said object.

Ex. 1001, 28:2–24.

E. Asserted Ground of Unpatentability

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

References	Basis	Challenged Claims
Jaffray 1999 SPIE,[1] Jaffray 1999 JRO,[2] Adler,[3] and Depp[4]	§ 103(a)	1–13 and 20–31

Pet. 3.

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

[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] David 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).

meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). We must be careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993). Only terms which are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

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

1. "substantially at a time"

Independent claims 1, 7, 20, and 26 each recite the limitation "substantially at a time." Petitioner first asserts that "substantially at a time" is "vague in itself because it is a term of degree, and no standard for determining the scope of the claimed degree is given by the patent specification." Pet. 15. Petitioner argues that Patent Owner attempted to amend the claims, which originally recited a "small probability," with "substantially at a time" in order to provide clarity to the limitation, but rather just replaced a vague term with another vague term. *Id.* at 15–16. Patent Owner argues that the limitation "substantially at a time" informs "'with reasonable certainty those skilled in the art about the scope of the invention,' when viewed in light of the specification and prosecution history." Prelim. Resp. 15–18 (quoting *Nautilus, Inc. v. Biosig Instruments,*

Inc., 134 S. Ct. 2120, 2124 (2014)). Patent Owner argues that the term "substantially" does not render patent claims so unclear as to render the claims indefinite. *Id.*

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

Petitioner argues that if "substantially at a time" does not render the claims indefinite, then "substantially at a time" should be construed to mean "substantially at the same time." Pet. 16–17. Petitioner argues, based on the Declaration of Dr. Balter, that a person of ordinary skill in the art would understand the term based on the intrinsic record. *Id.* (citing Ex. 1002 ¶ 38). Patent Owner argues that "substantially at a time," when read in light of the specification, should be construed as "the time when the patient is on the treatment table for treatment." Prelim. Resp. 19 (citing Ex. 1008, 13–14; Ex. 1001, 23:26–29). Patent Owner argues that the claims are directed to "online" image acquisition, which occurs while the patent is on the treatment

table for treatment. *Id.*

We are persuaded by Petitioner that "substantially at a time" should be construed to mean "substantially at the same time" based on the intrinsic evidence, and decline to restrict this limitation to being anytime when a "patient is on the treatment table for treatment," as proffered by Patent Owner. Specifically, as discussed above, independent claims 1, 7, 20, and 26 recite that "receiving said x-rays" occurs "substantially at a time of occurrence" of "controlling" the path of radiation. That is, the x-rays are received at "substantially at a time" that the path of radiation is controlled. Furthermore, the '765 patent specification supports such a construction. The '765 patent discloses that "the cone beam computerized tomography image is preferably acquired with the patient on the treatment table . . . immediately prior to treatment delivery." Ex. 1001, 23:26–29. The '765 patent specification further discloses that "the process is both 1) 'on-line' since the patient is on the treatment table during the process and 2) '*real-time*' since the image is acciuired [sic] *substantially at the time of the treatment delivery*." *Id.* at 23:29–33 (emphasis added). Therefore, the '765 patent specification distinguishes between "on-line," which is the patient is on the treatment table, and "real-time," which is substantially at the time of the treatment delivery, i.e., the controlling of the radiation path. Accordingly, on this record, we are persuaded by Petitioner that "substantially at a time" should be construed to mean "substantially at the same time," where the "receiving" of the x-rays is substantially at the same time of the "controlling" of the radiation path.

2. "three-dimensional information"

Independent claims 1, 7, 20, and 26 each recite "three-dimensional

information." Petitioner asserts that "three-dimensional information" should be construed as "information concerning three dimensions of an object (such as length, width, and depth)." Pet. 17–18 (citing Ex. 1001, 3:41–44; Ex. 1002 ¶ 39). Patent Owner disagrees, and asserts that "three-dimensional information" should be construed more narrowly as "volumetric data." Prelim. Resp. 39–43 (citing Ex. 1001, 2:44–50, 3:29–44, 9:54–56, 9:62–63, 10:66–11:2, 16:7–12, 16:24–28, 16:39–42, Fig. 14; Ex. 1002 ¶¶ 70, 102; Ex. 1003, 9:12–16). We agree with Petitioner.

We begin first with the claim language, and note that "three-dimensional information" appears facially to be co-extensive with any information relevant to three-dimensions. We discern that "length, width, and depth" are just such information. We have considered Patent Owner's above-cited portions of the '765 patent, but are unpersuaded that it narrows "three-dimensional information" with sufficient "reasonable clarity, deliberateness, and precision" such that one of ordinary skill would have understood "three-dimensional information" as co-extensive with Patent Owner's proffered construction. *In re Paulsen*, 30 F.3d at 1480. For example, column 3, lines 41–44 mentions "three-dimensional (3-D) images," which we agree would appear to require "volumetric data," however, the claim limitation at issue is the broader term "three-dimensional information." In another example, column 9, line 62 through column 10, line 5 clearly refers to "volumetric data," but does not indicate its relation to "three-dimensional information." In a further example, column 16, lines 29–66 do not recite "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."

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

Independent claims 1, 7, 20, and 26 recite a "computer," a "controller," a "structure," and a "support table," respectively, that "control[s] a path of said beam of radiation." Petitioner asserts that these are means-plus-function limitations that should be construed in accordance with § 112 ¶ 6. Pet. 18–24. Petitioner contends that the terms are indefinite because the '765 patent does not disclose an algorithm for programming the general purpose computer to perform the claimed function. *Id.* Petitioner contends, in the alternative, that the structure for performing the recited function is a computer performing the algorithm described at column 4, lines 56–61, column 26, lines 59–67, column 27, lines 16–57, and depicted in Figures 24 and 26. *Id.*

Patent Owner argues that the limitations of claims 1, 7, and 26 do not invoke § 112 ¶ 6. Prelim. Resp. 31–35. Patent Owner contends that claims 1 and 7 describe a computer or controller and its connections with other components. *Id.* at 33. Patent Owner also argues that claim 26 describes a support table. *Id.* Patent Owner argues that these claims have sufficient structure. *Id.* at 33–34. Patent Owner argues, in the alternative, that even if the limitation is construed under § 112 ¶ 6, the '765 patent discloses an algorithm for performing the recited function. *Id.* at 34.

On this record, we are not persuaded that claims 1, 7 and 26 recite 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 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. 18–24. Petitioner does not, however, provide any further analysis, evidence, or testimony to support its assertion, or even cite a case in which the term "computer," "controller," and "support table" have been construed as a means-plus-function limitation. *Id.*

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

Claim 20 recites a "structure." Petitioner argues that there is "insufficient structure . . . provided for performing the claimed function of

beam control relative to the patient based on the 3-D information obtained from the CBCT system." Pet. 22. Petitioner argues, in the alternative, that "should the Board conclude the term is not indefinite under § 112(6), then this 'structure for controlling' element should be construed as a means-plus-element, whose structure includes an algorithm based on the meager functional restatements provided in the specification." *Id.* (citing Ex. 1001, 4:56–61, 26:59–67, 27:16–57, Figs. 24, 26). Patent Owner does not dispute that claim 20 invokes § 112 ¶ 6. Patent Owner argues that the '765 patent specification provides the corresponding structure for the alleged functions and further provides such an algorithm. Prelim. Resp. 34–35 (citing Ex. 1001, 2:25–31, 16:66–17:3, 26:59–67, 27:16–57).

We disagree with Petitioner that claim 20 is indefinite, but rather agree with Patent Owner that the '765 patent specification adequately provides support for the claimed "structure." The '765 patent specification provides a computer for performing the recited function steps. *See* Ex. 1001, Fig. 4 (element 328), 8:27–40. As noted by Patent Owner, the '765 patent further provides an algorithm for performing the functional steps recited. *See id.* at 26:59–67, 27:16–57. Accordingly, we do not agree with Petitioner that claim 20 is indefinite.

B. Whether Jaffray 1999 SPIE and Jaffray 1999 JRO are Prior Art to Claims 1–13 and 20–31

Petitioner challenges claims 1–13 and 20–31. 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);[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. 24–29 (citing Exs. 1001, 1002, 1008, 1010). Patent Owner counters that (1) the 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 '765 patent. Prelim. Resp. 19–29 (citing Exs. 1001, 1002, 1005, 1006, 1008, 1009). 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. National 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 of production, 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.*

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

Section 102(a) of 35 U.S.C. 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, as did Blout, 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 1–13 and 20–31 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 claims 1, 7, 20, and 26 are 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. 24–29. Specifically, Petitioner asserts that because the '590 Application does not provide sufficient written description support for the limitation reciting that the x-rays are received "substantially at a time" of occurrence of controlling the path of the radiation beam, as recited in independent claims 1, 7, 20, and 26, the effective date of the claims is February 16, 2001, the filing date of U.S. Application No. 09/788,335, which issued as the '502 patent that the '765 patent is a continuation of. *Id.* 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). *Id.*

The burden of production having shifted to Patent Owner, Patent Owner asserts that independent claims 1, 7, 20, and 26 are entitled to the benefit of priority of the '590 Application because the '590 Application provides sufficient written description support for the x-rays are received "substantially at a time" of occurrence of controlling the path of the radiation beam. Prelim. Resp. 19–26 (citing *Polaris Wireless, Inc. v. TruePosition, Inc.*, Case No. IPR2013-00323, 2013 WL 8563953, Paper 9, at *17 (PTAB Nov. 15, 2013) ("the 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 claims 1, 7, 20, and 26.

Patent Owner identifies that the '590 Application discloses that "the position of the patient relative to the treatment beam is controlled based on 3-D images acquired while the patient is on the linear accelerator for

treatment." Prelim. Resp. 21–22 (citing Ex. 1001, Fig. 17(c); Ex. 1009, Fig. 3). Patent Owner further identifies that the '590 Application discloses "image-guided radiation therapy," "on-line guided radiation therapy," and "imaging is done at the time of treatment." *Id.* at 22–25 (citing Ex. 1009, 4–7, 9, 34).

We are persuaded, on this record, that Patent Owner has met its burden of production in identifying where the '590 Application provides description support for "substantially at a time." 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 claims 1, 7, 20, and 26 under 35 U.S.C. § 102(b).

3. Whether Jaffray 1999 SPIE, Jaffray 1999 JRO are Prior Art to Claims 1–13 and 20–31 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 1, 7, 20, and 26 under 35 U.S.C. § 102(a). Pet. 29 ("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 '765 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 1, 7, 20, and 26 under 35 U.S.C. § 102(a), because they are not the work "of another." Prelim. Resp. 26–30. 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. 2007, 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.

Id. at 28–29. 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 '765 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, we determine that it was reasonable for Petitioner to infer that different inventive and authoring entities are presumed to be "another" for the 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 1, 7, 20, and 26, and the challenged claims that depend therefrom, under 35 U.S.C. § 102(a).

C. Claims 1–13 and 20–31 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 1–13 and 20–31. Pet. 34–59 (citing Exs. 1002–1006). Patent Owner disagrees. Prelim. Resp. 31–54 (citing Exs. 1002–1006).

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. 1005, 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. *Id.* at 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. *Id.* at 16–17. According to Jaffray 1999 SPIE, a strong candidate is CBCT. *Id.* at 17. A single CBCT scan is obtained by acquiring 300 projection images over 360 degrees of rotation. *Id.* at 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. 1006, 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. 1006, 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. 1003, 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. *Id.* at 3:64–68. First and second diagnostic beams are then passed through the mapping region, and are used to produce respective first and second images of respective first and second projections within the mapping region. *Id.* at 4:5–10. Adler then 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. *Id.* at 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." *Id.* at 7:17–23.

4. Depp

Depp discloses 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 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.

Id. at 11:46–61.

5. Analysis

Petitioner asserts that a combination of Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp renders obvious claims 1–13 and 20–31. Pet. 34–59. For example, claim 1 recites "[a] radiation therapy system." Petitioner argues that Adler and Depp disclose a system for radiotherapy that is configured for selectively irradiating a target within a patient. *Id.* at 34–35 (citing Ex. 1003, Abstract, 3:62–68; Ex. 1004, Abstract, 1:6–12, 1:18–26; Ex. 1002 ¶¶ 76–78). Petitioner further argues that Jaffray 1999 JRO also discloses radiotherapy systems using a medical linear accelerator device. *Id.* at 35.

Claim 1 further recites "a radiation source that moves about an object and directs a beam of radiation towards said object." Petitioner argues that Adler/Depp discloses that the beaming apparatus can be adjusted such that

the collimated beam is continuously focused on the target region. *Id.* at 35–36 (citing Ex. 1003, 6:44–47, 7:52–58; Ex. 1004, 4:19–22, 5:25–31). Petitioner further argues that Jaffray 1999 references disclose medical linear accelerators, and, therefore, meets this limitation. *Id.* at 36.

Claim 1 also recites "a cone-beam computed tomography system comprising: an x-ray source that moves about said object and emits toward said object from multiple positions around said object x-ray beams in a cone-beam form." Petitioner argues that Jaffray 1999 SPIE discloses that a single CBCT scan is obtained by acquiring projection images at 1.2° increment rotations of the object across 360°. Pet. 36–37 (citing Ex. 1005, 25). Petitioner further argues that Jaffray 1999 JRO discloses that a series of radiographic exposures are acquired at regular angular intervals. *Id.* at 37 (citing Ex. 1006, 9; Ex. 1002 ¶ 82).

Claim 1 additionally recites "a flat-panel imager positioned to receive x-rays after at least a portion of said x-ray beams pass through said object, said imager providing an image that contains three-dimensional information concerning said object based on a plurality of two-dimensional projection images." Petitioner argues that Jaffray SPIE discloses a flat panel imager, and, as discussed above, discloses that a single CBCT scan is obtained by acquiring projection images at 1.2° increment rotations of the object across 360°. *Id.* at 37–38 (citing Ex. 1005, 17, 25; Ex. 1002 ¶¶ 83–84). Petitioner further argues that Jaffray 1999 JRO discloses the use of flat-panel imagers. *Id.* at 38 (citing Ex. 1006, 15). Petitioner argues that Adler/Depp disclose obtaining two x-ray images at a known angle relative to one another, and, therefore, provide three-dimensional information about the imaged object. *Id.* at 38–39 (citing 1003, 7:6–12, 7:17–23; Ex. 1002 ¶ 85).

Claim 1 further recites:

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

Petitioner argues that Adler discloses a computer, coupled to the x-ray system, that receives three dimensional information, as discussed above, and adjusts the position of the radiation beam in response to the real-time three dimensional location information of the target. *Id.* at 39–40 (citing Ex. 1003, 7:6–12, 7:37–40). Petitioner argues that the radiation source is adjusted in the gantry or by moving the patient table. Pet. 40 (citing Ex. 1003, 7:42–58). Petitioner further argues that Depp discloses the use of diagnostic beams that pass through target region and surrounding area, and then contain data indicating the position of the target. *Id*. at 40–41 (citing Ex. 1004, 8:32–34, 8:36–38, 11:46–61). The substantially real time position data is used to direct the radio surgical beam to the target region. *Id.* (citing Ex. 1004, 11:46–61).

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 47–51 of the Petition. Petitioner performs a similar analysis for dependent claims 2–6, 8–13, 21–25, and 27–31. *Id.* at 52–59.

Patent Owner asserts that "Petitioner has not shown that the cited references disclose 'control[ing] a path of said beam of radiation . . . by controlling a relative position' either 'based on' (claims 1 and 20) or 'in

response to' (claims 7 and 26) 'three dimensional information,'" because Adler/Depp's imager "creates two flat, two-dimensional pictures that contain no volumetric data." Prelim. Resp. 35–43. 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 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. 1002, ¶ 102.) As confirmed by Dr. Balter, the combination of the CBCT-FPI methodology of the Jaffray 1999 references with the radiotherapy control apparatus of Adler/Depp, as done by the '765 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/Depp. (*See* Ex. 1002, ¶ 102.) 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 beam) were the predictable work of combining the CBCT-FPI system of the Jaffray 1999 references with the radiotherapy systems of Adler/Depp. (*See* Ex. 1002, ¶¶ 98-103).

Pet. 50–51. We have considered Petitioner's proffered rationale in light of Patent Owner's assertions, and, on this record, determine they are persuasive. In particular, Adler 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 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. 48–50. 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 best practices, on this record, we are unpersuaded that they are 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 further argues that Petitioner also articulates no rational basis for "why it would have been obvious to combine any particular

elements of the cited references to achieve the claimed invention with all its limitations." Prelim. Resp. 51–52. We are not persuaded by Patent Owner. Petitioner argues that all of the references are in the field of medical imaging in conjunction with radiation therapy, and are all concerned with obtaining accurate 3-D information about the internal structure of objects. Pet. 47–51. Petitioner argues that the combination of the references results in the benefit of obtaining precise and accurate location of targeted areas for radiation. *Id.* Petitioner also argues that Dr. Balter explains that the results of the combination of these references was predictable. *Id.* (citing Ex. 1102 ¶¶ 98–103). On this record, we are not persuaded by Patent Owner that Petitioner has not provided a rational basis with a rational underpinning for combining the cited prior art.

Patent Owner asserts that Dr. Balter's Declaration largely parrots conclusory statements made in the Petition and should be afforded little or no weight. Prelim. Resp. 52–53. 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 identify such portions, 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 1014–1038 that are not referenced in the Petition, and which Petitioner only presents in a section of Dr. Balter's Declaration labelled "additional exhibits (Exs. 1012–1038)" to "Dr. Balter's declaration," and spanning paragraphs 126–161 of Dr. Balter's Declaration. Prelim. Resp. 54. Patent Owner asserts that Petitioner should not be permitted to rely on these references in this proceeding. *Id.* We agree. Insofar as Petitioner may attempt to use any of these references to *fill in* any *gap* in the Petition that has been or will be identified by Patent Owner, we determine that Petitioner is prohibited expressly from doing so.

6. Conclusion

On this record, we are persuaded that Petitioner has shown a reasonable likelihood that claims 1–13 and 20–31 are obvious over a combination of 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 1–13 and 20–31 of the '765 patent are unpatentable.

III. ORDER

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

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted as to the proposed ground of obviousness of claims 1–13 and 20–31 over Jaffray 1999 SPIE, Jaffray 1999 JRO, Adler, and Depp.

FURTHER ORDERED that no other grounds are instituted; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter*

partes review of the '765 Patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

PETITIONER:

Heidi L. Keefe
Daniel J. Knauss
Scott A. Cole
Adam Pivovar
Reuben Chen
COOLEY LLP
hkeefe@cooley.com
dknauss@cooley.com
scole@cooley.com
apivovar@cooley.com
rchen@cooley.com
zpatdcdocketing@cooley.com
Varian_PTAB_IPR@cooley.com

PATENT OWNER:

Theresa M. Gillis
Amanda K. Streff
B. Clayton McCraw
MAYER BROWN LLP
TGillis@mayerbrown.com
AStreff@mayerbrown.com
CMcCraw@mayerbrown.com

Gregory A. Morris
Jonathan P. O'Brien
J. Michael Huget
HONIGMAN MILLER SCHWARTZ AND COHN LLP
gmorris@honigman.com
jobrien@honigman.com
mhuget@honigman.com