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Paper 48
Entered: March 30, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ZAP SURGICAL SYSTEMS, INC.,
Petitioner,

v.

ELEKTA LIMITED,
Patent Owner.

IPR2019-01659
Patent 7,295,648 B2

Before BRYAN F. MOORE, JENNIFER S. BISK, and NORMAN H. BEAMER, *Administrative Patent Judges*.

BEAMER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Patent Owner's Revised Motion to Amend
Denying Patent Owner's Motion to Exclude
35 U.S.C. § 328(a)

I. INTRODUCTION

In response to a Petition filed by ZAP Surgical Systems, Inc. ("Petitioner"), we instituted *inter partes* review of claims 1–4, 7–13, 16–18, 20, and 22–23 of U.S. Patent No. 7,295,648 B2 (Ex. 1001, "the 648 patent"). Paper 1 ("Pet."); Paper 7 ("Dec."). Elekta Limited ("Patent Owner") filed a Response to the Petition, Petitioner filed a Reply, and Patent Owner filed a Sur-Reply. Paper 14 ("PO Resp."); Paper 19 ("Reply"); Paper 24 ("Sur-Reply"). Patent Owner also filed a Motion to Amend the claims, Petitioner filed an Opposition to that Motion, and we provided Preliminary Guidance under the Board's Motion to Amend Pilot Program. Papers 13, 18, 20.

Thereafter, Patent Owner filed a Revised Motion to Amend, Petitioner filed an Opposition, Patent Owner filed a Reply, and Petitioner filed a Sur-Reply. Paper 22 ("RMTA"); Paper 25 ("Opp. RMTA"); Paper 35 ("Reply RMTA"); Paper 43 ("Sur-Reply RMTA"). The Revised Motion to Amend states that it is contingent upon a finding that challenged independent claims 1 and/or 18 are unpatentable. RMTA 1.

In addition, Patent Owner filed a Motion to Exclude evidence, which Petitioner opposed, and in support of which Patent Owner filed a Reply. Papers 37, 38, 41.

An oral hearing took place on January 27, 2021. The Hearing Transcript ("Tr.") is included in the record as Paper 47. After considering the parties' arguments and supporting evidence, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1–4, 7–13, 16–18, 20, and 22–23 are unpatentable. Also, we determine that Patent Owner's Revised Motion to Amend should be denied. In addition, for the

reasons explained below, we deny Patent Owner's Motion to Exclude evidence.

II. BACKGROUND

A. The '648 Patent

The '648 patent, titled "Method And Apparatus For Treatment By Ionizing Radiation," was filed on October 21, 2004, issued on November 13, 2007, and cites Great Britain priority applications filed October 23, 2003 and November 4, 2003. Ex. 1001, codes (54), (22), (45), (30). The patent describes a radiation therapy/surgery device for treatment of, *e.g.*, tumors in the brain. *Id.* at code (57). Figure 5 of the '648 patent, annotated by the panel to show a "rotation axis" and a "support axis," is reproduced below.

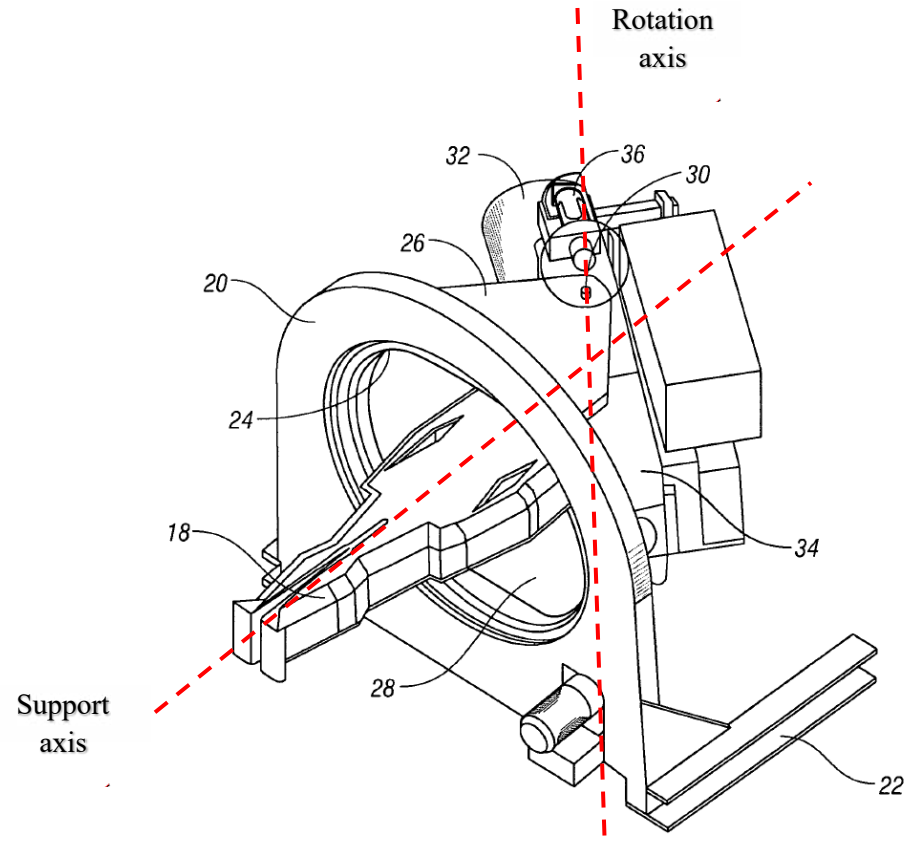

FIG. 5

Figure 5 illustrates a perspective view of the internal structure of an exemplary apparatus of the '648 patent. Ex. 1001, 5:8–9. A sturdy mounting ring 20 supports rotatable ring 24, which can rotate around patient 18 lying on a table. *Id.* at 7:5–14. The table support can be adjusted via a patient positioning system (not shown). *Id.* at 8:33–39. Mounting brackets 26 and 28 are attached to ring 24, which include pivotable mounting points 30 (only the upper such point is visible in Figure 5) spaced transversely from the plane of the ring, wherein an imaginary line drawn through the points 30 (the "rotation axis" shown above) would pass directly through the axis of rotation of the ring (the "support axis" shown above), and which point of intersection is at the same height as a patient lying on the patient table. *Id.* at 7:14–23.

A linear accelerator (linac) 32 is mounted on the pivotal mounting points 30 in a suitable housing 34. A motor 36 is provided to allow the linac housing 34, and thus the linac 32, to be rotated about the pivotal mounting points 30. The height of the linear accelerator 32 and its direction are set so that its beam axis passes through the intersection point referred to above. *Id.* at 7:24–30. This intersection point is referred to as the "isocentre." *Id.* at 6:44–49.

The linac can thereby rotate about the ring axis and the pivotable mounting point axis, allowing the beam to come from many directions and always pass through the intersection point, which is where the patient's head (for example) is positioned. *Id.* at 7:31–40. In operation, the patient is subjected to multiple radiation doses from multiple directions, with each dose at a relatively low level so as not to damage the undiseased tissue through which the beam passes, but with the cumulative doses at the target

intersection high enough to destroy the diseased tissue. *Id.* at 1:11–36, 7:41–44.

Because the target tissue can have an irregular shape, as the beam is directed to the target from different directions, its cross section is adjusted using a collimator at the output of the linac. *Id.* at 8:7–14. Also, the intensity of the beam, the speed of rotation of the linac about the axes of the system, and the position of the table supporting the patient can be varied during treatment. *Id.* at 8:1–13, 23–27, 33–37. The linac can also be used at lower intensities as an imaging device to calibrate the position of the patient or locate anatomical areas of the patient. *Id.* at 8:14–23. A control means can control the collimation, beam intensity and movement, and patient position, using, *inter alia*, feedback from the imaging device. *Id.* at 4:35–59.

The '648 patent asserts that the above-described arrangement has the advantage of accurately positioning the linac over a wide variety of approach angles, using only rotatable joints, such that the linac is suitably balanced around those joints, avoiding imprecision problems of prior art techniques that were less able to accommodate the heavy linac apparatus. *Id.* at 3:3–31, 5:36–46, 7:50–56. In addition, spacing the pivotable mounting points transversely from the plane of the ring allows the linac to pivot without fouling the support or irradiating unintended areas such as the patient's shoulder. *Id.* at 4:21–28, 8:67–9:1.

B. Illustrative Claim

Independent claim 1 of the '648 patent is illustrative of the challenged claims, and is reproduced below.

> 1. A device for treating a patient with ionising radiation comprising:

> a ring-shaped support, on which is provided a mount,
>
> a radiation source attached to the mount;
>
> the support being rotateable about an axis coincident with the centre of the ring;
>
> the source being attached to the mount via a rotateable union having a [sic] an axis of rotation axis [sic] which is non-parallel to the support axis;
>
> wherein the rotation axis of the mount passes through the support axis of the support and the radiation source is collimated so as to produce a beam which passes through the co-incidence of the rotation and support axes.

Ex. 1001, 9:54–67 (British standard spelling in original).

C. References

Petitioner relies on the following references (Pet. iv):

- Grady et al., US 4,649,560, issued March 10, 1987. Ex. 1009 ("Grady").
- K J Ruchala et al., "Megavoltage CT image reconstruction during tomotherapy treatments," Phys. Med. Biol. 45, 3545-3562 (2000). Ex. 1010 ("Ruchala").
- Lam et al., US 5,945,684, issued Aug. 31, 1999. Ex. 1013 ("Lam").
- Adler, US 5,207,223, issued May 4, 1993. Ex. 1012 ("Adler").
- Valentin, WO 01/12262 A1, pub. Feb. 22, 2001. Ex. 1014 ("Valentin").
- Roder, DE 3321057 A1, pub. Dec. 13, 1984. Ex. 1015 ("Roder").
- Winter, US 4,998,268, issued March 5, 1991. Ex. 1016 ("Winter").
- Schonberg, Russell G., "The History of the Portable Linear Accelerator," AAPM Meeting (2001). Ex. 1011 ("Schonberg").

Petitioner also relies on the declarations of J. Michael McCarthy and George Asmerom. Ex. 1003 ("McCarthy Decl."); Ex. 1026 (McCarthy MTA Decl.");

Ex. 1028 (McCarthy Reply Decl.”); Ex. 1036 (McCarthy RMTA Decl.”); Ex. 1027 (“Asmerom Decl.”).

Patent Owner relies on the declarations of K. David Steidley and Phillip Beron, M.D. Ex. 2001 (“Steidley Decl.”); Ex. 2007 (“Steidley 2nd Decl.”); Ex. 2040 (“Steidley 3rd Decl.”); Ex. 2008 (“Beron Decl.”).

D. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–4, 7–13, 16–18, 20, and 22–23 of the ’648 patent on the following grounds (Pet. 3)[1]:

Claims Challenged	35 U.S.C. §	References
1–4, 7–8, 11–12, 17–18, 20, 23	103(a)	Grady, Ruchala
9, 10, 13, 16, 22	103(a)	Grady, Ruchala, Lam
1–4, 7–8, 11–12, 17–18, 20, 23	103(a)	Adler, Grady
9, 10, 13, 16, 22	103(a)	Adler, Grady, Lam
1–4, 7–8, 11–12, 17–18, 20, 23	103(a)	Valentin, Roder
9, 10, 13, 16, 22	103(a)	Valentin, Roder, Lam

Petitioner also relies on Winter, Schonberg, and Adler as background art in connection with Grounds 1–4. Pet. 20–21, 46–50.

E. Real Parties in Interest

Petitioner identifies itself as the real party in interest. Pet. 77. Patent Owner identifies itself, and Elekta, Inc. as real parties in interest. Paper 5, 2.

[1] The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. §§ 102 and 103 that became effective after the filing of the application for the ’648 patent. Therefore, we apply the pre-AIA versions of these sections.

F. Related Proceedings

The parties identify *Elekta Limited and Elekta, Inc. v. Zap Surgical Systems, Inc.,* Case No. 4:19-cv-02269 (N.D. Cal.) as a related proceeding. Pet. 78; Paper 5, 2.

III. ANALYSIS

A. Legal Standards

A claim is unpatentable for obviousness if, to one of ordinary skill in the pertinent art, "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (quoting 35 U.S.C. § 103(a)). The question of obviousness is resolved on the basis of underlying factual determinations, including "the scope and content of the prior art"; "differences between the prior art and the claims at issue"; and "the level of ordinary skill in the pertinent art." *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Additionally, secondary considerations, such as "commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy." *Graham*, 383 U.S. at 17–18.

A patent claim "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. Rather, an obviousness determination requires finding "both 'that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in

doing so.'" *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016) (citation omitted); *see KSR*, 550 U.S. at 418 (for an obviousness analysis, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements [in the way the claimed] new invention does"). "Although the *KSR* test is flexible, the Board 'must still be careful not to allow hindsight reconstruction of references . . . without any explanation as to *how* or *why* the references would be combined to produce the claimed invention.'" *TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1066 (Fed. Cir. 2016) (citation omitted).

Further, an assertion of obviousness "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)); *accord In re NuVasive, Inc.*, 842 F.3d 1376, 1383 (Fed. Cir. 2016) (stating that "'conclusory statements'" amount to an "insufficient articulation[] of motivation to combine"; "instead, the finding must be supported by a 'reasoned explanation'" (citation omitted)); *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) ("To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements. The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.").

The motivation to combine must be "accompanied by a reasonable expectation of achieving what is claimed in the patent-at-issue." *Intelligent Bio-Sys, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). "The reasonable expectation of success requirement refers to the

likelihood of success in combining references to meet the limitations of the claimed invention." *Id*.

B. Level of Ordinary Skill in the Art

Petitioner relies on its expert, Dr. McCarthy, to contend:

> A POSITA [person of ordinary skill in the art] at the time of the claimed invention would have a bachelor's degree in mechanical engineering as well as at least five years of experience in the industry working with mechanical systems such as rotatable gantries, gyroscope gimbals and robotic systems, including robot arms and wrists; or without an undergraduate degree, a person of ordinary skill would have ten years of experience designing, manufacturing, or overseeing mechanical systems such as rotatable gantries, robotic systems, such as robot arms, robotic surgery systems, and robotic rehabilitation systems, all of which involve mechanical positioning systems. *See* [McCarthy Decl.] ¶ 16.

Pet. 13.

Patent Owner's expert, Dr. David Steidley, proposes:

> [A] POSITA, at the time of the '648 patent, would have an undergraduate degree in science, math, physics, engineering, or the like, and a graduate degree (M.S. or Ph.D.) in a similar field that includes study of engineering, natural science, physics, radiation physics or the like, together with at least five years of experience working with radiation imaging and radiation therapy systems beyond the completion of his or her degrees.

Steidley Decl. ¶ 52; Steidley 2nd Decl. ¶¶ 18, 45. Dr. Steidley testifies that one of ordinary skill in the art must have at least five years of radiation imaging and therapy experience, because the use of radiation to treat patients creates a serious risk to the health and safety of human life, and a person having less than five years' experience would be unable to appreciate and predict the medical risks encountered in the clinical practice of radiation therapy. Steidley 2nd Decl. ¶ 51.

As stated in the "Field Of The Invention" of the '648 patent:

> This invention relates to a device for treating a patient with ionising radiation. It is particularly suited to forms of radiosurgery and to certain forms of radiotherapy.

Ex. 1001, 1:6–8. The "Background Art" portion of the '648 patent further provides basic information about the treatment of pathological cells using radiation, including the fact that radiation can be used to kill tumor cells, the corresponding need to avoid damage to healthy cells, the use of radiation imaging to assist in treatment, the need for "pinpoint accuracy" in focusing the radiation beam when treating brain tumors, and characterizations of several then-known approaches for radiation treatment. *Id.* at 1:12–2:23.

The background section also provides a high-level description of linear accelerator ("linac") devices used for treatment, including their use of accelerated electrons to generate a collimated X-ray beam directed to the patient from a variety of directions, to "minimise the dosage outside the tumour and maximise it within the tumour." *Id.* at 2:24–43. The '648 patent asserts that a disadvantage of using a linac is that they are "extremely heavy," due to the linac components themselves as well as the required shielding to protect from radiation, and thus are hard to accurately position, particularly if the linac is mounted on a robotic arm. *Id.* at 2:44–3:31. Nonetheless, the'648 patent states that the use of linacs on robotic arms "can be constructed and find application to bodily tumours, [although] they are not sufficiently accurate for use with tumours of the brain." *Id.* at 3:15–17.

Beyond this background section, the bulk of the '648 patent is directed to detailed description of a sturdy mechanical apparatus capable of rotationally manipulating a linear accelerator in three dimensions oriented in

a variety of approach angles with high geometrical accuracy. Ex. 1001, Figs. 1–17, 3:65–4:48, 5:36–9:36. In particular, the '648 patent describes:

> a support, on which is provided a mount, a radiation source attached to the mount, the support being rotateable about an axis, the source being attached to the mount via a rotateable union having an axis of rotation which is non-parallel to the support axis, wherein the axis of the mount passes through the axis of the support and the radiation source is collimated so as to produce a beam which passes through the coincidence of those axes.

Id. at 4:5–13. In other words, the '648 patent is primarily directed to the mechanical engineering aspects of designing an apparatus using a linac for radiation treatment, not the details about the linac itself, or how such devices are used in a clinical context.

Accordingly, we agree with Petitioner's proposal requiring a person of ordinary skill to have education and training in mechanical engineering. Pet. 13. However, Petitioner's proposal does not sufficiently take into account the radiation imaging and radiation therapy environment of the pertinent field, which Patent Owner emphasizes. PO Resp. 12–13. But Patent Owner's proposal omits the predominately mechanical engineering aspects of the pertinent field, and disproportionately requires five years of experience in radiation imaging and therapy. The person of ordinary skill in the context of the '648 patent is not the user of the radiation device, but the designer of that device. We are not persuaded by Patent Owner's expert Dr. Steidley's opinion that a mechanical engineer of ordinary skill would not have been able to fully take into account the well-known dangers of radiation in designing a radiation treatment device. Steidley 2nd Decl. ¶ 51.

Therefore, based on the preponderance of the evidence before us, we determine that Petitioner's proposal should be modified to add the

requirement that a person of ordinary skill in the art would also have several years of experience designing radiation imaging and radiation therapy systems. Alternatively, given that a person skilled in the art of mechanical engineering would have been capable of applying engineering skills to a wide variety of applications if given the necessary information and specifications pertaining to such applications, it is sufficient for the person of ordinary skill in the art of the '648 patent to be skilled in the art of mechanical engineering and to have access to sources of information (such as collaborators in a development team) about the capabilities, constraints and specifications of radiation imaging and radiation therapy systems, at least to the extent of the general background information set forth in the '648 patent. *See In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994) (affirming rejection of a laptop computer hinge as obvious over hinged cabinets, piano lids, etc., because the "problem is not unique to portable computers"); *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 314 (Fed. Cir.1985) (affirming invalidation of a patent for a hinged pen arm because a person skilled in pen art would have looked to hinge and fastener art for a way to attach a pen to a pen arm); *Sci. Plastic Prod., Inc. v. Biotage AB*, 766 F.3d 1355, 1360 (Fed. Cir. 2014) ("[W]hen the problem an invention is designed to solve is not unique to the specific field of the invention, it is not improper for the trier of fact to consider whether a person of ordinary skill would consult a different art in order to solve the problem.").

Either of these articulations are consistent with the level of ordinary skill in the art reflected by the prior art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). They are also consistent with the evidence that actual radiation

therapy devices are developed by design teams that include mechanical engineers with limited prior experience working specifically with radiation treatment systems, who are able to consult with radiation therapists as necessary. Asmerom Decl. ¶¶ 30–41.

C. Claim Construction

For petitions filed after November 13, 2018, as here, a claim "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019). We apply the claim construction standard from *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (*en banc*).

Under that standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one with ordinary skill in the art in the context of the specification, the prosecution history, other claims, and even extrinsic evidence including expert and inventor testimony, dictionaries and learned treatises, although extrinsic evidence is less significant than the intrinsic record. *Phillips*, 415 F.3d at 1312–17. Usually, the specification is dispositive, and it is the single best guide to the meaning of a disputed term. *Id.* at 1315.

"Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic*

Sofamor Danek, Inc., 469 F.3d 1005, 1014 (Fed. Cir. 2006) (*citing Phillips*, 415 F.3d at 1312–17). However, in construing the claims, care should be taken to avoid improperly importing a limitation from the specification into the claims. *See Cont'l Circuits LLC v. Intel Corp.*, 915 F.3d 788, 797–98 (Fed. Cir. 2019) ("[U]se of the phrase 'present invention' or 'this invention' is not always . . . limiting, such as where . . . other portions of the intrinsic evidence do not support applying the limitation to the entire patent." (citations omitted)). An inventor may provide a meaning for a term that is different from its ordinary meaning by defining the term in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Claim terms need only be construed to the extent necessary to resolve the controversy. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011).

1. claim 1: rotateable union

Petitioner proposes to construe the claim term "rotateable union" to mean "a pivot between two components that provides rotating movement of one component about the same axis along which the pivot itself rotates." Pet. 8.[2] The term "rotateable union" was included in the original application claims and specification. Ex. 1003 ¶¶ 341, 343, 352, 378. Although not explicitly identified as such, we agree with Petitioner that, in the illustrative embodiment of the claimed invention described in the '648 patent, the two "pivotal mounting point[s] 30," illustrated in Figure 5 and described above, which together establish that the rotation axis of the mount, correspond to

[2] The record includes some instances of the United States spelling: "rotatable union." *E.g.*, Ex. 1002, 18; Ex. 1008, 56.

the claimed rotatable union. Pet. 8–9; *see* Ex. 1001, Fig. 5, 7:16–28. The "pivotal mounting point 30" is also referred to as merely a "pivot," and also as "pivot axis 30." Ex. 1001, code(57), 8:47. Also, in the Great Britain priority application, the claims were originally directed to a "pivot," and subsequently amended to "rotateable union." Ex. 1007, 3, 157.

Therefore, we agree with Petitioner that, in the context of the preferred embodiments of the '648 patent, "a person of ordinary skill in the art ('POSITA') would understand the term 'rotateable union' equates to a physical 'pivot,'" with the caveat that two such opposing pivots are required to define the rotatable union. Pet. 9. However, we do not agree that it is necessary or helpful to construe "rotatable union" as proposed. The term "rotateable union" is clear in the context of the claims and specification, and there is no need to instead revert to calling it a "pivot," or "pivots." Moreover, the portion of the proposed construction, "the same axis along which the pivot itself rotates," is confusing, because a "pivot" itself does not rotate, but rather establishes the axis about which something else rotates — in this instance the "source." *See* Ex. 1001, 12:10–12 ("the rotateable union comprises a connection allowing rotation of the source around the mount").

Patent Owner urges that "the term 'rotateable union' should not be limited to a 'pivot' or any particular pivot." PO Resp. 23. Patent Owner also argues that Petitioner's proposed construction of "rotatable union" should be rejected. *Id.* at 26–27. As discussed above, we agree as to both of these points.

2. rotation axis of the mount; support axis of the support

Petitioner points out that "rotation axis of the mount" in claim 1 has no explicit antecedent, and proposes to resolve any uncertainty on that score

by construing the phrase to mean "the rotation axis of the rotateable union." Pet. 12-13. Patent Owner states that it "agrees with Petitioner that 'the rotation axis of the mount' refers to the 'axis of rotation' in the claim language." PO Resp. 21. However, Patent Owner argues that "'rotation axis of the mount' is best understood as 'the rotation axis of the source relative to the mount,'" and maintains that Petitioner's construction "does not properly capture the antecedent claim language." *Id.*

Literally, the "rotation axis of the mount" in the fifth limitation of claim 1 most closely corresponds to the "rotateable union having a [sic] an axis of rotation axis [sic]" of the fourth limitation, which, after removing obvious errors, reads "rotateable union having an axis of rotation."[3] Ex. 1001, 9:60–61. Thus, we agree with Petitioner's interpretation, and we adopt it for purposes of this decision. Although Patent Owner is correct that the mount rotates about the rotation axis, the claim specifically states that it is the "rotatable union" that has an "axis of rotation." Ex. 1001, 9:60–61. Petitioner's construction more directly corresponds to the structure of the claim — that the "rotation axis of the mount" is the "rotation axis of the rotateable union."

In addition, we note that the claimed "support axis of the support" in the fifth limitation of claim 1 refers to the "axis coincident with the centre of the ring" in the third limitation. Ex. 1001, 9:58–59. Petitioner does not

[3] *See Novo Industries, L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1357 (Fed. Cir. 2003) (correct on of errors in a claim is permitted if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims); *Fitbit, Inc. v. Valencell, Inc.*, 964 F.3d 1112, 1119–20 (Fed. Cir. 2020) (re Board's ability to correct certain errors).

address this issue, and Patent Owner agrees with our interpretation. PO Resp. 21.

In sum, there are two axes required by claim 1: a rotation axis and a support axis. Examples of those axes are illustrated in the annotated figure reproduced above at page 3. The rotation axis is referred to in the claim language: "rotateable union having a [sic] an *axis of rotation* axis [sic]," and "the *rotation axis* of the mount" (emphasis supplied). The radiation source rotates about the rotation axis. The support axis is referred to in the claim language: "an *axis* coincident with the centre of the ring," and "the *support axis* of the support" (emphasis supplied). The ring-shaped support rotates about the support axis. *See* Ex. 1001, Fig. 1, 9:55–67.

3. ring-shaped support

Although not specifically raised as a claim construction issue, the meaning of "ring-shaped support" in the claims is at issue, in connection with the fifth ground asserted by Petitioner. Pet. 53. In particular, the question arises as to whether a "C-shaped," or semicircular, structure is ring-shaped. *Id.* We conclude it is not: a ring-shaped support must encompass a full, 360-degree circle, in accord with the plain meaning of "ring." Patent Owner agrees with this interpretation. PO Resp. 21–22. Our interpretation is confirmed by the fact that the '648 patent specifically distinguishes between the ring-shaped support of the illustrative embodiment *versus* the prior art that uses a "C-arm" or "U-arm" described in the background of the invention:

> Nakagawa et al [Ex. 2003] . . . proposes a system . . . in which some flexibility of movement is sacrificed in favour of greater accuracy. The linear accelerator is mounted on one end of a C-arm, which is (in turn) held in a rotateable support. The

> C-arm can move on its support; thus at its two extremities of motion it resembles more a U-arm or an inverted U. . . . [A]s the C-arm moves, the centre of gravity of the apparatus will shift, causing errors. To counteract this, Nakagawa et al require a complex system of retractable balance weights in order to prevent movement; this is a potential weakness in the accuracy of the apparatus.
>
> * * *
>
> [In the present invention, t]he rotation of the rotateable support will be eased *if this part of the apparatus is circular*.

Ex. 1001, 3:18–31, 4:18–20 (emphasis added).

4. claim 18: rotatable union

Unlike claim 1, independent claim 18 does not recite a "mount" that is "provided" by the "ring-shaped support," and to which is "attached" a "radiation source." Ex. 1001, 10:63–11:9. Rather, the claim requires a "ring-shaped support for the source," where the support permits "rotation about two axes," the source rotates "about the two axes," and the "rotation takes place via a rotateable union of the source to the support." We do not understand by this that the claim requires a rotateable union that permits rotation about two axes. We construe claim 18 as requiring a rotateable union to permit rotation about one axis, with no explicit requirement as to how the support permits rotation about the second axis. Patent Owner agrees with this interpretation. PO Resp. 27–28. Petitioner does not address this issue.

D. Objective Indicia of Non-Obviousness

Patent Owner submits evidence that it argues demonstrates the presence of objective indicia of non-obviousness, applicable to Petitioner's asserted grounds of unpatentability — in particular, that Petitioner's sales of its "ZAP-X" product demonstrate commercial success of

claims of the '648 patent, and that Petitioner copied the '648 patent in developing ZAP-X. PO Resp. 62–68, Sur-Reply 23–26.

Factual inquiries for an obviousness determination include secondary considerations based on evaluation and crediting of objective evidence of nonobviousness. *Graham*, 383 U.S. at 17. Notwithstanding what the teachings of the prior art would have suggested to one with ordinary skill in the art at the time of the invention, the totality of the evidence submitted, including objective evidence of nonobviousness, may lead to a conclusion that the claimed invention would not have been obvious to one with ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471–1472 (Fed. Cir. 1984).

"Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art." *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). But commercial success is relevant only when it is "due to [something] disclosed in the patent . . . which was not readily available in the prior art." *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983). That is, "[i]f commercial success is due to an element in the prior art, no nexus exists" between the commercial success and the claimed invention. *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011).

Patent Owner bears a burden of production with respect to evidence of commercial success; it must show "significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent." *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1377 (Fed.

Cir. 2000); *see also Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (nexus depends on the "correspondence between the objective evidence and the claim scope"); *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper No. 33 at 32 (PTAB Jan. 24, 2020) (Precedential) (noting rebuttable presumption). If a presumption of nexus is inappropriate, the Patent Owner may yet prove nexus by showing the evidence of secondary considerations is the "direct result of the unique characteristics of the claimed invention." *See In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996). If Patent Owner makes such a showing, Petitioner may rebut the evidence of commercial success by showing that "the commercial success was instead due to other factors extraneous to the patented invention." *Ecolochem*, 227 F.3d at 1377.

Patent Owner asserts that ZAP-X embodies 15 of the 17 challenged '648 claims, coextensive with ZAP-X, which is the only product of Petitioner, and therefore nexus may be presumed. PO Resp. 63–64 (citing Steidley 2nd Decl. ¶¶ 148–152, Ex. 2019).[4] As evidence of commercial success, Patent Owner cites FDA approval of ZAP-X, announcements of third-parties investing in Petitioner, and actual showings of ZAP-X and the installation of the ZAP-X at several medical facilities. *Id.* at 66–68 (citing Ex. 2022 ¶¶ 9–20; Exs. 2027–2038).[5] Patent Owner alleges that Petitioner

[4] The cited paragraphs of the Steidley declaration in turn cite Exhibits 2014–2018, and two videos relating to ZAP-X.

[5] On January 15, 2021, we denied as untimely Patent Owner's motion to submit supplemental information consisting of three additional exhibits regarding the use of ZAP-X to treat a patient, regulatory approvals, and a ZAP-X presentation. Paper 40.

has sold "several" ZAP-X products that cost "millions of dollars." Sur-Reply 24.

Patent Owner also asserts, as an indicia of nonobviousness, that Petitioner copied the subject matter of the '648 patent, based on the fact that Petitioner's CEO, John Adler, is the named inventor of a patent application that identified the '648 patent in an information disclosure statement. PO Resp. 64–65 (citing Ex. 2022 ¶¶ 4–7; Exs. 2020–2021). Patent Owner further asserts that the Adler application copies the '648 patent, and in turn that ZAP-X embodies the subject matter of that application. *Id.* at 65–66 (citing Steidley 2nd Decl. ¶¶ 153–154; Ex. 2022 ¶¶ 5–8; Exs. 2021, 2025, 2026).

Petitioner argues that Patent Owner has improperly attempted to show nexus by incorporating by reference 25 pages of arguments in the form of a claim chart comparing the '648 patent claims to five publications and two videos allegedly describing ZAP-X. Reply 22 (citing Steidley 2nd Decl. ¶¶ 148–152 (which in turn cites Exs. 2014–2018); Ex. 2019). *See* 37 C.F.R. § 42.6(a)(3); *Blackberry Corp. v. MobileMedia Ideas LLC,* Case No. IPR2013-00016, Paper 32 at 21 (P.T.A.B. Feb. 25, 2014).

Petitioner also submits that any presumption of nexus is rebutted by the fact that ZAP-X uses subject matter of a patent directed to a "self-shielded radiation treatment system," which is a key feature that has been the focus of the publicity surrounding ZAP-X. Reply 23–24 (citing Ex. 1031, 4:34–40; Ex. 2037, 2; Ex. 1025, 155:10–156:2, 156:16–24, 157:13–158:7). Petitioner also points out that the handful of sales of ZAP-X are insufficient evidence of commercial success. *Id.* at 24.

Petitioner also challenges Patent Owner's evidence of copying as insufficient, contrasting the facts here with cases involving evidence of actual copying efforts. Reply 24–25.

Based on our review of the record we have considered the secondary considerations of non-obviousness and accorded them appropriate weight along with all of the *Graham* factors, and for the reasons further set forth below we agree with the Petitioner that the challenged claims would have been obvious in light of submitted references. We are not prepared to accept Patent Owner's conclusory assertions of nexus, which are: supported only by attorney arguments (not evidence); presented in the form of claim charts that are incorporated by reference rather than being included on Patent Owner's Response; and dependent on hearsay descriptions of ZAP-X. In addition, the record does not demonstrate that the alleged "millions of dollars" of sales of ZAP-X (consisting of a few such items sold) are attributable to the subject matter of the '648 patent. For example, the record shows that the use of linacs for radiation treatment preexisted the invention of the '648 patent. Ex. 1001, 2:24–62. There is no evidence to differentiate the sales attributable to the invention from the sale of a linac, together with the required shielding and control mechanisms generally required for treatment irrespective of whether or not the invention is used.

In addition, we find Patent Owner's allegation of copying speculative and not persuasive. The fact that the '648 patent was cited in an information disclosure statement during prosecution of a patent

application that named the CEO of Petitioner, without more, is not sufficient evidence of copying.

E. Ground 1: Obviousness of Claims 1–4, 7–8, 11–12, 17–18, 20, and 23 Over Grady and Ruchala

Petitioner challenges claims 1–4, 7–8, 11–12, 17–18, 20, and 23 as unpatentable under pre-AIA 35 U.S.C. § 103(a) over the combination of Grady and Ruchala. Pet. 16–38. In support of this prior art combination, Petitioner also relies on Winter, Schonberg, and Adler as evidence of the pertinent prior art background. Pet. 20–21.

1. Grady

Grady, titled "Digital X-Ray Stand," was filed January 30, 1984 and issued March 10, 1987. Ex. 1009, codes (54), (22), (45). Because Grady issued before the earliest priority date of the '648 patent, this reference is prior art to the '648 patent under pre-AIA 35 U.S.C. § 102(a).

Grady discloses an X-ray tube mounted on sliding arm connected to a rotating support. *Id.* at code (57). Figure 1 is reproduced below.

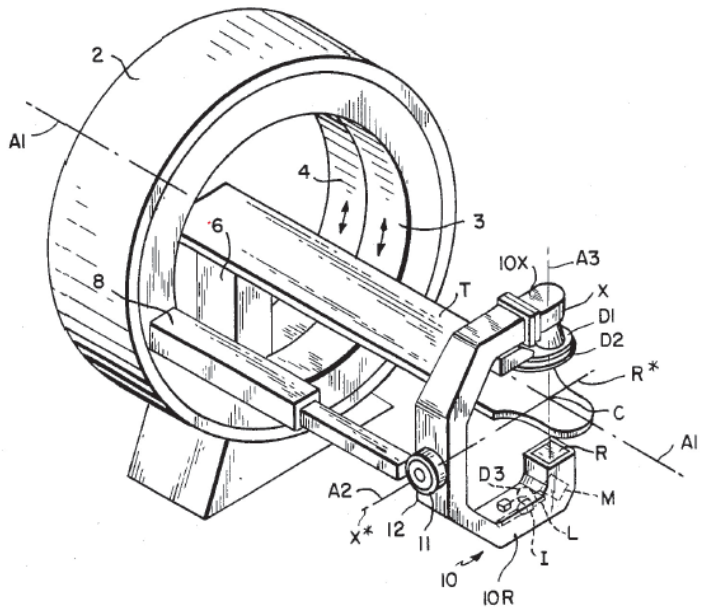

FIG. 1

Figure 1 shows fixed outer ring 2, within which front ring 3 and rear ring 4 can rotate manually or via a motor drive. *Id.* at 1:46–49. Patient table T is attached to rear ring 4, positioned along the axis of rotation A1 of the rings, and longitudinally adjustable along that axis. *Id.* at 1:49–53. An arm extends from sleeve 8 attached to front rotating ring 3, which arm can slide in and out of the sleeve parallel to axis A1. *Id.* at 1:53–56. Carriage 10 is attached to the arm via rotary bearing 11, and can rotate about axis A2. *Id.* at 1:56–60. X-ray tube X is carried by carriage 10 and is aligned on radiation axis A3 which intersects axes A1 and A2 at isocenter C. *Id.* at 1:61–66. As explained in Grady:

> The present structure affords rotation of the radiation source means X and receptor R about both the first axis Al and second axis A2 for radiation of a subject from substantially throughout spherical loci around the subject position at the isocenter C.

Id. at 2:25–29. The X-ray device of Grady is used to obtain X-ray images for examining patients. *Id.* at 1:27–28, 2:5–14.

2. Ruchala

The article by Ruchala, titled "Megavoltage CT image reconstruction during tomotherapy treatments," appears on its face to have been published in the journal, "Phys. Med. Biol.," in 2000. Ex. 1010. Although Petitioner does not explicitly address publication date, the document itself indicates that it was published in a professional journal and was copyrighted in 2000. A copyright date in and of itself does not necessarily fix the exact date of public accessibility. *In-Depth Geophysical, Inc. v. Conocophillips Co.*, IPR2019-00849, Paper 14 at 4–13 (PTAB Sept. 6, 2019). However, the article also includes a header with a conventional journal reference:

> Phys. Med. Biol. 45 (2000) 3545-3562. Printed in the UK.[6]

Ex. 1010, 1. The occurrence of "2000" in the header of the article strongly evidences publication as of that year or at least reasonably soon thereafter.

> [I]ndicia on the face of a reference, such as printed dates and stamps, are considered as part of the totality of the evidence.
>
> * * *
>
> The Board has often found a reasonable likelihood that a reference is a printed publication for institution of an inter partes review when the evidence relied on in a petition provides strong indicia that an asserted reference was publicly accessible.

Hulu, LLC v Sound View Innovations, LLC, IPR2018-01039, Paper No. 29 at 17–18 (PTAB Dec. 20, 2019) (Precedential). Accordingly, we determine that the preponderance of the evidence establishes that the referenced journal

[6] A Google search indicates "Phys. Med. Biol." refers to the journal, *Physics in Medicine & Biology.*

containing this article was publically accessible prior to the earliest priority date (October 23, 2003) of the '648 patent. Ex. 1001, code (30).

Ruchala describes an "integrated tomotherapy system" that combines CT imaging of a patient using a linac that is also used to treat tumors in the patient. Ex. 1010, 3545, 3547. The linac is fitted with a "multileaf collimator" to "allow for a highly conformal treatment that will deliver dose to the tumour while sparing sensitive structures." *Id.* at 3545. The CT imaging capability ensures "properly positioning the patient's body and interior organs, [and] it is also vital to know that the treatment was delivered as intended." *Id.* In the system, "the patient remains still, but the linac and detector rotate about the patient." *Id.* at 3548.

3. The Combination of Grady and Ruchala

For the combination of Grady and Ruchala, Petitioner relies on its expert Dr. McCarthy's testimony that one of ordinary skill would have been motivated to use the flexible targeting capabilities of Grady to treat tumors with radiation sources, such as linacs, as described in Ruchala. Pet. 19–20 (*citing* McCarthy Decl. ¶ 74). The three-dimensional manipulation capabilities of Grady adapted to use a radiation source for treatment of tumors allows "therapy [to] be highly articulable and able to be directed to a critical location from virtually any angle or direction." *Id.*; Reply 18–20.

Dr. McCarthy further cites Ruchala as providing a motivation to adapt Grady for use in treatment, because it teaches that the integration of imaging and therapy delivery allows for more accurate delivery and verification of dose delivery to the tumor, thus allowing imaging before, during, and after therapy delivery, which provides benefits of potential increased patient throughput, reductions in imaging dose, and visualization of the patient

during treatment. McCarthy Decl. ¶ 73 (*citing* Ex. 1010, Abstr., 3545); Reply 18. Dr. McCarthy testifies that Ruchala shows that a "person of ordinary skill would have known of the benefits of mounting a linear accelerator with a collimator on a gantry both for treatment and imaging." *Id.*

Dr. McCarthy also cites Winter as evidence that a person of ordinary skill would have been motivated to combine a CT scanner with a radiation source to treat tumors, in order to "'add a therapeutic dimension' to . . . existing imaging apparatus." McCarthy Decl. ¶ 74; Ex. 1016, code (57), 1:65–2:1.[7] Winter teaches that this combination provides the benefit of "more accurate positioning of the patient due to the fact that a single device having diagnostic imaging capability is used for both imaging and therapy purposes." Ex. 1016, 2:41–45.

Relying in part on Adler, Dr. McCarthy further testifies that, notwithstanding the assertions in the '648 patent that the "great weight" of linacs created problems that the patent solved (*e.g.*, Ex. 1001, 3:3–17), it was well known at the time of the priority date of the patent that "relatively light weight" linacs were available, thus facilitating using technology such as disclosed in Grady in combination with a linac as a therapeutic radiation source, and confirming that a person of ordinary skill would be motivated to

[7] Petitioner's use of Winter (and Adler) as evidence of the state of the art, to support why a POSITA would be motivated to combine Grady and Ruchala, is appropriate. See *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015) (prior art references to show the state of the art at the time of the invention "can legitimately serve to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness"); *Genzyme Therapeutic Prod. Ltd. P'ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1369 (Fed. Cir. 2016).

arrive at the combination of Grady and Ruchala. Pet. 20–22 (*citing* McCarthy Decl. ¶ 38; Ex. 1012, 1:8–10, 6:44–68.); *see also* Reply 3–5.[8] Dr. McCarthy testifies:

> Given the identical purpose of the positioning system for imaging and therapy and the availability and use of small, lightweight portable linear accelerators by 2000, a person of ordinary skill in the art would have been motivated to use a linear accelerator as the X-ray radiation source of Grady to perform radiotherapy in conjunction with imaging.

McCarthy Decl. ¶ 74.

As a threshold matter, Patent Owner challenges the testimony of Dr. McCarthy.[9] PO Resp. 2–3, 15–16, 18–20; Sur-Reply 6–9. Patent Owner points out that Dr. McCarthy's experience with Accuray, which developed and sold the "CyberKnife" radiation treatment device, was primarily supervisory, and not involved with the development of the CyberKnife. *Id.* at 15 (citing Ex. 2010, 80:10–23, 81:1–9, 82:4–7, 82:8–13; 83:23–84:2); Sur-Reply 7. In addition, Patent Owner cites the fact that Dr. McCarthy has no experience in operating radiation therapy devices or creating treatment

[8] Petitioner also relies on Schonberg for additional details of light-weight linacs. Pet. 21, Ex. 1011. Unlike Ruchala, Schonberg appears to be a document handed out at a meeting, and the record does not show that it was publically accessible as of the priority date of the '648 patent. *See Medtronic, Inc. v. Barry*, 891 F.3d 1368 (Fed. Cir. 2018). Therefore, we do not consider it.

[9] In the context of its revised motion to amend, Patent Owner also moves to exclude Dr. McCarthy's declarations submitted in support of Petitioner's Opposition to Patent Owner's original motion to amend (Exhibit 1026), and revised motion to amend (Exhibit 1036). Paper 37; Paper 41. This aspect of Patent Owner's challenges to Dr. McCarthy's testimony is discussed further below at Section V.

plans using such devices. *Id.* at 16 (citing Ex. 2010, 22:23–23:7; 24:8–9; 26:22–25, 27:8–18).

Patent Owner in particular alleges that Dr. McCarthy misunderstands the teachings of Winter which, according to Dr. McCarthy, support his testimony that one of ordinary skill in the art would have been aware of the benefits of combining radiation therapy with imaging. *See* McCarthy Decl. ¶ 74. According to Patent Owner, the approach of Winter would not be clinically acceptable for the types of treatments that Dr. McCarthy assumes to be the case. PO Resp. 18–20 (citing Steidley Decl. ¶¶ 108–109; Steidley 2nd Decl. ¶¶ 54–56, 75).

In addition to challenging Petitioner's reliance on its expert Dr. McCarthy's testimony, Patent Owner challenges Petitioner's overall rationale for making the combination, arguing that one of ordinary skill in the art of radiation treatment devices would not consider diagnostic imaging devices such as disclosed in Grady, because such devices serve a completely different purpose, require "very different and completely separate training and experience" to use, employ "orders of magnitude" lower radiation energies, and use fan-shaped radiation beams that do not need to be narrowly focused or shaped at specific distances and from different directions to treat diseased tissue but avoid healthy tissue. PO Resp. 29–34 (citing Steidley 2nd Decl. ¶¶ 59–82, 87–88; Beron Decl. ¶¶ 44–57, 73–77, 79–82, 90–91, 102, 105–117, 119–123).

Patent Owner submits that Grady discloses a diagnostic imaging device and does not disclose anything about radiation treatment. Therefore, Patent Owner argues, a person of ordinary skill in the art would not consider it when designing a radiation treatment device, because it operated at an

unsuitable low radiation energy range, and was not engineered to accurately carry and aim heavy linac radiation sources. PO Resp. 35–38 (citing Steidley Decl. ¶¶ 80, 111–115; Steidley 2nd Decl. ¶¶ 61–66, 94–97; Beron Decl. ¶¶ 114–116); *see also* Sur-Reply 4–6.

Patent Owner contrasts Grady with Ruchala and Adler, which use linacs for radiation treatment, operate in the higher megavolt range, and require more accurate aiming capability. PO Resp. 39–44 (citing Steidley Decl. ¶¶ 97, 116–121, 146–150; Steidley 2nd Decl. ¶¶ 98, 118, 124–126; Beron Decl. ¶ 45); Sur-Reply 19–20. Patent Owner argues that Grady's single extending arm is not designed to hold or properly aim a heavier, high powered linac to deliver radiation treatment. In addition, Patent Owner argues that Grady would need automated control capability to carry out the required treatment, and therefore a person of ordinary skill in the art would not have expected the structure of Grady to provide a viable solution for focusing a therapeutic radiation source on the target. PO Resp. 44–46 (citing Steidley Decl. ¶¶ 125–126; Steidley 2nd Decl. ¶¶ 85, 102–108; Beron Decl. ¶¶ 39–40, 74–77, 112–123, 124–129).

Patent Owner takes issue with Dr. McCarthy's reliance on the disclosures in Ruchala and Winter of combining CT scanning and radiation treatment. PO Resp. 47–55. Patent Owner points out that the type of imaging contemplated by those references uses different voltage ranges compared to Grady, resulting in lower resolution images. PO Resp. 47–48 (citing Steidley 2nd Decl. ¶ 111). In addition, as discussed, Patent Owner argues that incorporating the heavy linac of Ruchala would require substantial redesign of the Grady apparatus. *Id.* at 48 (citing Steidley 2nd Decl. ¶ 112). Patent Owner argues that even the lighter linac of Adler would be considerably

heavier than the X-ray device of Grady. *Id.* at 49 (citing Steidley 2nd Decl. ¶ 112). As discussed above in connection with Patent Owner's challenge to Dr. McCarthy's testimony, Patent Owner argues that Winter discloses practices that were outdated by the priority date of the '648 patent, and that Winter would not have worked as a therapeutic device. *Id.* at 51–53 (citing Steidley Decl. ¶¶ 107–110; Steidley 2nd Decl. ¶¶ 54–56, 74–78, 107; Beron Decl. ¶¶ 79, 83); Sur-Reply 21–22.

In response to Patent Owner's arguments against Dr. McCarthy's testimony, Petitioner reiterates its position that the primary focus of the'648 patent claims is on the mechanical engineering aspects of a radiation therapy device, not on the details of treatment of brain tumors. Reply 11–12. Petitioner cites Dr. McCarthy's experience in training mechanical engineers to design radiation therapy devices in his position as Chief Technical Officer of Accuray. *Id.* (citing McCarthy Reply Decl. ¶¶ 1–12, 39). Moreover, Petitioner cites evidence that the design of radiation therapy devices involves collaboration between mechanical engineers and persons with clinical experience. *Id.* at 12 (citing Asmerom Decl. ¶¶ 8–22, 28–41, 51).

Petitioner further points out that during the prosecution of the '648 patent, patents directed to imaging devices were cited, and were not distinguished based on an argument that imaging devices were not relevant art. Reply 1–2. Petitioner also submits the deposition testimony of Patent Owner's experts admitting that linacs were available at the pertinent time period that weighed in the 100–175 kg range, which could be handled by available industrial robot arms. *Id.* at 4–5 (citing Ex. 1025, 142:12–15, 144:17–19, 146:8–23; Ex. 1024, 36:23–38:23). Petitioner points out that,

notwithstanding the reference in the '648 specification to heavy linacs, the claims are not limited to any particular type of linac. *Id.* at 5.

Petitioner also argues that the preambles of independent claims 1 and 18, which recite "treating a patient," are not limiting, and in any event the claims do not require any particular form of treatment, such as treatment for brain tumors, or any particular level of efficacy, precision, voltage level, or pre-treatment planning. Reply 6–9. Petitioner also submits that Patent Owner's experts lack mechanical engineering experience, and therefore their opinions regarding whether one of ordinary skill would be motivated to combine Grady and Ruchala are not persuasive. Reply 13–14.

Regarding the imaging capabilities of Grady, Petitioner cites evidence that Grady is designed for both kilovolt and megavolt energy ranges, and thus does not have the resolution problems that Patent Owner alleges. Reply 15–16 (citing Ex. 2004, 1:13–16, 4:48–51). Petitioner also disputes Patent Owner's criticism of Winter, given that kilovolt-level radiation is suitable for various type of treatments, and that irrespective of the suitability of using "beam masks," Winter nevertheless teaches the desirability of using a radiation source for both imaging and treatment. Reply 16–17 (citing Ex. 1024, 137:19–138: 3, 165:5–23).

We determine that the preponderance of the evidence demonstrates that one of ordinary skill would have been motivated to combine the three-dimensional flexible targeting capabilities of Grady to treat tumors with radiation sources, such as linacs, as described in Ruchala, to arrive at a radiation therapeutic device that meets the challenged claims of the '648 patent. Obviousness entails an inquiry that is "expansive and flexible" and takes into account "the inferences and creative steps a person of ordinary

skill in the art would employ" when presented with the teachings of the prior art. *KSR*, 550 U.S. at 415–18. "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. . . . A person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 420–421. Also, "[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference . . . . 'Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.'" *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). "Combining the *teachings* of references does not involve an ability to combine their specific structures." *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973).

As discussed above in Section III.B, the pertinent field of the invention includes the engineering design of sturdy mechanical apparatus capable of rotationally manipulating heavy devices in three dimensions oriented in a variety of approach angles with high geometrical accuracy, in the context of the radiation imaging and radiation therapy environment. One of ordinary skill in the art would have been a mechanical engineer, either with experience in radiation therapy devices or with access to information concerning such devices. We credit Petitioner's expert Dr. McCarthy as qualified to testify about the mechanical engineering aspects of radiation therapy devices, which is the principal focus of the '648 patent claims. The record shows that Dr. McCarthy has extensive experience and knowledge of mechanical engineering design, including sufficient experience with radiation imaging and radiation therapy devices. McCarthy Decl. ¶¶ 3–10; Ex. 1004. In addition, he has reviewed and analyzed the art of radiation

imaging and radiation therapy systems pertinent to the invalidity issues raised by Petitioner. McCarthy Decl. ¶¶ 12–13, 32–43, 74, 77. We are not persuaded that Dr. McCarthy's testimony should be disregarded.

We acknowledge that there are differences between lower voltage X-Ray devices used for imaging, and higher voltage linacs used for treatment. But we are not persuaded by Patent Owner's expert's testimony that, because Grady is an X-ray imaging apparatus used as a diagnostic device for imaging soft tissue, one of ordinary skill in the art of radiation treatment devices would not consider diagnostic imaging devices such as disclosed in Grady. Indeed, we find that Patent Owner's experts' testimony on this score lacks credibility — persons of ordinary skill in the applicable art would have readily understood the advantages of the three-dimensional manipulation capabilities of the Grady approach, would have appreciated their applicability to radiation treatment, and would have not have been dissuaded from making the combination despite the various differences between imaging and treatment that Patent Owner's experts rely on. The Patent Owner's experts' arguments directed to the need for high degree of precision required for treatment of brain tumors are not commensurate with the scope of the claims, which do not require any particular degree of precision and are not limited to the treatment of brain tumors. Likewise, Patent Owner's experts' testimony regarding orders of magnitude difference in radiation energies, fan-shaped versus narrow beams, difficulty in accommodating heavy linacs, and differences in efficacy, precision, and pre-treatment planning are not factors which would dissuade one of ordinary skill from making the combination.

In sum, the preponderance of the evidence establishes that a person of ordinary skill would have been motivated to use the flexible targeting capabilities of Grady to treat tumors with radiation sources, such as linacs, as taught by Ruchala.

4. Independent Claim 1

The preamble of claim 1 requires, "A device for treating a patient with ionising radiation."[10] Ex. 1001, 9:54–55. Petitioner relies on the combination of Grady and Ruchala as teaching or suggesting such a device, and in particular the disclosure in Ruchala of the use of a linac for radiotherapy. Pet. 23–24 (*citing* McCarthy Decl. ¶¶ 72–75; Ex. 1010, 3545, 3547).

The first limitation of claim 1 requires, "a ring-shaped support, on which is provided a mount, a radiation source attached to the mount." Ex. 1001, 9:56–57. Petitioner identifies front ring 4 of Grady as the ring-shaped support, sleeve 8 with its sliding arm as the mount, to which is attached carriage 10 which holds the radiation source, which in the combination is the linac of Ruchala. Pet. 24–25 (*citing* Ex. 1009, Fig. 1, 1:46-60).

The second limitation of claim 1 requires, "the support being rotateable about an axis coincident with the centre of the ring." Ex. 1001,

[10] The petition apparently assumes the preamble is limiting, but Petitioner argues in the Reply that it is not limiting. Pet. 23–24; Reply 6–7. Patent Owner argues otherwise. Sur-Reply 10–13. Because the record has shown that the recitation in the preamble is satisfied by the prior art, there is no need to determine whether the preamble is limiting. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

9:58–59. Petitioner relies on the fact that front ring 4 rotates about axis A1. Pet. 25 (*citing* McCarthy Decl. ¶ 72; Ex. 1009, Fig. 1, 2:18–24).

The third limitation of claim 1 requires, "the source being attached to the mount via a rotateable union having a [sic] an axis of rotation axis [sic] which is non-parallel to the support axis." Ex. 1001, 9:60–62. Petitioner relies on the fact that carriage 10 rotates on rotary bearing 11 about axis A2, which is perpendicular to axis A1. Pet. 25–26 (*citing* Ex. 1009, Fig. 2, 1:56–66).

The fourth limitation of claim 1 requires, "wherein the rotation axis of the mount passes through the support axis of the support and the radiation source is collimated so as to produce a beam which passes through the co-incidence of the rotation and support axes." Ex. 1001, 9:63–67. Petitioner relies on the fact that the isocenter C is defined by the intersection of axes A1, A2, and the radiation axis A3. Petitioner also relies on the disclosure in Ruchala that the linac beam is equipped with a collimator. Pet. 26–27 (*citing* Ex. 1009, Fig. 1, 1:56–66; Ex. 1010 at 3547).

Other than arguing that Petitioner's combination of Grady and Ruchala is improper, and that objective indicia require a conclusion of nonobviousness (which arguments, for the reasons discussed above, we find unpersuasive), Patent Owner does not have any specific arguments refuting Petitioner's comparison of the combination to the requirements of claim 1.

Having considered both the evidence of obviousness and Patent Owner's submitted evidence of nonobviousness, and weighed the entirety of the evidence, we determine that Petitioner has proved by a preponderance of the evidence that claim 1 would have been obvious over the combination of Grady and Ruchala.

5. Independent Claim 18

The preamble of claim 18 requires, "A method of treating a patient with a source that emits a beam of radiation in a direction emanating therefrom." Ex. 1001, 10:63–65. Petitioner relies on its analysis of the preamble of claim 1 for the claim 18 preamble. Pet. 33.

The first limitation of claim 18 requires, "providing a ring-shaped support for the source, the support permitting rotation about two axes each offset from the source, with both axes and the beam direction all being co-incident at a single isocentre." Ex. 1001, 10:66–11:2. For this claim requirement, Petitioner relies on the same features of Grady identified for claim 1. Pet. 33–35.

The second and third limitations of claim 18 require, "positioning the patient such that a diseased area of tissue is located at the isocentre" and "activating the source." Ex. 1001, 11:3–5. Petitioner relies on the combination of Grady and Ruchala for these requirements, including the Grady Figure 2 disclosure of a patient P positioned on table T at isocenter C, which is the target of the radiation beam, which in the combination is the linac used to treat the patient's tumor. Pet. 35–36 (*citing* McCarthy Decl. ¶¶ 155–158; Ex. 1009, Fig. 2; Ex. 1010, 3551, 3560).

The fourth limitation of claim 18 requires, "causing rotation of the source about the two axes to achieve a greater dosage at the isocentre than around the isocentre, wherein the rotation takes place via a rotateable union of the source to the support."[11] Ex. 1001, 11:6–9. Petitioner relies on the

[11] We note that, unlike claim 1, claim 18 does not recite a "mount" that is "provided" by the "ring-shaped support," and to which is "attached" a "radiation source." Rather, the claim requires a "ring-shaped support for the source," where the support permits "rotation about two axes," the source

ability of Grady to rotate the source about axes A1 and A2, together with the description in Ruchala of "deliver[ing] doses to the tumour while sparing sensitive structures." Pet. 36–37 (*citing* McCarthy Decl. ¶¶ 155–157; Ex. 1009, 2:25–29; Ex. 1010, 3545).

Other than arguing that Petitioner's combination of Grady and Ruchala is improper, and that objective indicia require a conclusion of nonobviousness (which arguments, for the reasons discussed above, we find unpersuasive), Patent Owner does not have any specific arguments refuting Petitioner's comparison of the combination to the requirements of claim 18.

Having considered both the evidence of obviousness and Patent Owner's submitted evidence of nonobviousness, and weighed the entirety of the evidence, we determine that Petitioner has proved by a preponderance of the evidence that claim 18 would have been obvious over the combination of Grady and Ruchala.

6. Dependent Claims 2–4, 7–8, 11–12, 17, 20, and 23

Claims 2–4, 7, and 23 depend from claim 1, and add the limitations, respectively, "the support is disposed in an upright disposition"; "the support and rotation axes are transverse"; "the mount extends transverse to the support"; "the beam direction is perpendicular to the rotation axis of the mount"; and "the rotateable union comprises a connection allowing rotation of the source around the mount." Ex. 1001, 10:1–9, 10:16–18, 12:10–12. Petitioner relies on the disclosed orientation of the components and axes of

---

rotates "about the two axes," and the "rotation takes place via a rotateable union of the source to the support." As discussed in Section III.C.4 above, we construe this claim as requiring a rotateable union to permit rotation about one axis.

the embodiment shown in Figure 1 of Grady as discussed above in connection with claim 1. Pet. 28–31, 37 (*citing* McCarthy Decl. ¶¶ 90–95; Ex. 1009, Fig. 1, 2:25–29).

Claim 8 depends from claim 1, and adds the limitation, "the radiation source is a linear accelerator." Ex. 1001, 10:19–21. Petitioner relies on the disclosed linac of Ruchala, in combination with Grady. Pet. 31–32 (*citing* McCarthy Decl. ¶¶ 101–105; Ex. 1010, 3547–48).

Claim 11 depends from claim 1, and adds the limitation, "including a patient support," and claim 12 depends from claim 11, and adds the limitation, "a position of the patient support is adjustable." Ex. 1001, 10:31–34. Petitioner relies on patient table T described in Grady, which is longitudinally adjustable parallel to the rotation axis A1. Pet. 32 (*citing* Ex. 1009, 1:49–53.)

Claim 17 depends from claim 1, and adds the limitation, "an integral imaging device is used to determine a position of the patient." Ex. 1001, 10:60–62. Petitioner relies on the description in Ruchala on the use of a linac for both treatment as well as scanning capabilities at low energy levels, used to properly position the patient's body, in combination with the apparatus of Grady, including table T. Pet. 32–37 (*citing* McCarthy Decl. ¶¶ 147–148; Ex. 1010, 3545, 3548).

Claim 20 depends from claim 18, and adds the limitation, "the source is de-activated when the source is in specific positions relative to the two axes." Ex. 1001, 11:13–15. Petitioner argues that a person of ordinary skill would know that the source is activated only when properly focused on the target region, and is normally otherwise not activated. Pet. 32–33 (*citing* McCarthy Decl. ¶¶ 170–171).

Other than arguing that Petitioner's combination of Grady and Ruchala is improper, and that objective indicia require a conclusion of nonobviousness (which arguments, for the reasons discussed above, we find unpersuasive), Patent Owner does not have any specific arguments refuting Petitioner's comparison of the combination to the requirements of these claims.

Having considered both the evidence of obviousness and Patent Owner's submitted evidence of nonobviousness, and weighed the entirety of the evidence, we determine that Petitioner has proved by a preponderance of the evidence that claims 2–4, 7–8, 11–12, 17, 20, and 23 would have been obvious over the combination of Grady and Ruchala.

F. Ground 2: Obviousness of Claims 9, 10, 13, 16, and 22 Over Grady, Ruchala, and Lam

Petitioner challenges claims 9, 10, 13, 16, and 22 as unpatentable under pre-AIA 35 U.S.C. § 103(a) over the combination of Grady, Ruchala, and Lam. Pet. 38–46.

Lam, titled "Computer Controlled Collimator Changer," was filed September 5, 1997 and issued August 31, 1999. Ex. 1013, codes (54), (22), (45). Because Lam issued before the earliest priority date of the '648 patent, this reference is prior art to the '648 patent under pre-AIA 35 U.S.C. § 102(a). Lam discloses controlling radiation doses from a linac mounted on a gantry using a computer that controls the beam position and intensity, the collimators that shape the beam, and the orientation and position of the assembly supporting the patient. Ex. 1013, code (57), Fig. 4, 4:17–29, 53–61.

Claims 9 and 10 depend from claim 1, and claims 13, 16, and 22 depend from claim 10, and add the limitations, respectively:

> "the collimation of the radiation source is adjustable" (claim 9);
>
> "a control means for programmably controlling the collimation of the radiation source in a manner correlated with a movement of the radiation source" (claim 10);
>
> "a patient table having a position which is adjustable under the control of the control means, the control means being adapted to adjust the position of the patient table in a manner correlated with the movement of the radiation source" (claims 13 and 22);
>
> "at least one rotation speed of the radiation source is controllable by the control means, the control means being adapted to adjust the at least one rotation speed in a manner correlated with at least one of the movement of the radiation source, the collimation of the radiation source, and the position of a patient table" (claim 16).

Ex. 1001, 10:23–29, 10:36–41, 10:53–59, 12:3–9. Petitioner summarizes these claims as "relating to adjustment of the collimation of the radiation, and 'a control means for programmably controlling' the collimation of the radiation source, position of the patient table, [and] rotation speed of the rotation source in relation to various parameters." Pet. 38–39. Petitioner cites the admission in the '648 patent that much of this claimed functionality is commonplace and well known:

> [T]he use of a linear accelerator allows dynamic changes to the intensity of the beam or its temporary interruption. . . . it is well known that to conform to irregular distributions of pathological tissue that combinations of beams collimated to different sizes are often required. As this device only has a single source a programmable collimator such as a multileaf collimator or selection of different sized collimators can be provided. The size of the collimator can be programmed to change at certain times in the treatment.

Pet. 39 (*citing* Ex. 1001, 8:1–17).

In support of the combination of Grady, Ruchala, and Lam, Petitioner refers to its arguments discussed above for the combination of Grady and Ruchala, and supplements them by arguing that a person of ordinary skill in the art would have been further motivated to implement the computer control of Lam, given that each of Lam, Grady, and Ruchala relate to the use of radiation sources mounted on a gantry, that Ruchala discloses that the treatment beam is modulated with collimators controlled by software, and that Lam provides a more detailed teaching of such control. Pet. 42–43 (*citing* McCarthy Decl. ¶¶ 106–121, 132–144, 172–176; Ex. 1009, 1:23–37; Ex. 1010, 3545, 3547, 3548, 3552; Ex. 1013, Fig. 4, 4:17–29, 53–61).

Other than arguing that Petitioner's combination of Grady and Ruchala is improper, and that objective indicia require a conclusion of nonobviousness (which arguments, for the reasons discussed above, we find unpersuasive), Patent Owner does not have any specific arguments refuting Petitioner's reliance on the combination of Grady, Ruchala, and Lam for this ground. Accordingly, the preponderance of the evidence establishes that a person of ordinary skill would have been motivated to combine Grady, Ruchala, and Lam as argued by Petitioner.

For the claims 9 and 10, Petitioner relies on the disclosure in Lam of the use of collimators to adjust the shale of the beam, controlled by a computer as a function of beam position. Pet. 44 (*citing* Ex. 1013, 3:28–35, 5:35–39).

For claims 13, 16, and 22, Petitioner relies on the disclosure in Lam of a computer that controls the beam position and intensity, the collimators that shape the beam, and the orientation and position of the assembly supporting

the patient, with such adjustments correlated with each other. Pet. 44–46 (*citing* Ex. 1013, 4:53–61).

Other than arguing that Petitioner's combination of Grady and Ruchala is improper, and that objective indicia require a conclusion of nonobviousness (which arguments, for the reasons discussed above, we find unpersuasive), Patent Owner does not have any specific arguments refuting Petitioner's Ground 2 challenge.

Having considered both the evidence of obviousness and Patent Owner's submitted evidence of nonobviousness, and weighed the entirety of the evidence, we determine that Petitioner has proved by a preponderance of the evidence that claims 9, 10, 13, 16, and 22 would have been obvious over the combination of Grady, Ruchala, and Lam.

G. Grounds 3 and 4: Obviousness of Claims 1–4, 7–8, 11–12, 17–18, 20, and 23 Over Adler and Grady, and of Claims 9, 10, 13, 16, and 22 Over Adler, Grady, and Lam

Petitioner challenges claims 1–4, 7–8, 11–12, 17–18, 20, and 23 as unpatentable under pre-AIA 35 U.S.C. § 103(a) over the combination of Adler and Grady, and of Claims 9, 10, 13, 16, and 22 Over Adler, Grady, and Lam. Pet. 46–52.

Adler, titled "Apparatus For And Method Of Performing Stereotaxic Surgery," was filed October 19, 1990 and issued May 4, 1993. Ex. 1012, codes (54), (22), (45). Because Adler issued before the earliest priority date of the '648 patent, this reference is prior art to the '648 patent under pre-AIA 35 U.S.C. § 102(a). Adler discloses using a linac mounted on a robotic arm, using collimators to treat tumors. Ex. 1012, 1:6–12. Figure 3 of Adler is reproduced below.

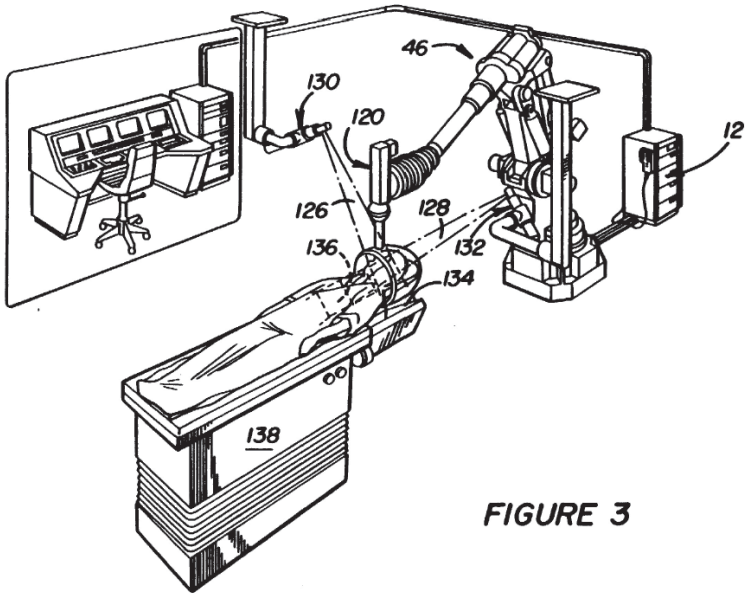

FIGURE 3

Figure 3 depicts beaming apparatus 120 supported and positioned by processor controllable robotic arm 46 which has six axes of motion to target the patient from multiple angles. *Id.* at 7:66–8:4. A disclosed example of apparatus 120 is a "relatively small size and relatively light weight" linac. *Id.* at 6:65–67. The beam is collimated and focused on the target region, controlled by a microprocessor. *Id.* at 8:26–31. Diagnostic x-ray beams 126 and 128 are directed at the target to generate images use to control the treatment. *Id.* at 8:14–31.

Petitioner's arguments in support of Grounds 3 and 4 are substantially the same as its arguments for Grounds 1 and 2, except that the combinations involve Adler in place of Ruchala, and the claim requirements argued to be satisfied by Ruchala for Grounds 1 and 2 are argued to be satisfied by corresponding disclosures in Adler for Grounds 3 and 4. Pet. 48–52.

Likewise, Patent Owner's arguments refuting Petitioner's Grounds 3 and 4 track those for Grounds 1 and 2. PO Resp. 41–44, 50–51.[12]

For substantially the same reasons as discussed above for Grounds 1 and 2, and having considered both the evidence of obviousness and Patent Owner's submitted evidence of nonobviousness, and weighed the entirety of the evidence, we determine that Petitioner has proved by a preponderance of the evidence that claims 1–4, 7–8, 11–12, 17–18, 20, and 23 would have been obvious over the combination of Adler and Grady, and that claims 9, 10, 13, 16, and 22 would have been obvious over the combination of Adler, Grady, and Lam.

H. Grounds 5 and 6: Obviousness of Claims 1–4, 7–8, 11–12, 17–18, 20, and 23 Over Valentin and Roder, and of Claims 9, 10, 13, 16, and 22 Over Valentin, Roder, and Lam

Petitioner challenges claims 1–4, 7–8, 11–12, 17–18, 20, and 23 as unpatentable under pre-AIA 35 U.S.C. § 103(a) over the combination of Valentin and Roder, and claims 9, 10, 13, 16, and 22 over the combination of Valentin, Roder, and Lam. Pet. 52–77.

Valentin, titled "Device For Stereotactic Radiotherapy," was filed August 8, 2000 and published February 22, 2001. Ex. 1014, codes (54),

[12] Patent Owner also objects to the fact that Petitioner argues for Ground 3 both that it would have been obvious to place Adler's LINAC in the Grady device, and to place Grady's gantry in the Adler device. Sur-Reply 22–23. This objection is without merit. *See In re Bush*, 296 F.2d 491, 496 (CCPA 1961) (where obviousness "is predicated on two references each containing pertinent disclosure . . . we deem it to be of no significance, but merely a matter of exposition, that the rejection is stated to be on A in view of B instead of on B in view of A, or to term one reference primary and the other secondary").

(22), (43). Because Valentin published before the earliest priority date of the '648 patent, this reference is prior art to the '648 patent under pre-AIA 35 U.S.C. § 102(a). Figure 1 of Valentin is reproduced below.

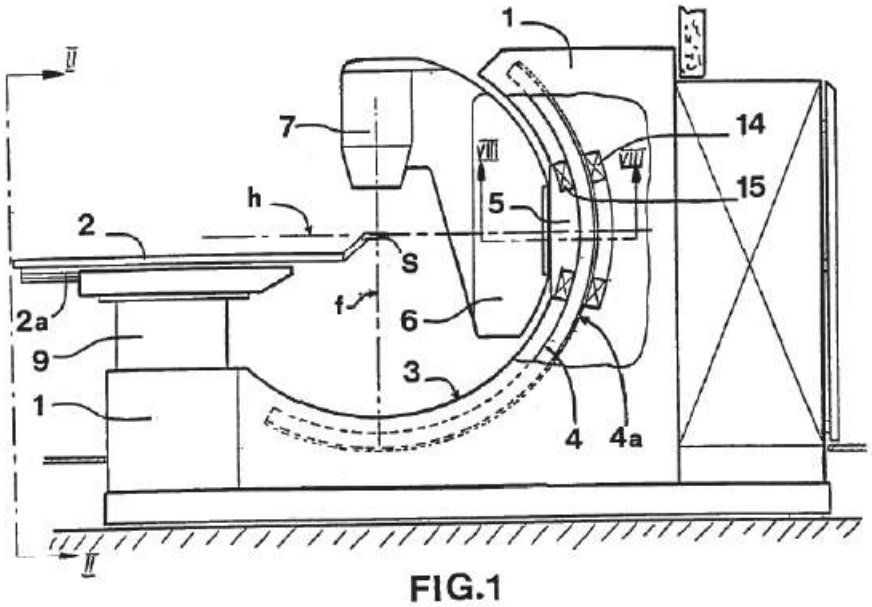

FIG.1

Figure 1 depicts patient table 2 aligned along axis h, with the position of the table remotely controlled "with micrometric precision." Ex. 1014, 11–12. Semicircular opening 3 is formed around transversal axis s. *Id*. Guide rail 4 is coaxial to opening 3, and carriage 5 is attached to guide rail 4 so that it can move along the rail in a circular trajectory around axis S. *Id.* at 12. Carriage 5 carries support arm 6 of head 7 and is pivotally mounted about axis h which intersects the axis s. *Id.* Head 7 includes two radiation sources, a collimated linac for treatment, and a low dose X-ray source for imaging. *Id.* at 13. The point of intersection of the axes h and s is the isocenter of the device. *Id.* at 12. The beams from head 7 are directed along axis f which intersects the isocenter. *Id.* at 13.

Roder, titled "Apparatus For Examination Or Treatment Of A Patient By Means Of Penetrating Radiation," was filed June 9, 1983 and published

Dec. 13, 1984. Ex. 1015, codes (54), (22), (43). Because Roder published before the earliest priority date of the '648 patent, this reference is prior art to the '648 patent under pre-AIA 35 U.S.C. § 102(a). Figure 1 of Roder is reproduced below.

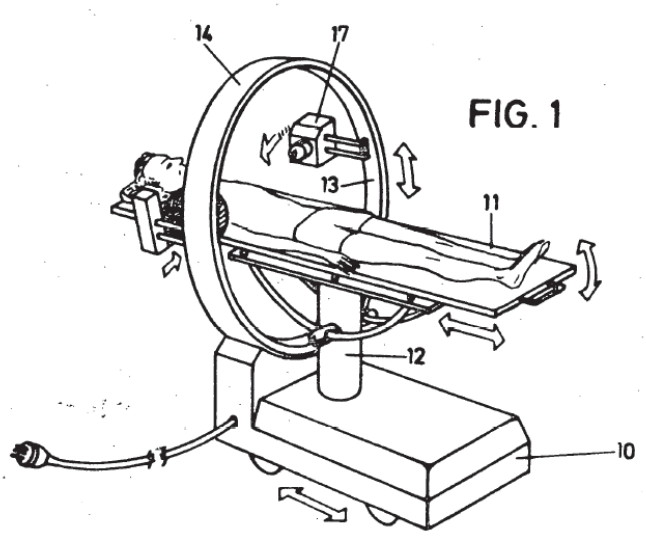

Figure 1 shows adjustable patient table 11 centered within circular raceway 13 mounted within ring 14, within which raceway 13 can rotate. *Id.* at 5. Radiation source 17 is attached to raceway 13. *Id.* at 6.

Petitioner admits that Valentin does not disclose a "ring-shaped support," as required by the claims, assuming that term is construed "to require a full, 360-degree ring" (which as discussed above, is the construction we adopt). Pet. 53. Under that assumption, Petitioner argues one of ordinary skill would combine Valentin with Roder, modifying the semicircular guide rail of Valentin to form a ring in the manner of the circular raceway of Roder. Pet. 55–57. Petitioner argues that, given the teachings of Roder, a person of ordinary skill would have recognized the structural deficiencies of a C-shaped structure such as disclosed in Valentin, and thus modified Valentin accordingly. Pet. 55–56 (*citing* Ex. 1015, 5:4–16.) However, Petitioner recognizes that such modification would not work

if patient table 2 of Valentin remained aligned along axis h, and instead argues the combination would be implemented to realign the table along axis S. Pet. 56–57 (*citing* McCarthy Decl. ¶¶ 82, 165.)

Patent Owner argues that the proposed modification of the orientation of the patient table would not have been adopted by a person of ordinary skill in the art, because even with the modification the mobility of the head around the patient would still be limited to the same extent as would have been the case without the modification, and therefore one of ordinary skill would have had no reason to make the modification that Petitioner urges. PO Resp. 55–59 (*citing* Steidley Decl. ¶¶ 171–193; Steidley 2nd Decl. ¶¶ 135–146).

Petitioner does not respond to this argument in the Reply, and based on our review of the record we agree with Patent Owner's arguments. Therefore, we determine Petitioner has not established by a preponderance of the evidence that a person of ordinary skill in the art would have been motivated to combine the teachings of Valentin and Roder as proposed by Petitioner. In particular, the alignment of the patient table in Valentin, whether or not rearranged, is incompatible with a ring-shaped support.

Accordingly, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 1–4, 7–8, 11–12, 17–18, 20, and 23 would have been obvious over the combination of Valentin and Roder. The addition of Lam to the combination does not remedy the deficiencies discussed above, and accordingly we also determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 9, 10, 13, 16, and 22 would have been obvious over the combination of Valentin, Roder, and Lam.

IV. REVISED MOTION TO AMEND

Because we conclude that all of the challenged claims are unpatentable, we consider Patent Owner's Revised Motion to Amend. *See* RMTA 1 (stating that "[i]f the Board finds independent claim 1 and/or 18 unpatentable, Elekta requests that the Board grant this revised Motion to Amend and issue the appropriate corresponding substitute claims as presented herein").

"Before considering the patentability of any substitute claims, . . . the Board first must determine whether the motion to amend meets the statutory and regulatory requirements set forth in 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121." *Lectrosonics*, Paper 15 at 4 (PTAB Feb. 25, 2019) (precedential). Accordingly, a patent owner must provide a claim listing reproducing each proposed substitute claim, and must make an initial showing to demonstrate the following: (1) the amendment proposes a reasonable number of substitute claims; (2) the proposed claims are supported in the original disclosure (and any earlier filed disclosure for which the benefit of the earlier filing date is sought); (3) the amendment responds to a ground of unpatentability involved in the trial; and (4) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter. *See* 35 U.S.C. § 326(d); 37 C.F.R. § 42.121.

The Board also must assess the patentability of proposed substitute claims "without placing the burden of persuasion on the patent owner." *Aqua Prods.*, 872 F.3d at 1328; *see Lectrosonics*, Paper 15 at 3–4 (discussing *Aqua Products* and the burden of persuasion). After *Aqua Products*, the Federal Circuit further clarified the burden of persuasion in *Bosch Automotive Service Solutions, LLC v. Matal*, 878 F.3d 1027 (Fed. Cir.

2017), *amended by Bosch Automotive Service Solutions, LLC v. Iancu*, No. 2015-1928 (Fed. Cir. Mar. 15, 2018). According to *Aqua Products*, *Bosch*, and *Lectrosonics*, a patent owner does not bear the burden of persuasion to show that the proposed substitute claims are patentable. Rather, ordinarily "the petitioner bears the burden of proving that the proposed amended claims are unpatentable by a preponderance of the evidence." *Bosch*, 878 F.3d at 1040 (as amended on rehearing); *Lectrosonics*, Paper 15 at 3–4. To determine whether a petitioner has proven the substitute claims are unpatentable, the Board focuses on "arguments and theories raised by the petitioner in its petition or opposition to the motion to amend." *Nike, Inc. v. Adidas AG*, 955 F.3d 45, 51 (Fed. Cir. 2020). The Board itself also may justify any finding of unpatentability by referring to evidence of record in the proceeding. *Lectrosonics*, Paper 15 at 4 (citing *Aqua Products*, 872 F.3d at 1311 (O'Malley, J.)).

A. Proposed Substitute Claims

Patent Owner proposes a set of substitute claims in one-to-one correspondence with the set of original claims. RMTA App'x A. That is, proposed claim 24 substitutes for original claim 1; proposed claim 25 substitutes for original claim 4; proposed claim 26 substitutes for original claim 3; proposed claim 27 substitutes for original claim 2; proposed claims 28–34 substitute for original claims 7–13, respectively; proposed claims 35–37 substitute for original claims 16–18, respectively; proposed claim 38 substitutes for original claim 20; and proposed claims 39 and 40 substitute

for original claims 22 and 23, respectively.[13] *Id.* Of the proposed substitute claims, claims 24 and 37 are independent. *Id.*

Proposed substitute claim 24 is illustrative, and is reproduced below with underlining to indicate text added to original claim 1 and strike-outs to indicate text removed from original claim 1.

> 24. A device for treating a patient with ionising radiation comprising:
>
> a ring-shaped support, on which is provided a mount,
>
> a therapeutic radiation source attached to the mount to provide the ionizing radiation to treat the patient;
>
> the ring-shaped support being rotateable about ~~an axis~~ a support axis, the support axis being coincident with the centre of the ~~ring~~ ring-shaped support;
>
> the therapeutic radiation source being attached to the mount via a rotateable union having a ~~an axis of~~ rotation axis which is non-parallel to the support axis;
>
> wherein the rotation axis of the mount passes through the support axis of the support and the therapeutic radiation source is collimated so as to produce a therapeutic beam which passes through the co-incidence of the rotation and support axes to treat the patient with the ionising radiation.

RMTA App'x 1.

Patent Owner submits that, given that there is a one-to-one correspondence between the challenged claims and the proposed substitute claims, its proposal is presumptively reasonable. RMTA 3 (citing 37 C.F.R. § 42.121(a)(3); *Lectrosonics*, IPR2018-01129, Paper 33 at 45).

[13] In the Appendix, proposed substitute claim 25 is worded as a substitute for claim 2. RMTA App'x A, 1. At the hearing, Patent Owner corrected that to refer to claim 4. Paper 47, 31:23–32:10. We accept that correction.

Petitioner disagrees as to proposed substitute claims 32 and 33, arguing that in effect, "Patent Owner both cancels claim 12 by striking its original limitation and amending it to be substitute claim 33 while also amending claim 11 in order to recreate and retain claim 12 as substitute claim 32." Opp. RMTA 2. Petitioner argues "this results in an unreasonable number of proposed substitute claims." *Id.*

However, because proposed substitute claim 32 depends from proposed substitute claim 25 rather than challenged claim 1, it is not a recreated version of claim 12. *See* Reply RMTA 16. We agree with Patent Owner that because there is only one proposed substitute claim per original challenged claim, Patent Owner proposes a reasonable number of substitute claims.

B. *Support for Proposed Substitute Claims*

New subject matter is any addition to the claims that lacks sufficient support in the subject patent's original disclosure. *See TurboCare Div. of Demag Delaval Turbomach. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) ("When [an] applicant adds a claim . . . , the new claim[] must . . . find support in the original specification."). The Board requires that a patent owner show in a motion to amend that there is written-description support in the originally filed disclosure of the subject patent for each proposed substitute claim, and also set forth support in an earlier-filed disclosure for each claim for which the patent owner seeks the benefit of the earlier-filed disclosure's filing date. *See* 37 C.F.R. §§ 42.121(b)(1), 42.121(b)(2).

To support its contention that the proposed substitute claims have sufficient support, Patent Owner provides a chart that identifies support for the proposed substitute claims in the '648 Patent. RMTA 6–17. Patent

Owner submits that a "person of ordinary skill in the art . . . would understand the '648 Patent and its corresponding application 'as describing with sufficient particularity the material to be incorporated.'"[14] RMTA 17.

Petitioner contends that the original '648 disclosure does not support proposed substitute claim 34's requirement of "a shielding enclosure which encloses at least the linear accelerator, the collimator, and the beam stop." Opp. RMTA 3–4. As support for this limitation, Patent Owner cites the following disclosure in the '648 patent:

> [A] shielding can be provided more easily and more inexpensively since only the main source needs to be shielded as opposed to the shielding of a large number of sources. *This shielding is achieved by the enclosure 34*, the beam stop 42 and the collimator 43 which will be formed of a material which is generally radiopaque so as to limit unnecessary exposure of staff and patients outside the device. The weight of such a reduced amount of shielding will also be significantly less.

RMTA 13–14 (citing Ex. 1001 at 7:59–67) (emphasis supplied). This is illustrated in Figure 9 of the '648 patent set forth below.

[14] Our review of the prosecution history of the '648 patent indicates that there were no substantive amendments to the specification during prosecution. Ex. 1002. In this particular instance, we deem that fact that Patent Owner does not explicitly compare the proposed substitute claims to the October 21, 2004 application to be harmless error.

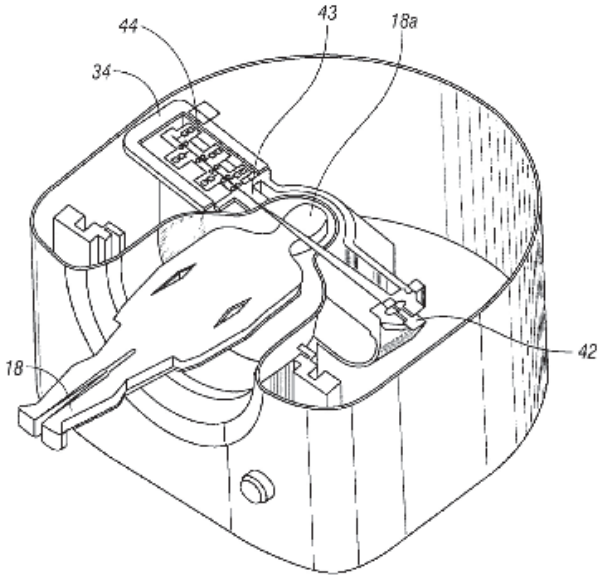

FIG. 9

Figure 9 is a view of the radiation treatment device showing the general geometry of the device relative to patient 18, including linac 44 with enclosure 34, beam stop 42 and collimator 43. Ex. 1001, Figs. 9, 12–15, 7:59–66, 8:53–60.

Petitioner argues that enclosure 34 "does not 'enclose' the linear accelerator, collimator and beam stop." Opp. RMTA 4 (citing McCarthy RMTA Decl. ¶ 84). Indeed, as shown in Figure 9, as well as Figures 12–15, enclosure 34 at most encloses the linac. Confirming this, the '648 patent emphasizes that this arrangement reduces the amount of shielding to minimize the weight of the apparatus. Ex. 1001, 7:62–67, 8:58–60.

In response, Patent Owner asserts that, according to Figures 5–10 of the '648 patent, linac housing 34 surrounds the linac, beam stop, and collimator. Reply RMTA 17. However, that statement is not supported by the above-cited figures and excerpts from the specification, which explicitly differentiates between "enclosure 34," versus "beam stop 42" and

"collimator 43." Ex. 1001, 7:62–63. The only "enclosure" disclosed in the '648 patent that encloses a larger area of the device is specifically described as "radio-transparent so as to allow transmission of the therapeutic beam into the enclosure," and thus is not part of any shielding. *Id.* at Fig.3, 6:56–64.

Therefore, we agree with Petitioner that proposed substitute claim 34 is not supported by the original disclosure. Petitioner does not raise disclosure issues as to the other proposed substitute claims, and based on our review of the record, we conclude that Patent Owner has made a sufficient showing that identifies adequate written-description support for the remaining proposed substitute claims.

C. *Responsiveness to a Ground of Unpatentability Involved in the Trial*

Patent Owner submits that each proposed substitute claim is responsive to one or more grounds of patentability raised for independent claims 1 and 18. RMTA 3 (citing 37 C.F.R. § 42.121(a)(2)(i)). In particular, Patent Owner's proposed substitute independent claims 24 and 37 add a requirements for use of therapeutic radiation source for treating a patient with ionizing radiation, in order to render moot any argument that the preambles are not limiting, and in an attempt to further distinguish the asserted combination involving Grady. Reply RMTA 3.

Patent Owner also includes: (i) in proposed substitute claims 25 and 40, a limitation requiring "a single isocentre at a plurality of approach angles relative to the patient," with the location of one axis "fixed relative to" the other; (ii) in proposed substitute claims 26 and 39, a limitation specifying "the radiation source is moveable" or "causing rotation of the therapeutic radiation source," with a requirement "to achieve a greater dosage of therapeutic radiation at the isocentre than around the isocentre to treat the

patient"; (iii) in proposed substitute claim 27, a limitation requiring "the therapeutic radiation source is rotateable about the rotation axis"; and (iv) in proposed substitute claims 29 and 33–35, various limitations requiring shielding and a shielding enclosure. RMTA 4–5. Patent Owner asserts these amendments further distinguish the asserted combination involving Grady. *Id*. In addition, the proposed substitute claims include clarifying amendments and amendments to provide appropriate antecedents.[15] *Id.*

Petitioner alleges that proposed substitute claims 32 and 33 do not respond to any ground of unpatentability, arguing that substitute claim 32 would be of identical scope to claim 12. Opp. RMTA 2. However, as discussed above in addressing Petitioner's argument that Patent Owner does not propose a reasonable number of substitute claims, this argument fails because proposed substitute claim 32 depends from proposed substitute claim 25, rather than from claim 1, and proposed substitute claim 25 has different limitations than claim 1. Petitioner does not make this assertion for any of the other proposed substitute claims. Accordingly, we conclude that

[15] It is not required "that every word added to or removed from a claim in a motion to amend be solely for the purpose of overcoming an instituted ground." *Lectrosonics*, Paper 15 at 5. Even though challenges for *inter partes* reviews may be based only on "ground[s] that could be raised under section 102 or 103," a patent owner "also may include additional limitations [in proposing a claim amendment] to address potential § 101 or § 112 issues" once the proposed claim "includes amendments to address a prior art ground in the trial." 35 U.S.C. § 311(b); *Lectrosonics*, Paper 15 at 6. "Allowing an amendment to address such issues . . . serves the public interest by helping to ensure the patentability of amended claims." *Lectrosonics*, Paper 15 at 6 (citing *Veeam Software Corp. v. Veritas Techs., LLC*, IPR2014-00090, Paper 48 at 26–29 (PTAB July 17, 2017)).

Patent Owner has made a sufficient showing that the proposed amendments are responsive to a ground of unpatentability involved in the trial.

D. *Scope of Proposed Substitute Claims*

Patent Owner submits that none of the proposed substitute claims seeks to enlarge the scope of the original patent claims. RMTA 5 (citing 37 C.F.R. § 42.121(a)(2)(ii)). However, Petitioner argues proposed substitute claim 24 broadens the scope of challenged claim 1 by eliminating the "ring" limitation from the claims. Opp. RMTA 3. Given that proposed substitute claims 25–34 and 36, depend from claim 24, Petitioner argues that those claims also enlarge the scope of the claims. *Id.*

Comparing challenged claim 1 to proposed substitute claim 24, and considering the claims as a whole, we conclude that amending "ring" to "ring-shaped support" is clarifying, by providing a clear antecedent relationship to the previous occurrence of that phrase, rather than broadening. *See* Reply RMTA 16. Therefore, based on our review of the record we conclude that Patent Owner has made a sufficient showing that the proposed substitute claims do not enlarge the scope of the claims.

E. Patentability of the Proposed Substitute Claims

1. Obviousness of proposed substitute Claims 24 and 37 over the combination of Grady and Ruchala and of Grady and Adler

Petitioner argues that proposed substitute claims 24 and 37 are obvious over the combination of Grady with Ruchala or Adler. Opp. RMTA 5–8. As Petitioner points out, the amended claims make "treatment . . . with ionizing radiation" an express limitation as opposed to part of the preamble, and require the radiation source to be "therapeutic." *Id.* Petitioner submits that its arguments and evidence for obviousness of challenged claims 1 and 18 apply equally to proposed substitute claims 24 and 37. *Id.* Petitioner

argues that, although Grady discloses an imaging radiation source rather than a therapeutic source, and does not treat a patient, but rather is used for imaging, the combination of Grady with Ruchala or Adler does meet those requirements, because the latter two references disclose therapeutic treatment with ionizing radiation. *Id.*

Patent Owner responds with, in substance, the same arguments and evidence that it offers for the original invalidity Grounds 1–4 raised in the Petition. RMTA 18–19; Reply RMTA 2–5. As argued against Grounds 1–4, Patent Owner points out that Grady only discloses the use of radiation for imaging, that it entails much different requirements for voltages and precision compared with therapeutic radiation devices, and that linacs used for therapeutic treatment are heavier than X-ray sources and impose much more rigorous safety and treatment concerns. *Id.* As discussed in connection with Grounds 1–4 asserted against the challenged original claims, we are not persuaded by these arguments, and in particular reject the assertion that a person of ordinary skill would not have considered the three-dimensional manipulation capabilities of Grady as applicable to radiation therapy devices such as disclosed in Ruchala or Adler. We therefore have determined that the preponderance of the evidence supports the asserted combination of Grady with Ruchala or Adler, and that those combinations render obvious claims 1 and 18, and those determinations apply equally to our consideration of proposed substitute claims 24 and 37.

Patent Owner asserts that Petitioner "does not identify a prior art device having the features of claim 24 that acts 'to treat the patient with the ionising radiation,' or a method 'to treat the patient' with a device as recited in claim 37." Reply RMTA 3. However, as we determined for Grounds

1 and 3 (Sections III.E, III.G above), Ruchala and Adler disclose linacs that treat patients with ionising radiation, and the combination of Grady with Ruchala or Adler satisfy the additional requirements of claims 1 and 18 that are common to proposed substitute claims 24 and 37. *See* Sur-Reply RMTA 2–6.

Therefore, having considered both the evidence of obviousness and Patent Owner's submitted evidence of nonobviousness, and weighed the entirety of the evidence, we determine that Petitioner has proved by a preponderance of the evidence that proposed substitute claims 24 and 37 would have been obvious over the combination of Grady and Ruchala, and also would have been obvious over the combination of Adler and Grady.

2. Obviousness of proposed substitute Claims 24 and 37 over the combination of Lajus and Ruchala and of Lajus and Adler

In the alternative, Petitioner argues that proposed substitute claims 24 and 37 are obvious over the combination of Lajus with Ruchala or Adler. Opp. RMTA 5–8.

Lajus, titled "Radiological Examination Apparatus," was filed July 6, 1980 and issued June 13, 1972. Ex. 1022, codes (54), (22), (45). Because Lajus issued before the earliest priority date of the '648 patent, this reference is prior art to the '648 patent under pre-AIA 35 U.S.C. § 102(a). Figure 1 of Lajus is reproduced below.

Fig 1

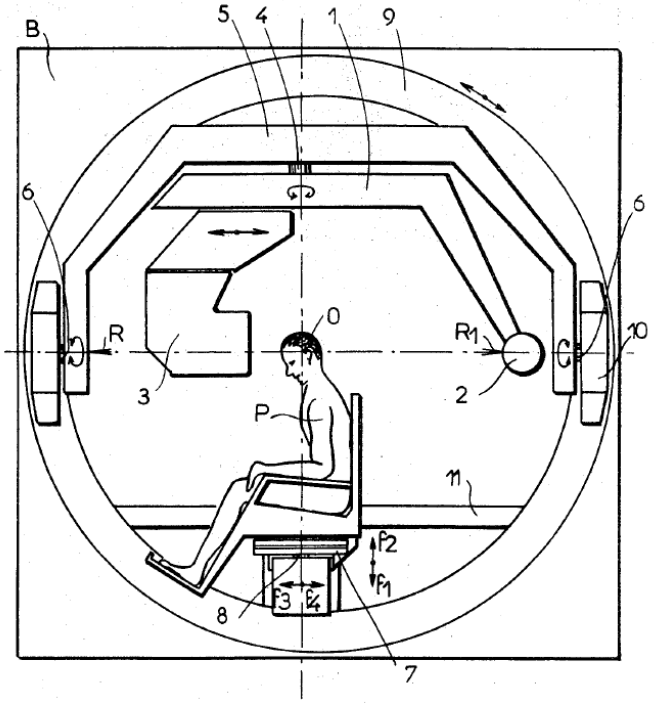

Figure 1 is a front view of the apparatus, depicting patient P positioned so that his head is at point O, in the path of an X-ray beam passing form X-ray source 2 to X-ray image pickup 3. Ex. 1022, 1:66–75. The X-ray devices are supported on carrying arm 1, which rotates about shaft axis 4. *Id.* at 2:2–5. Shaft 4 is mounted in gimbal 5, which rotates about an axis defined by shafts 6. *Id.* at 2:5–8. Shafts 6 are mounted on arms 10, which in turn are mounted on ring-shaped support 9. *Id.* at 2:9–11. Ring 9 rotates in the vertical plane about an axis passing through point O. *Id.* at 2:33–42. Point O defines the intersection of axis 4 and the axis defined by shafts 6. *Id.* at 2:11–15.

Petitioner argues that Lajus serves essentially the same role in the patentability analysis as Grady, disclosing a gantry arrangement including a ring shaped support (ring 9) which rotates about an axis, a mount attached to the ring shaped support (arms 10), an X-ray source attached to the mount via

a rotatable union (shafts 6), each of these components having the same physical relationships as Grady. Opp. RMTA 8–10 (citing Paper 18, 14–19; McCarthy Suppl. Decl. ¶¶ 37–44). Petitioner marshals essentially the same rationale for why a person of ordinary skill would have combined Lajus with Ruchala or Adler, and thus arrived at the subject matter of proposed substitute claims 24 and 37. *Id.*; *see also* Sur-Reply RMTA 9.

Similarly, Patent Owner's arguments challenging the combination of Lajus with Ruchala or Adler are for the most part essentially the same as for the Grady/Ruchala and Grady/Adler combinations. RMTA 18–19; Reply RMTA 6–7. Additional arguments raised by Patent Owner are that Lajus' patient support apparatus 7 can be rotated in the vertical plane, which would be undesirable for radiation therapy, and that the X-Ray source is not attached to the mount, but rather attached to carrying arm 1. Reply RMTA 6. In response, Petitioner cites evidence that the ability to move the patient during radiation treatment was an acceptable practice, and argues that the additional degree of freedom introduced by axis of rotation 4 is not excluded by the claims. Sur-Reply RMTA 9–10.

We agree with Petitioner's analysis for the same reasons as discussed above in connection with Grounds 1–4, and we agree that Patent Owner's additional arguments are unpersuasive for the reasons stated by Petitioner. Therefore, having considered both the evidence of obviousness and Patent Owner's submitted evidence of nonobviousness, and weighed the entirety of the evidence, we determine that Petitioner has proved by a preponderance of the evidence that proposed substitute claims 24 and 37 would have been

obvious over the combination of Lajus and Ruchala, and also would have been obvious over the combination of Lajus and Adler.[16]

3. Proposed Substitute Claims 25, 26, 39, and 40

Proposed substitute claim 25 depends from independent proposed substitute 24 and additionally requires "the rotation axis is fixed relative to the support axis, and the therapeutic beam, the rotation axis, and the support axis are co-incident at a single isocentre for a plurality of approach angles of the therapeutic beam relative to the patient." RMTA App'x 1. Proposed substitute claim 26 depends from claim 25 and additionally requires "the therapeutic radiation source is movable to provide the therapeutic beam at the plurality of approach angles relative to the patient to achieve a greater dosage of therapeutic radiation at the isocentre than around the isocentre to treat the patient with the ionising radiation." *Id.*

Proposed substitute claim 39 depends from independent proposed substitute claim 37, and additionally requires "causing rotation of the therapeutic radiation source about the two axes provides the therapeutic beam at a plurality of approach angles relative to the patient to treat the patient with the therapeutic beam." RMTA App'x 4. Proposed substitute claim 40 depends from claim 39 and additionally requires "the therapeutic beam and the two axes are co-incident at a single isocentre for the plurality

[16] Petitioner also argues additional combinations of references render obvious proposed substitute claims 24 and 37 — *viz.*, (i) Grady and Ruchala further in view of Lajus; (ii) Adler and Grady further in view of Lajus; (iii) Brown (Ex. 1023) and Lajus; and (iv) Nafstadius (Ex. 1037). Opp. RMTA 8–13. Given our determination regarding the combinations involving Grady, Lajus, Ruchala, and Adler, it is unnecessary to consider these alternative arguments.

of approach angles, the location of one of the two axes being fixed relative to the location of the other of the two axes." *Id.*

Petitioner relies, *inter alia*, on the combination of Lajus and Ruchala or Lajus and Adler as rendering these claims obvious. In addition to rendering obvious the limitations of proposed substitute claims 24 and 37, discussed above, Petitioner argues that the combination of Lajus with Ruchala or Adler would have taught all the additional limitations of these proposed substitute claims. Opp. RMTA 13–17. In particular, Petitioner relies on Lajus as disclosing: (i) for proposed substitute claims 25 and 40, that the rotation axis is fixed relative to the support axis, and the radiation beam, the rotation axis, and the support axis are co-incident at a single isocentre for a plurality of approach angles; and (ii) for proposed substitute claims 26 and 39, that the radiation source is movable, or can be rotated about the two axes, to provide the beam at the plurality of approach angles. *Id.* Petitioner additionally relies on the teachings of Ruchala and Adler for the claim requirements of treating a patient with a therapeutic beam, which is manipulated to achieve a greater dosage of therapeutic radiation at the isocentre than around the isocentre. *Id.*

For example, Petitioner cites Ruchala's teaching that "a highly conformal treatment that will deliver dose to the tumour while sparing sensitive structures" and Adler's teaching of selective irradiation of the target region where the collimated beam is "continuously focused on the target region while the healthy tissue through which the collimated beam passes is changed." Opp. RMTA 16 (citing Ex. 1010, 3545; Ex. 1012, 7:54–57).

Patent Owner repeats its arguments that Lajus is confined to radiation imaging and that one of ordinary skill would not have been motivated to apply the three-dimensional rotation capabilities of that reference to the therapeutic applications described in Ruchala and Adler. Reply RMTA 6–7. As discussed above, we are not persuaded by these arguments. In addition, Patent Owner argues that Petitioner has failed to address the requirement of proposed substitute claim 25 that the "rotation axis is fixed relative to the support axis," and the commensurate requirement of proposed substitute claim 40. *Id.* at 12. To the contrary, Petitioner cites to Lajus as disclosing this aspect of the claims, and our review of that reference confirms that Lajus discloses the fixed axes relationship.[17] Ex. 1022, Figs. 1, 2; Opp. RMTA 13–14; Sur-Reply RMTA 14.

Therefore, having considered both the evidence of obviousness and Patent Owner's submitted evidence of nonobviousness, and weighed the entirety of the evidence, we determine that Petitioner has proved by a preponderance of the evidence that proposed substitute claims 25, 26, 39, and 40 would have been obvious over the combination of Lajus and Ruchala, and also would have been obvious over the combination of Lajus and Adler.

4. Proposed Substitute Claim 27

Proposed substitute claim 27 depends from proposed substitute claim 24, and additionally requires "the therapeutic radiation source is attached to the mount such that the therapeutic radiation source is rotateable about the

[17] Petitioner also argues that the fixed axes requirement of proposed substitute claim 25 would have been obvious over the combination of Grady and Ruchala or Adler. Opp. RMTA 13–14. We need not consider that argument, given our determination with respect to Lajus.

rotation axis." RMTA App'x 2. Petitioner cites the fact that the radiation source of Grady is attached to carriage 10, which rotates about axis A2, and relies on the combination of Grady with Ruchala or Adler to teach the use of a therapeutic radiation source. Opp. RMTA 18. Petitioner propounds similar arguments relying on the combination of Lajus with Ruchala or Adler. *Id.*

In this context, Patent Owner raises the issue, discussed above, regarding the construction of rotateable union. RMTA 22–23. However, Patent Owner's only substantive argument addressing obviousness of proposed substitute claim 27 is a reiteration of its arguments that Grady and Lajus are not therapeutic devices and that one of ordinary skill would not have been motivated to combine Grady or Lajus with Ruchala or Adler. *Id.*

For the reasons discussed above, we are not persuaded by these arguments. Therefore, having considered both the evidence of obviousness and Patent Owner's submitted evidence of nonobviousness, and weighed the entirety of the evidence, we determine that Petitioner has proved by a preponderance of the evidence that proposed substitute claim 27 would have been obvious over the combination of Grady and Ruchala, Grady and Adler, Lajus and Ruchala, and Lajus and Adler.

5. Proposed Substitute Claims 33 and 35

Proposed substitute claim 33 depends from proposed substitute claim 29, and additionally requires "collimator, a beam stop, and shielding, the linear accelerator, the collimator, the beam stop, and the shielding forming a linear accelerator structure, the linear accelerator structure being attached to the mount via the rotateable union." RMTA App'x 2. Proposed substitute

claim 35, which depends from proposed substitute claim 37, adds a commensurate requirement. RMTA App'x 3.

Petitioner contends that these limitations would have been obvious over the combination of Grady with Ruchala or Adler, and in particular that one of ordinary skill would have known that shielding material is necessary when treating a patient with a linac, and would also have known that beam stops would be part of such devices. Opp. RMTA 19–21. Again, Patent Owner relies on the arguments that Grady and Lajus are not therapeutic devices, and that one of ordinary skill would not have been motivated to combine Grady or Lajus with Ruchala or Adler. Reply RMTA 14.

For the reasons discussed above, we are not persuaded by these arguments. Therefore, having considered both the evidence of obviousness and Patent Owner's submitted evidence of nonobviousness, and weighed the entirety of the evidence, we determine that Petitioner has proved by a preponderance of the evidence that proposed substitute claims 33 and 35 would have been obvious over the combination of Grady and Ruchala, Grady and Adler, Lajus and Ruchala, and Lajus and Adler.[18]

6. Proposed Substitute Claims 28–32, 36, and 38

Proposed substitute claims 28–32, 36, and 38 depend from one of the proposed substitute claims discussed above. RMTA App'x 2–3. These claims raise no additional issues that have not been resolved in the above

[18] Proposed substitute claim 34 depends from claim 33, and additionally requires "a shielding enclosure which encloses at least the linear accelerator, the collimator, and the beam stop." RMTA App'x 2. As discussed above, we have determined that this claim is not supported by the original disclosure of the '648 patent. Therefore, it is not necessary to consider Petitioner's invalidity arguments with respect to this claim.

analyses of the claims from which they depend, or in connection with our analysis of Grounds 1–4. RMTA 25; Opp. RMTA 24–25. Therefore, having considered both the evidence of obviousness and Patent Owner's submitted evidence of nonobviousness, and weighed the entirety of the evidence, we determine that Petitioner has proved by a preponderance of the evidence that proposed substitute claims 28–32, 36, and 38 would have been obvious over the combination of Lajus and Ruchala, and also would have been obvious over the combination of Lajus and Adler.

Also, proposed substitute claims 30, 36 and 38 do not depend from claim 25, and therefore do not require the fixed axes relationship of that claim. Therefore, we determine that Petitioner has proved by a preponderance of the evidence that claims 30, 36 and 38 would have been obvious over the combination of Grady and Ruchala, and also would have been obvious over the combination of Grady and Adler.

F. Summary

Because we have determined that Patent Owner has not demonstrated that proposed substitute claim 34 is supported by the original disclosure, and because Petitioner has demonstrated by a preponderance of the evidence that proposed substitute claims 24–33 and 35–40 are unpatentable, we deny Patent Owner's revised motion to amend.

V. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner requests that we exclude portions of Dr. McCarthy's testimony in support of Petitioner's opposition to the revised motion to amend, set forth in his declarations filed as Exhibits 1026 and 1036. Paper 37, 1. As discussed above, Patent Owner argues that Dr. McCarthy is not

qualified as an expert in this case, because he has not had sufficient experience with radiation imaging and treatment devices. *Id.* at 4–8.

For the reasons discussed above, we are not persuaded that Dr. McCarthy is unqualified to render opinions in this case. To be qualified as an expert, Dr. McCarthy does not necessarily need to be a person of ordinary skill in the art as to the precise subject matter of the patent at issue. Rather, a witness may qualify as an expert if he or she has "knowledge, skill, experience, training, or education" of a "scientific, technical, or other specialized" nature that is likely to help the Board "to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702; *see also* PTAB Consolidated Trial Practice Guide, 34 (Nov. 2019), https://go.usa.gov/xpvPF ("CTPG") ("There is . . . no requirement of a perfect match between the expert's experience and the relevant field." (citing *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010))).

We consider the admissibility of Dr. McCarthy's testimony in light of this standard. We have found Dr. McCarthy's testimony helpful, and deny Patent Owner's motion to exclude it.

Patent Owner also moves to exclude references — Exhibit 1022 (Lajus), Exhibit 1023 (Brown), and Exhibit 1037 (Nafstadius) — submitted by Petitioner in opposition to the revised motion to amend, on the ground that those references are not responsive to the proposed amendments, but rather are submitted as alternative grounds of unpatentability of the originally challenged claims. Paper 37, 1–2. With respect to Brown and Nafstadius, we have not considered these references in our analysis, and therefore the motion to exclude is moot. We have considered Lajus in connection with the new fixed axes relationship requirement introduced by

proposed substitute claims 25 and 40. Therefore, Patent Owner's premise that Lajus is not directed to the proposed amendments is without merit.

Accordingly, we deny Patent Owner's Motion to Exclude.

VI. CONCLUSION[19]

For the reasons above, Petitioner has shown by a preponderance of the evidence that claims 1–4, 7–13, 16–18, 20, 22, and 23 of the '648 patent are unpatentable, as summarized in the following table.

Claims	35 U.S.C. §	References/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–4, 7–8, 11, 12, 17, 18, 20, 23	103(a)	Grady, Ruchala	1–4, 7–8, 11, 12, 17, 18, 20, 23	
9, 10, 13, 16, 22	103(a)	Grady, Ruchala, Lam	9, 10, 13, 16, 22	
1–4, 7–8, 11, 12, 17, 18, 20, 23	103(a)	Adler, Grady	1–4, 7–8, 11, 12, 17, 18, 20, 23	
9, 10, 13, 16, 22	103(a)	Adler, Grady, Lam	9, 10, 13, 16, 22	
1–4, 7–8, 11, 12, 17, 18, 20, 23	103(a)	Valentin, Roder		1–4, 7–8, 11, 12, 17, 18, 20, 23
9, 10, 13, 16,	103(a)	Valentin,		9, 10, 13, 16,

[19] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

Claims	35 U.S.C. §	References/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
22		Roder, Lam		22
Overall Outcome			1–4, 7–13, 16–18, 20, 22, 23	

The table below summarizes our conclusions as to Patent Owner's Revised Motion to Amend the claims.

Motion to Amend Outcome	Claims
Original Claims Canceled by Amendment	
Substitute Claims Proposed in the Amendment	24–40
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	24–40
Substitute Claims: Not Reached	

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, based on a preponderance of the evidence, claims 1–4, 7–13, 16–18, 20, 22, and 23 of U.S. Patent No. 7,295,648 B2 are held to be unpatentable;

FURTHER ORDERED that Patent Owner's Revised Motion to Amend (Paper 24) is *denied*;

FURTHER ORDERED that Patent Owner's Motion to Exclude (Paper 25) is *denied*; and

FURTHER ORDERED that, because this is a final written decision, parties to this proceeding seeking judicial review of our decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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