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Paper 14
Date: April 24, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VARIAN MEDICAL SYSTEMS, INC.,
Petitioner,

v.

BEST MEDICAL INTERNATIONAL, INC.,
Patent Owner.

IPR2020-00076
Patent 7,015,490 B2

Before KARL D. EASTHOM, WILLIAM V. SAINDON, and JOHN A. HUDALLA, *Administrative Patent Judges*.

HUDALLA, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

Varian Medical Systems, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1, 4, and 17–19 of U.S. Patent No. 7,015,490 B2 (Ex. 1001, "the '490 patent"). Petitioner filed a Declaration of Timothy D. Solberg, Ph.D. (Ex. 1002) with its Petition. Patent Owner, Best Medical International, Inc. ("Patent Owner"), filed a

Preliminary Response (Paper 6, "Prelim. Resp."). Patent Owner filed a Declaration of Daniel J. Chase (Ex. 2002) with its Preliminary Response.

With our authorization (Paper 7), Petitioner also filed a Reply (Paper 8, "Pet. Reply") and Patent Owner filed a Sur-Reply (Paper 9, "PO Sur-reply") addressing certain issues related to service of the Petition raised by Patent Owner in the Preliminary Response.

We have authority to determine whether to institute an *inter partes* review. *See* 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). Under 35 U.S.C. § 314(a), we may not authorize an *inter partes* review unless the information in the petition and the preliminary response "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." For the reasons that follow, we institute an *inter partes* review as to claims 1, 4, and 17–19 of the '490 patent on the ground of unpatentability presented.

I. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies Varian Medical Systems, Inc., VMS International AG, VMS International Holdings, Inc., VMS Netherlands Holdings, Inc., and VMS Nederland BV as real parties-in-interest. Pet. 2. Patent Owner identifies Best Medical International, Inc. as the real party-in-interest. Paper 4, 1.

B. Related Proceedings

The parties identify the following proceedings related to the '490 patent (Pet. 2; Paper 4, 1–2):

Best Med. Int'l, Inc. v. Elekta Inc., No. 1:19-cv-03409-MLB (N.D. Ga.);

Best Med. Int'l, Inc. v. Elekta AB, No. 1:18-cv-01600-MN (D. Del.);

Best Med. Int'l, Inc. v. Varian Med. Sys., Inc., No. 1:18-cv-01599 (D. Del.); and

Elekta Inc. v. Best Medical Int'l, Inc., IPR2020-00067.

We also note that Petitioner has challenged other patents owned by Patent Owner in IPR2020-00053, IPR2020-00071, IPR2020-00072, IPR2020-00075, and IPR2020-00077.

C. The '490 patent

The '490 patent relates to "optimization of collimator angles for multileaf collimators ('MLC') used in intensity modulated radiation therapy [IMRT] treatment." Ex. 1001, 1:27–31. In particular, the '490 patent discloses an "algorithm to determine collimator angles in favoring, or enhancing, IMRT radiation therapy treatment plan delivery efficiency." *Id.* at 2:1–4. An intended advantage of the algorithm is to minimize the maximum travel distance of the MLC leaf pairs. *Id.* a 2:14–19.

The method disclosed in the '490 patent utilizes a "cost function obtained by combining the prior algorithm based upon Brahme's orientation theory with the algorithm utilized in the present invention."[1] *Id.* at 2:7–11. The cost function includes a delivery efficiency portion that is "designed to enhance delivery efficiency by reducing at least one of a number of radiation beam segments and reducing a number of radiation beam monitor units

[1] Brahme's orientation theory prioritizes conformity with the targets/lesions being treated. *Id.* at 5:65–6:1.

[MUs] required for delivery of the desired prescription." *Id.* at 2:35–40. The cost function also includes a target conformity portion "to enhance conformity of the radiation beam arrangement to a target shape as viewed through the opening in the multi-leaf collimator." *Id.* at 2:40–42. "[A] preference can be selected between delivery efficiency and target conformity by assigning weights to the delivery efficiency and target conformity portions of the function." *Id.* at 3:29–34.

The '490 patent issued from an application that was filed August 11, 2004, which claims priority to a provisional application filed on August 11, 2003. *Id.*, codes (22), (60). As discussed below, Petitioner's asserted references qualify as prior art relative to the August 11, 2003, filing date of the provisional application.

D. Illustrative Claim

Of the challenged claims, claims 1 and 17 are independent. Claim 4 depends from claim 1, and claims 18 and 19 depend directly or indirectly from claim 17. Claim 1 is illustrative of the challenged claims and recites:

> 1. A computer-implemented method of determining a collimator angle of a multi-leaf collimator having an opening and a plurality of multi-leaf collimator leaf pairs for closing portions of the opening to form a radiation beam arrangement having a plurality of radiation beam segments to apply radiation to a tumor target, the method comprising the steps of:
>
> calculating an initial radiation beam arrangement according to a desired prescription; and
>
> changing the radiation beam arrangement by incorporating a first cost function to determine the collimator angle of the multi-leaf collimator, the first cost function including both a second cost function to enhance delivery efficiency by reducing a number of radiation beam segments

> and reducing a number of radiation beam monitor units required for delivery of the desired prescription and a third cost function to enhance conformity of the radiation beam arrangement to a target shape.

Id. at 10:11–29.

E. Prior Art

Petitioner relies on the following prior art:

> U.S. Patent Application Publication No. 2003/0086530 A1, filed Sept. 25, 2002, published May 8, 2003 (Ex. 1003, "Otto");
>
> U.S. Patent No. 6,853,705 B2, filed Mar. 28, 2003, issued Feb. 8, 2005 (Ex. 1004, "Chang");
>
> Webb, S. (1993). *The Physics of Three-Dimensional Radiation Therapy: Conformal Radiotherapy, Radiosurgery and Treatment Planning*. CRC Press (Ex. 1005, "Webb"); and
>
> Mohan, R. et al. (2000). The Impact of Fluctuations on Intensity Patterns on the Number of Monitor Units and the Quality and Accuracy of Intensity Modulated Radiotherapy. *Medical Physics*, 27(6), 1226–37 (Ex. 1006, "Mohan").

F. The Asserted Ground

Petitioner challenges claims 1, 4, and 17–19 of the '490 patent on the following ground (Pet. 3):

Claims Challenged	35 U.S.C. §	References
1, 4, 17–19	103(a)[2]	Otto, Chang, Webb, Mohan

[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103. Because the '490 patent was filed before March 16, 2013 (the effective date of the relevant amendment), the pre-AIA version of § 103 applies.

II. ANALYSIS

We now consider Petitioner's asserted ground and Patent Owner's arguments in the Preliminary Response to determine whether Petitioner has met the "reasonable likelihood" standard for institution under 35 U.S.C. § 314(a).

A. Legal Standards

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We also recognize that prior art references must be "considered together with the knowledge of one of ordinary skill in the pertinent art." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (citing *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)).

B. Level of Ordinary Skill in the Art

Citing testimony from Dr. Solberg, Petitioner contends a person having ordinary skill in the art would have been

> a medical physicist with a Ph.D. (or similar advanced degree) in physics, medical physics, or a related field, and two or more

> years of experience in radiation oncology physics, treatment planning, treatment plan optimization related to radiation oncology applications, and computer programming associated with treatment plan optimization (or equivalent degree or experience).

Pet. 4 (citing Ex. 1002 ¶ 13). Patent Owner cites testimony from Mr. Chase and contends an ordinarily skilled artisan would have "earned at least a master's or doctoral degree in radiation dosimetry, physics, medical physics, or medicine, or equivalent disciplines" and would have had "three years of clinical experience in radiation treatment planning." Prelim. Resp. 16 (citing Ex. 2002 ¶¶ 50, 57–60).

For purposes of this Decision, we adopt Patent Owner's definition of the level of ordinary skill in the art. On the present record, we are satisfied that this definition comports with the relatively high level of skill necessary to understand and implement the teachings of the '490 patent and the asserted prior art.

C. Claim Interpretation

In an *inter partes* review, we construe each claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b) (2019). Accordingly, our claim construction standard is the same as that of a district court. *See id*. Under the standard applied by district courts, claim terms are generally given their plain and ordinary meaning as would have been understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). "There are only two exceptions to this general rule: 1) when a

patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

Neither party puts forth terms for construction. *See* Pet. 11; Prelim. Resp. 17. Based on the current record, we determine that no terms require explicit construction. *See, e.g.*, *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy' . . . ." (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

D. Patent Owner's Arguments Regarding Discretionary Denial

Patent Owner contends we should not institute trial because Otto and Chang, as well as Webb's teachings on Brahme's theory, were already considered by the patent examiner during prosecution. Prelim. Resp. 40–44. Patent Owner argues that: (1) Otto "was considered by the Examiner and is listed on the face of the '490 Patent"; (2) a publication of the patent application leading to Chang "was also considered by the Examiner and is listed on the face of the '490 Patent";[3] and (3) during prosecution, the Examiner considered Brahme's theory, and Petitioner cites Webb for teaching this theory. *Id.* at 41. Patent Owner further argues Petitioner "does

[3] Petitioner notes that the patent application publication is substantively identical to Chang. Pet. 42 (citing, *inter alia*, Ex. 2002 ¶ 100). For purposes of our analysis, we treat the patent application publication and Chang as the same reference.

not explain how the Examiner erred in his consideration of the art and does not offer additional evidence or facts explaining why reconsideration of the art is warranted." *Id.* at 41–42.

Petitioner argues that neither Otto nor Chang was substantively discussed during prosecution. Pet. 4. Petitioner further argues the patent examiner never considered Webb and Mohan, and that Petitioner's particular combination of four references was never evaluated by the patent examiner. *Id.*

Institution of *inter partes* review is discretionary. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("[T]he [Office] is permitted, but never compelled, to institute an [*inter partes* review] proceeding."); 35 U.S.C. § 314(a) ("The Director *may not* authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." (emphasis added)). Pursuant to 35 U.S.C. § 325(d), in determining whether to institute an *inter partes* review, "the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office."

The Board uses a two-part framework in determining whether to exercise its discretion under § 325(d), specifically:

> (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the

> Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential). In applying the two-part framework, we consider several non-exclusive factors, including:

> (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph) ("*Becton, Dickinson*"). If, after review of factors (a), (b), and (d), we determine that the same or substantially the same art or arguments previously were presented to the Office, then factors (c), (e), and (f) relate to whether the petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics*, Paper 6 at 10.

Based on the patent examiner's citation of Otto, Chang, and Brahme's theory as discussed above, Patent Owner contends *Becton, Dickinson* factors (a)–(c) favor Patent Owner. Prelim. Resp. 43. Patent Owner also contends factors (d) and (e) favor Patent Owner because Petitioner has "failed to point

out sufficiently how the Examiner erred in its consideration of the asserted prior art and failed to present additional evidence and facts to warrant reconsideration of the asserted prior art." *Id.* at 43–44 (internal quotations omitted).

We agree with Petitioner that Webb and Mohan were never before the patent examiner. Pet. 4. And, contrary to Patent Owner's argument (Prelim. Resp. 41, 43), Petitioner cites Webb for more than just Brahme's theory; Petitioner also cites Webb for teaching the use of cost functions for evaluating various beam arrangements, as in the "first cost function" of claim 1. *See* Pet. 16–17, 36–37. Specifically, Petitioner cites Webb's teachings for the proposition that "a cost function allows the computer running an optimization process to identify when it has arrived at the optimal solution for a beam arrangement." *Id.* at 36–37 (citing Ex. 1002 ¶ 83; Ex. 1005, 344). Thus, the patent examiner's consideration of Brahme's theory could not have been coextensive with Webb's cited teachings. In addition, Petitioner cites Mohan for teaching a mathematical function that may be used to quantify delivery efficiency. *See id.* at 40–44. This aspect of claim 1 relates to the recited "second cost function," for which Petitioner applies Mohan's mathematical function to "minimize[] the number of MUs ('beam-on time') required to deliver a desired radiation field . . . to enhance delivery efficiency by reducing a number of beam segments and MUs." *Id.* at 49 (citing Ex. 1002 ¶ 97; Ex. 1006, 1229, 1237). The limitations in claim 1 directed to a cost function for changing beam arrangements, and to a specific cost function for enhancing delivery efficiency, are material to the patentability of the claims. Accordingly, we agree with Petitioner (*see id.* at 4) that the patent examiner never considered

the specific combination of Otto, Chang, Webb, and Mohan proposed by Petitioner.

Therefore, we determine that the same or substantially the same prior art relied on by Petitioner in this proceeding was not previously presented to the Office. Because the first part of the *Advanced Bionics* test is not satisfied, we need not proceed to the second part of the test. *Advanced Bionics*, Paper 6 at 8 (second step of the framework only applies "*if* either condition of the first part of the framework is satisfied") (emphasis added). Having considered Patent Owner's arguments, we decline to exercise our discretion under 35 U.S.C. § 325(d) to deny *inter partes* review.

E. Obviousness Ground Based on Otto, Chang, Webb, and Mohan

Petitioner contends the subject matter of claims 1, 4, and 17–19 would have been obvious over the combination of Otto, Chang, Webb, and Mohan. Pet. 18–70. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 44–57.

1. Otto

Otto relates to controlling radiotherapy devices equipped with a multi-leaf collimator (MLC) to deliver radiation treatments. Ex. 1003 ¶ 2. The MLC uses leaves to modify the spatial distribution of the radiation beam by selectively blocking areas where lower amounts of radiation are desired. *Id.* ¶ 4. Intensity modulation may be used to tailor a radiation field to further reduce the amount of radiation received by healthy tissue. *Id.* ¶ 5. A non-uniform field may be delivered by delivering radiation in each of a set of uniform sub-fields, each having a different MLC configuration. *Id.* ¶ 6. For

static delivery, each sub-field is shaped while the radiation beam is off and then a radiation sub-field is delivered once the leaves are in position. *Id.* For dynamic delivery, the leaves are moved and/or the MLC is rotated while the beam is on. *Id.* ¶¶ 6, 35.

Figure 1 of Otto is reproduced below.

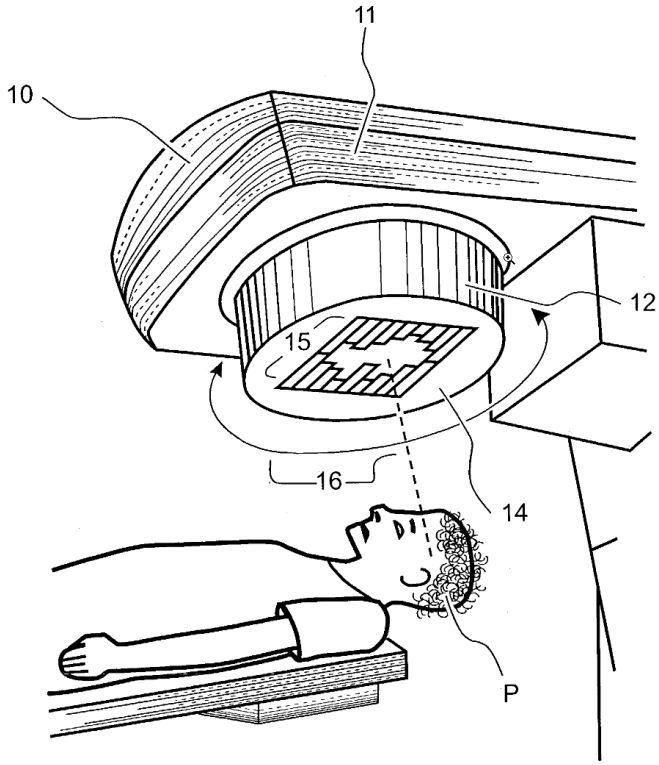

Figure 1 depicts the radiation emitting portion of a radiation treatment device with a rotating MLC. *Id.* ¶ 17. Patient P is positioned to receive radiation from radiotherapy device 10. *Id.* ¶ 25. Radiation exits through multi-leaf collimator 14 within collimator 12 and impinges onto patient P. *Id.* Multi-leaf collimator 14 has multiple movable leaves 15. *Id.* A control system within radiotherapy device 10 moves leaves 15 and rotates multi-leaf collimator 14. *Id.* ¶ 26.

Figure 5 of Otto is reproduced below.

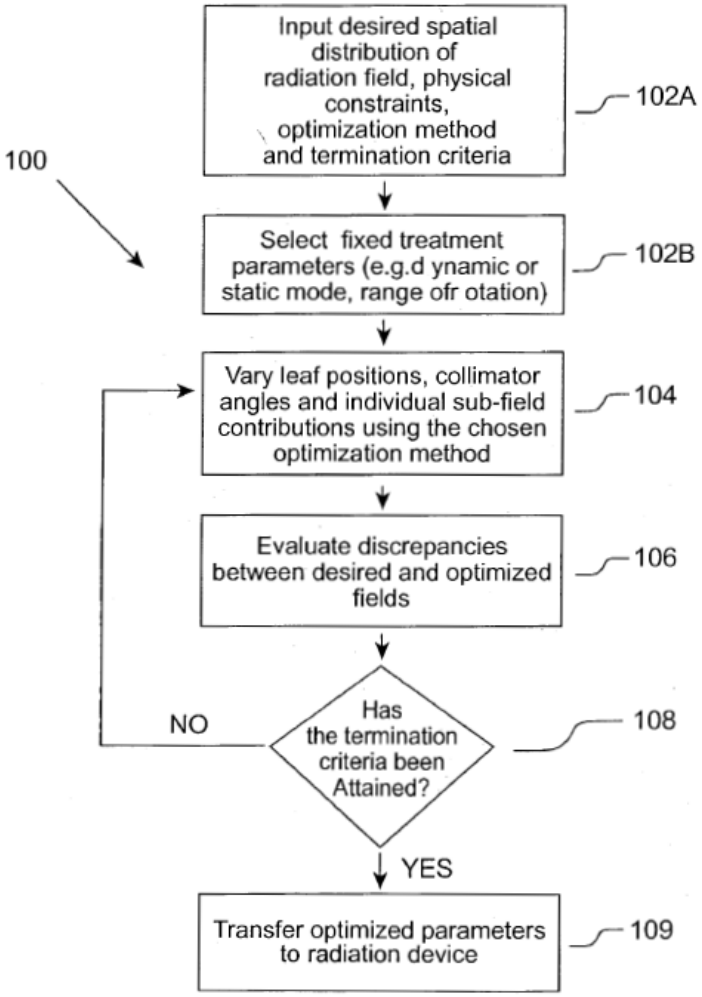

FIGURE 5

Figure 5 is a flowchart illustrating method 100 for identifying a set of sub-fields which will produce a desired overall radiation field on a treatment planning computer system. *Id.* ¶ 44. In block 102,[4] the desired overall radiation field is inputted and a set of available optimization routines and termination criteria is selected. *Id.* at ¶¶ 44, 51. The operator may also specify values for certain parameters, including whether the radiation is to be delivered statically or dynamically, the maximum range of rotation of the

[4] Although the flowchart of Figure 5 includes separate blocks 102A and 102B, the written description treats these blocks as a single block 102.

collimator, and the maximum number of sub-fields. *Id.* ¶ 52. In block 104, a set of configurations is determined, including leaf positions, collimator angles, and sub-field contributions. *Id.* ¶ 53. All the parameters that are not fixed may be varied according to the chosen optimization method. *Id.* In block 106, discrepancies are evaluated between the calculated spatial distribution of radiation resulting from the configurations determined in block 104 and the desired spatial distribution of radiation. *Id.* ¶ 54. If one or more termination criteria have not been attained in block 108, then method 100 returns to block 104 for further optimization. *Id.* ¶ 56.

Petitioner contends Otto qualifies as prior art under, *inter alia*, 35 U.S.C. § 102(e) based on its filing date. Pet. 12. Patent Owner does not contest the prior art status of Otto.

On the present record, we have no evidence of an invention date other than the earliest possible effective filing date of the challenged claims. Thus, for purposes of this Decision, we determine that Otto qualifies as prior art under 35 U.S.C. § 102(e) because Otto's filing date of September 25, 2002, is before the earliest possible effective filing date of the challenged claims, which is August 11, 2003. Ex. 1001, code (60); Ex. 1003, code (22).

2. Chang

Chang is a U.S. patent directed to the optimized configuration of multi-leaf collimator (MLC) leaves for delivery of intensity-modulated radiotherapy (IMRT). Ex. 1004, 1:7–10. Chang describes both "dynamic" and "step-and-shoot" MLC techniques: the dynamic MLC technique delivers an intensity modulated photon field by moving the collimator leaves during irradiation, while the step-and-shoot MLC technique delivers an

intensity modulated photon field via a sequence of static MLC ports. *Id.* at 2:38–45. According to Chang, the orientation of the MLC leaves can have a considerable influence on the quality and efficiency of the treatment. *Id.* at 9:52–55.

Chang describes two solutions or algorithms for searching for the optimal collimator angle for the MLC segment-field. *Id.* at 10:32–45. The first solution finds the collimator angle that conforms to the contour as closely as possible. *Id.* at 10:34–36. The second solution searches for the optimal collimator angle that better preserves the high-gradient regions of the map section. *Id.* at 10:39–41. The final solution may be chosen based on the influence of a solution on treatment delivery efficiency. *Id.* at 11:10–12. An optimal collimator angle can also be selected for all segments of the same IM field to increase treatment delivery efficiency. *Id.* at 11:7–9.

Petitioner contends Chang qualifies as prior art under 35 U.S.C. § 102(e) based on its filing date. Pet. 15. Patent Owner does not contest the prior art status of Chang.

On the present record, we have no evidence of an invention date other than the earliest possible effective filing date of the challenged claims. Thus, for purposes of this Decision, we determine that Chang qualifies as prior art under 35 U.S.C. § 102(e) because Chang's filing date of March 28, 2003, is before the earliest possible effective filing date of the challenged claims, which is August 11, 2003. Ex. 1001, code (60); Ex. 1004, code (22).

3. Webb

Webb is a portion of a book titled *The Physics of Three-Dimensional Radiation Therapy: Conformal Radiotherapy, Radiosurgery and Treatment*

Planning. Ex. 1005, title page. Webb describes Brahme's theory of orientation as "the optimal angulation of the MLC leaves (at some particular static orientation relative to the target volume)." *Id.* at 233. Brahme's theory posits that "the leaves should be aligned to minimize the opening of the collimator from the fully closed position." *Id.* at 234. According to Webb, "[t]he problem reduces to finding the optimum way of arranging the leaves so as to minimize the volume (represented by an area 'seen' in the beam's-eye-view) of normal tissue outside the target volume." *Id.*

Webb also defines a "cost function" as a "[m]athematical function parametrizing the effect of arranging beams in some particular way." *Id.* at 344. Webb's definition also states that "[t]he aim of optimization [is] to minimize the cost function, possibly subject to constraints." *Id.*

Petitioner contends Webb qualifies as prior art under 35 U.S.C. § 102(b) and cites the testimony of Sylvia D. Hall-Ellis, Ph.D. Pet. 16 (citing Ex. 1011 ¶¶ 48–54). Dr. Hall-Ellis is a professor with experience in the field of library science. Ex. 1011 ¶¶ 6–8. She testifies that Webb "was publicly accessible as early as 1993, and in any event, at least a year before the August 11, 2003 priority date" based on a record of Webb in the Library of Congress. *Id.* ¶¶ 48–54. We further note that Webb bears a Library of Congress stamp and a copyright notice dated 1993. *See* Ex. 1005, 5. Patent Owner does not contest the prior art status of Webb.

On the present record, and based on Dr. Hall-Ellis's uncontested testimony, we determine that Webb qualifies as prior art under 35 U.S.C. § 102(b) because Webb's publication date in 1993 is more than one year before the earliest possible effective filing date of the challenged claims,

which is August 11, 2003. Ex. 1001, code (60); Ex. 1005, 5; Ex. 1011 ¶¶ 48–54.

4. Mohan

Mohan is a paper "examin[ing] the potential impact of the frequency and amplitude fluctuations ('complexity') in intensity-modulated radiotherapy (IMRT) dose distributions." Ex. 1006, 1226. The paper uses a schematic example of IMRT for head and neck carcinomas as delivered by a dynamic multileaf collimator (DMLC) using the "sweeping window" technique. *Id.* at 1226–27. According to Mohan, "more complex intensity patterns take longer (i.e., require more MUs) to deliver." *Id.* at 1226.

Mohan states:

> Coordinates (*x,y*) are in the "fanline" system, *x* being the direction parallel to leaf motion. Ω(*x,y*) is that portion of the total 'beam-on time' for which the point (*x,y,z*) is exposed to the source of the primary direct radiation unobstructed by dynamic leaves as the window formed by the leaves sweeps across the field. The term "beam-on time" is used here not to describe the actual time but to describe the number of MUs for which the beam is on.

Id. at 1227.

Mohan's equation for calculating beam-on time is reproduced below.

$$M^l = (1-\tau)\frac{x_{i_{\text{last}}} - x_{i_{\text{start}}}}{v_{\max}} + \sum_{\substack{i=i_{\text{start}} \\ \Omega(x_{i+1})>\Omega(x_i)}}^{i_{\text{last}}-1} [\Omega_e(x_{i+1}) - \Omega_e(x_i)].$$

This equation from Mohan above represents the beam-on time M^l for a leaf pair *l*. *Id.* at 1229 (equation 7). "The contribution of the first term to the beam-on time is the same regardless of the intensity fluctuations, but the contribution of the second term depends upon the complexity of the opening

density profile." *Id.* "The total beam-on time *M* is the maximum of the beam-on times of individual leaf pairs." *Id.*

Mohan addresses the problem of transmission through and scattering from the MLC the radiation dose, which it calls "indirect contributions," "indirect sources," or "indirect radiation." *Id.* at 1226–28, 1231–33, 1237. One of the ways Mohan proposes to reduce indirect contributions "may be to optimize the collimator angle for each beam in order to find orientations which minimize fluctuations to dose at a point from indirect sources," which Mohan characterizes as "possible but not trivial." *Id.* at 1237.

Petitioner contends Mohan qualifies as prior art under 35 U.S.C. § 102(b) and again cites the testimony of Dr. Hall-Ellis. Pet. 17 (citing Ex. 1011 ¶¶ 42–47). Dr. Hall-Ellis testifies that Mohan "was publicly accessible as early as June 29, 2000, and in any event, more than one year before the August 11, 2003 priority date" based on the stamp on the June 2000 edition of *Medical Physics* (which included Mohan) in the University of Minnesota Bio-Medical Library and various records regarding the journal *Medical Physics*. Ex. 1011 ¶¶ 42–47, p. 84. Patent Owner does not contest the prior art status of Mohan.

On the present record, and based on Dr. Hall-Ellis's uncontested testimony, we determine that Mohan qualifies as prior art under 35 U.S.C. § 102(b) because Mohan's publication date of June 29, 2000, is more than one year before the earliest possible effective filing date of the challenged claims, which is August 11, 2003. Ex. 1001, code (60); Ex. 1011 ¶¶ 42–47, p. 84.

5. Claim 1

a. Preamble and Claim Limitations

The preamble of claim 1 recites

> [a] computer-implemented method of determining a collimator angle of a multi-leaf collimator having an opening and a plurality of multi-leaf collimator leaf pairs for closing portions of the opening to form a radiation beam arrangement having a plurality of radiation beam segments to apply radiation to a tumor target, the method comprising the steps of[.]

Ex. 1001, 10:11–17. For the "multi-leaf collimator . . . having multi-leaf collimator leaf pairs," Petitioner cites Otto's "multileaf collimator [with] two opposing banks of adjacent blocking leaves." Pet. 18–20 (citing, *inter alia*, Ex. 1003 ¶ 4, Fig. 1). For the leaf pairs "closing portions of the opening to form a radiation beam arrangement having a plurality of radiation beam segments to apply radiation to a tumor target," Petitioner cites Otto's teachings on moving leaves "in and out of the radiation beam to define arbitrary field shapes." *Id.* at 20–21 (quoting, *inter alia*, Ex. 1003 ¶ 4). Petitioner further cites Otto's teaching of delivering "a radiation field which closely approximates an ideal radiation field" by "delivering several appropriately configured sub-fields at different times."[5] *Id.* at 22 (quoting Ex. 1003 ¶ 27). Petitioner contends such "a sequence of distinct MLC leaf shapes or configurations used to deliver the radiation" is commensurate with the recited "plurality of radiation beam segments." *Id.* at 22–23 (citing Ex. 1002 ¶ 61).

[5] Petitioner relies specifically on Otto's dynamic delivery method in which "the leaves are moved while the beam is on." Pet. 23 (quoting Ex. 1003 ¶ 6); *see also id.* at 49 (citing same).

For the "computer-implemented method of determining a collimator angle," Petitioner cites Otto's teachings on rotating the collimator. Pet. 23–24 (citing Ex. 1003 ¶¶ 18, 25–26, 28, Figs. 2A, 2B). Petitioner further cites Otto's teachings on determining a set of configurations for delivering sub-fields, which may include varying collimator angles according to a chosen optimization method. *Id.* at 24–25 (citing, *inter alia*, Ex. 1003 ¶ 53, Fig. 5).

Patent Owner does not dispute Petitioner's analysis of the preamble of claim 1. Neither party addresses whether the preamble is limiting. Because Petitioner has shown that the combination of Otto, Chang, Webb, and Mohan teaches the preamble, we need not determine whether the preamble is limiting. *See Nidec*, 868 F.3d at 1017.

Claim 1 further recites "calculating an initial radiation beam arrangement according to a desired prescription." Ex. 1001, 10:18–19. For the recited "desired prescription," Petitioner cites Otto's teaching of a "desired overall radiation field" as an input to the optimization method depicted in Otto's Figure 5. Pet. 25–26 (citing Ex. 1003 ¶ 44, Fig. 5). For "calculating an initial radiation beam arrangement," Petitioner also cites Chang's teaching about generating a "continuous, smooth intensity maps representing the ideal treatment for a patient afflicted with a tumor." *Id.* at 28 (quoting Ex. 1004, 7:66–8:5) (emphasis omitted).

Patent Owner does not dispute Petitioner's analysis of the "calculating an initial radiation beam arrangement" limitation. Based on Petitioner's analysis, we are persuaded that the combination of Otto, Chang, Webb, and Mohan teaches this limitation.

Claim 1 further recites

> changing the radiation beam arrangement by incorporating a first cost function to determine the collimator angle of the

> multi-leaf collimator, the first cost function including both a second cost function to enhance delivery efficiency by reducing a number of radiation beam segments and reducing a number of radiation beam monitor units required for delivery of the desired prescription and a third cost function to enhance conformity of the radiation beam arrangement to a target shape.

Ex. 1001, 10:20–29. Regarding "changing the radiation beam arrangement . . . to determine the collimator angle of the multi-leaf collimator," Petitioner cites Otto's generation of "MLC configurations for a desired radiation field by iteratively varying certain parameters, including collimator angle, according to a chosen optimization method." Pet. 32–33 (citing Ex. 1003 ¶ 53, Fig. 5). Petitioner notes that Otto does not teach any particular criteria for evaluating when an optimal collimator angle has been achieved. *Id.* at 33–34. As such, Petitioner cites Chang's "specific technique in which the final optimal solution for collimator angle is chosen to fulfill the dual objectives of (1) 'find[ing] the collimator angle that conforms to the contour as closely as possible' . . . while (2) factoring in 'the influence of such solution . . . on treatment delivery efficiency.'" *Id.* at 34 (citing Ex. 1004, 10:34–36, 11:10–12, Figs. 8A, 8B) (alteration in original) (emphases omitted). Petitioner alternatively cites Chang's teaching on choosing a single, optimal collimator angle to increase delivery efficiency. *Id.* (citing Ex. 1004, 11:10–12).

The claim recites that the "first cost function" includes the "second cost function" and the "third cost function." *See* Ex. 1001, 10:20–29. Petitioner analyzes the three recited cost functions together. *See* Pet. 36–48. For "enhanc[ing] conformity of the radiation beam arrangement to a target shape," Petitioner cites Webb's discussion of Brahme's theory and its aim to "minimize the volume (represented by an area 'seen' in the beam's-eye-

view) of normal tissue outside the target volume." *Id.* at 38 (quoting Ex. 1002 ¶ 85; Ex. 1005, 233–34). Petitioner also cites the same two objectives from Chang discussed directly above related to (1) conforming to the intensity map contour and (2) increasing efficiency. *Id.* at 36 (citing Ex. 1004, 10:34–36, 11:10–12, Figs. 8A, 8B); *see also id.* at 39–40 (citing same). Petitioner concedes "Chang does not detail of the precise computational technique that would be used to achieve" these objectives, but contends that "it would have been natural and obvious to use a '**cost function**' as claimed." *Id.* (citing Ex. 1002 ¶¶ 32–33, 49, 82). Petitioner further cites Webb's teachings for the proposition that "a cost function allows the computer running an optimization process to identify when it has arrived at the optimal solution for a beam arrangement." *Id.* at 36–37 (citing Ex. 1002 ¶ 83; Ex. 1005, 344).

In light of these teachings, Petitioner contends

> [i]t would . . . have been obvious that to achieve Chang's dual objectives in the context of an iterative optimization process as disclosed in Otto, a cost function would be used that included not just a mathematical function that quantified conformity, but also a function that quantified delivery efficiency. And for this, a person of ordinary skill would have looked to **Mohan**.

Pet. 40 (citing Ex. 1003, Fig. 5; Ex. 1005, 234) (footnote omitted). As such, Petitioner cites Mohan's "mathematical function for the minimum number of MUs, also referred to as 'beam-on time,' required to deliver a given radiation field from a particular direction of leaf travel." *Id.* at 40–41 (citing Ex. 1006, 1227–29, equations 7, 10). Petitioner further cites Mohan's teaching of "optimiz[ing] the collimator angle for each beam in order to find orientations which minimize fluctuations." *Id.* at 43 (quoting Ex. 1006, 1237). According to Petitioner, an ordinarily skilled artisan considering this

teaching and Mohan's mathematical function would have been motivated "to implement Mohan's equations as part of a cost function." *Id.* (citing Ex. 1002 ¶¶ 91, 107).

Petitioner characterizes the combined system of Otto, Chang, Webb, and Mohan as follows:

> Under the combination of Otto and Chang with Webb and Mohan . . . , the overall "**cost function**" used to achieve Chang's dual objectives in the context of Otto's optimization would include not only (1) a mathematical function that minimized the "area 'seen' in the beam's-eye-view" of normal tissue outside the target volume, i.e., "**a [] cost function to enhance conformity of the radiation beam arrangement to a target shape**," but also (2) a function that minimized the number of MUs ("beam-on time") required to deliver a given radiation field from a particular orientation of leaf travel, i.e., "**a second cost function to enhance delivery efficiency by reducing a number of radiation beam segments and reducing a number of radiation beam monitor units required for delivery of the desired prescription**."

Pet. 44–45 (citing Ex. 1002 ¶ 93; Ex. 1005, 234; Ex. 1006, 1229, 1237). Petitioner concedes that Mohan does not discuss "radiation beam segments," but Petitioner notes "there exists a general correlation between the number of MUs and the number of segments – in Mohan's parlance, 'windows formed by the leaves' – used to deliver a treatment plan." *Id.* at 45–46 (citing Ex. 1002 ¶ 94; Ex. 1006, 1232). As such, Petitioner contends Mohan's mathematical function for MUs, when used in a cost function, would result in a reduced number of radiation beam segments. *Id.*

Patent Owner argues that none of Otto, Chang, Webb, and Mohan provides "a cost function 'to determine the collimator angle of the multi-leaf collimator' that reduces the 'number of radiation beam segments' and reduces the 'number of radiation beam monitor units required for delivery of

the desired prescription.'" Prelim. Resp. 54 (citing, *inter alia*, Ex. 2002 ¶ 120). Specifically, Patent Owner argues "Otto does not consider reducing segments in the selection of collimator angles" and instead "teaches the *doubling* of segments during optimization for dynamic delivery." *Id.* (citing Ex. 1003 ¶ 77; Ex. 2002 ¶ 120). Patent Owner also argues Chang's three criteria for selecting a collimator angle are all "directed to conforming the shapes that can be made by the collimator to the shapes of the intensity map." *Id.* at 54–55 (citing Ex. 1004, 9:12–25, 10:32–48; Ex. 2002 ¶ 120).

We do not agree with Patent Owner's arguments. Petitioner cites Otto for determining the collimator angle based on optimization. *See* Pet. 32–33. Petitioner does not cite Otto for teaching the details of the second cost function; in fact, Petitioner acknowledges that Otto does not teach any particular criteria for its optimization method. *See id.* at 33–34. In addition, Patent Owner's cited doubling of segments from Otto (*see* Ex. 1003 ¶ 77) pertains to Otto's method of "developing a set of configurations for dynamic delivery of radiation" by "commenc[ing] with a few sub-fields and . . . increasing the number of sub-fields as the method proceeds." *See id.* ¶ 75. As such, the goal of this method is not to increase the number of sub-fields, as Patent Owner seems to imply. Rather, Otto discloses doubling sub-fields as one way to iteratively reach a set of configurations required to provide treatment. *See id.* ¶ 77.

Patent Owner's criticism of Chang is likewise misplaced. Petitioner cites Mohan, not Chang, for a cost function that seeks to "reduc[e] a number of radiation beam segments and reduc[e] a number of radiation beam monitor units required for delivery of the desired prescription." *See* Pet. 44–46 (citing Ex. 1003 ¶¶ 93, 94; Ex. 1006, 1229, 1237). In contrast, Petitioner

only cites Chang for the objective of achieving delivery efficiency. *See id.* at 36. The fact that Chang also teaches how to conform treatment to the shape of the intensity map (*see, e.g.*, Ex. 1004, 10:32–48) does not undermine Petitioner's analysis of radiation beam segments and radiation beam monitor units, which is based primarily on Mohan.

Based on the present record, Petitioner has established that the combination of Otto, Chang, Webb, and Mohan teaches all limitations of claim 1.

b. Reasons for the Combination

Petitioner contends "[a] person of ordinary skill, looking to implement or enhance the MLC techniques of Otto, would have naturally consulted Chang" because "Chang provides an implementation detail missing from Otto – the format in which the desired radiation field can be provided." Pet. 30 (citing Ex. 1002 ¶ 72). In particular, Petitioner refers to Chang's "'smooth' intensity map[, which] has a higher spatial resolution than 'discrete' maps used by alternative techniques, and therefore provides a superior representation of the desired treatment." *Id.* at 30–31 (citing Ex. 1004, 1:43–57, 8:8–15, 8:59–67). In this way, Otto's method of determining optimized parameters would have been extended such that "the desired prescription is provided in the form of a high resolution intensity map as disclosed in Chang." *Id.* at 29 (citing Ex. 1002 ¶¶ 72–74; Ex. 1003 ¶¶ 44–56, Fig. 5; Ex. 1004, 7:66–8:5, Fig. 4).

Petitioner further contends that an ordinarily skilled artisan would have combined Chang, Webb, and Mohan with Otto such that Otto's method of determining the optimized parameters included a cost function to

determine the optimized collimator angle. Pet. 48 (citing Ex. 1002 ¶ 91; Ex. 1003 ¶¶ 44–56, Fig. 5; Ex. 1004, 10:34–36, 11:10–12; Ex. 1005, 234; Ex. 1006, 1229). In particular, Petitioner contends Chang has "dual objectives to 'find[] the collimator angle that conforms to the contour as closely as possible,' while also factoring in 'the influence of such solution . . . on treatment delivery efficiency.'" *Id.* (quoting Ex. 1004, 10:34–35, 11:10–12). Petitioner also cites Webb's disclosure about Brahme's theory and its "mathematical function that minimizes the 'area "seen" in the beam's-eye-view' of normal tissue outside the target volume . . . to enhance conformity of the beam arrangement to a target shape." *Id.* at 49 (quoting Ex. 1005, 234). Petitioner further cites Mohan for teaching "a mathematical function that minimizes the number of MUs ('beam-on time') required to deliver a desired radiation field . . . to enhance delivery efficiency by reducing a number of beam segments and MUs." *Id.* (citing Ex. 1002 ¶ 97; Ex. 1006, 1229, 1237).

Petitioner presents Dr. Solberg's description of an "exemplary implementation of how the proposed combination of Otto, Chang, Webb, and Mohan would work in practice." Pet. 49–52 (citing Ex. 1002 ¶ 99–102). In this example, "Otto would generate MLC configurations for a desired radiation field for 'dynamic' delivery by iteratively varying certain parameters, including collimator angle." *Id.* at 49 (citing Ex. 1002 ¶ 99; Ex. 1003 ¶¶ 6, 53, Fig. 5). Furthermore, "the desired radiation field would be input into Otto in the form of a high resolution, 'smooth' intensity map as taught by Chang." *Id.* at 50 (citing Ex. 1004, 7:66–8:5, Fig. 4).

Continuing Petitioner's example, a cost function would be calculated for each collimator angle evaluated as part of Otto's optimization process.

Pet. 50 (citing Ex. 1002 ¶ 100; Ex. 1003 ¶ 53). According to Petitioner, the cost function would combine a calculation related to Brahme's theory, as taught by Webb, with "the value for minimum MUs required to deliver the desired radiation in the orientation of leaf travel (corresponding to the collimator angle being evaluated)," as taught by Mohan. *Id.* at 50–51 (citing Ex. 1005, 234; Ex. 1006, 1229 (equations 7, 10), 1237). Petitioner contends "[t]he optimum collimator angle is achieved when the value of the overall cost function is at a minimum." *Id.* at 51 (citing Ex. 1002 ¶ 101; Ex. 1005, 344). Petitioner characterizes this minimum value as

> the collimator angle that draws the appropriate balance between allowing the collimator leaves to conform as closely as possible to the contour of the target (as represented by the contour of [Chang's] "smooth" intensity map), and allowing the collimator leaves to travel in a direction with a short leaf travel distance and minimized fluctuations in intensity, and thereby deliver the desired radiation with improved efficiency.

Id. (citing Ex. 1004, Fig. 8B; Ex. 1005, 234; Ex. 1006, 1229, 1231, 1237). As an alternative, Petitioner points to Chang's teaching on using "[a] single optimized collimator angle could accordingly be used for the entire sequence of MLC configurations to deliver the desired field (i.e., from a particular gantry angle) to further enhance delivery efficiency." *Id.* at 51–52 (citing Ex. 1002 ¶ 102; Ex. 1004, 11:7–12).

Patent Owner disputes Petitioner's rationale for the combination. Patent Owner argues that "Mohan's delivery time equation would not provide a measure of delivery time for Otto's and Chang's step-and-shoot delivery mode" because "Mohan's equation for treatment delivery time is specific to the sliding window form of IMRT delivery." Prelim. Resp. 45 (citing Ex. 2002 ¶¶ 109–110). Patent Owner also notes that Chang's and

Otto's step-and-shoot mode also differs insofar as it includes collimator rotation, in contrast to Mohan. *Id.* at 46 (citing Ex. 2002 ¶ 110). Another point of distinction raised by Patent Owner is that Mohan's leaves move in one direction, whereas Otto's and Chang's leaves move bidirectionally. *Id.*

Based on the present record, we do not agree with Patent Owner's arguments. Petitioner relies specifically on Otto's dynamic delivery method (*see* Pet. 23, 40, 49), so Patent Owner's arguments against Otto regarding step-and-shoot delivery are misplaced. Nor does the present record establish that the difference between Mohan's unidirectional and Otto's (or Chang's) bidirectional leaves would meaningfully affect Petitioner's proposed combination.

In addition, Petitioner's citations to Chang are not limited to or peculiar to step-and-shoot delivery. Petitioner cites Chang for its smooth intensity map (*see* Pet. 28–29) and its dual objectives of finding a collimator angle that best conforms to a treatment map and increasing efficiency (*see id.* at 33–36). Petitioner contends Chang's high resolution intensity map would have been used as an input Otto's optimization process. *See id.* at 29–30. Petitioner further contends Chang's dual objectives would have been the optimization criteria for Otto's process. *See id.* at 39–40. On the present record, we do not agree that Chang's step-and-shoot teachings, which are not cited here, would have undermined Petitioner's combination.

Patent Owner also contends it would not have been obvious to apply Mohan's equation to Otto's "dynamically rotating MLC method." *Id.* at 46–47 (citing Ex. 2002 ¶ 111). Patent Owner again notes Otto's bidirectional leaves and further argues Otto's rotating MLC would result in leaves not traveling in a straight line. *Id.* at 47 (citing Ex. 2002 ¶ 111). Patent Owner

additionally argues an ordinarily skilled artisan "would have had no motivation to combine either Otto or Chang where the collimator will rotate to multiple angles during each field with Mohan and Webb where the collimator is fixed at a constant angle for each field." *Id.* at 48 (citing Ex. 2002 ¶ 105). Patent Owner further argues that rotating the collimator decreases delivery efficiency because it would increase treatment time. *Id.* at 49 (citing Ex. 2002 ¶ 107).

Based on the present record, we do not agree with Patent Owner's arguments. Otto discloses "dynamic delivery" in at least two ways: moving the leaves while the beam is on (*see* Ex. 1003 ¶ 6) and rotating the collimator while radiation is being delivered (*see id.* ¶ 35). Petitioner's combination relies on dynamic movement of the leaves. *See* Pet. 18–23 (referring to Otto's moving leaves), 50–51 (referring to Mohan regarding the "orientation of leaf travel" and "the collimator leaves . . . travel[ing] in a direction with a short leaf travel distance"). In addition, Petitioner cites Mohan's teachings in conjunction with one particular collimator angle being evaluated. *See id.* at 50–51. Petitioner does not rely on Otto's teachings of a collimator that rotates during radiation delivery. Furthermore, Petitioner cites Chang's teachings on finding an optimal collimator angle, and, in particular, choosing a single collimator angle for all MLC configurations. *See id.* at 33–34, 48, 51–52. Again, Petitioner does not invoke rotating the collimator during radiation delivery. As such, Patent Owner's arguments are not commensurate with Petitioner's proposed combination.

Patent Owner also argues Petitioner has not established a reasonable expectation of success in combining the prior art references. Prelim. Resp. 50 (citing *In re Magnum Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed.

Cir. 2016)). Specifically, Patent Owner criticizes Petitioner's citation of Mohan for teaching "optimiz[ation of] the collimator angle for each beam in order to find orientations which minimize fluctuations." *Id.* at 51 (citing Pet. 18, 43, 51, 55, 69; quoting Ex. 1006, 1237). Patent Owner notes that Petitioner omits the next sentence in Mohan, which states "[t]his is possible but not trivial." *Id.* (quoting Ex. 1006, 1237). According to Patent Owner, this omitted sentence "can be understood to mean that Mohan recognized that it would not be simple, it would not be routine, and it is not obvious how, to actually optimize the collimator angle for each beam in order to find orientations which minimize fluctuations." *Id.* (citing Ex. 2002 ¶ 98). Patent Owner further contends that, in light of this sentence, an ordinarily skilled artisan would not have had a reasonable expectation of success. *Id.* (citing Ex. 2002 ¶¶ 98, 115–118).

Again, we do not understand Petitioner's combination to rely on delivery of radiation while the collimator is rotating. Petitioner's combination evaluates various collimator angles and ultimately uses a single optimized collimator angle. *See* Pet. 33–34, 48, 50–52. As such, Patent Owner's arguments based on the non-trivial nature of optimizing the collimator angle for each beam do not undermine Petitioner's combination. On the present record, we are satisfied that an ordinarily skilled artisan would have expected success in making Petitioner's "exemplary implementation of how the proposed combination of Otto, Chang, Webb, and Mohan would work in practice." *Id.* at 49–52 (citing, *inter alia*, Ex. 1002 ¶¶ 99–102).

Thus, based on the present record, we are persuaded that an ordinarily skilled artisan would have had reasons to combine Otto, Chang, Webb, and Mohan.

c. Conclusion Regarding Claim 1

Petitioner has persuasively shown that the combination of Otto, Chang, Webb, and Mohan teaches all limitations of claim 1. Petitioner has also put forth persuasive reasons for combining these references. Based on the present record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing that the subject matter of claim 1 would have been obvious over the combination of Otto, Chang, Webb, and Mohan.

6. Claims 4 and 17–19

We have reviewed Petitioner's analysis for claims 4 and 17–19. Pet. 56–65. Patent Owner relies on the same arguments discussed above. Based on the present record, Petitioner has established a reasonable likelihood that it would prevail in showing that the subject matter of claims 4 and 17–19 would have been obvious over the combination of Otto, Chang, Webb, and Mohan.

F. Patent Owner's Arguments Regarding Service of the Petition

Patent Owner contends we should dismiss the Petition because Petitioner "did not timely and properly serve [Patent Owner] with the [Petition] documents required by paragraphs (2), (3), and (4) of 35 U.S.C. § 312(a) until after October 18, 2019, the one-year bar date." PO

Sur-reply 1; *see also* Prelim. Resp. 57–58. Specifically, Patent Owner contends that Petitioner dropped off the Petition with FedEx on Friday, October 18, 2019, after the deadline for FedEx overnight delivery, so the Petition materials were not delivered timely. Prelim. Resp. 60. Patent Owner contends it received the Petition on Monday, October 21, 2019, which is two days after delivery "by means at least as fast and reliable as Priority Mail Express" would have been completed in accordance with 37 C.F.R. § 42.105(b). *Id.* at 59. Patent Owner contends this is "not harmless error, and prejudicial to [Patent Owner's] right to repose." PO Sur-reply 1.

Petitioner argues "Patent Owner does not contend that the mere use of 'FedEx Priority Overnight' delivery is a *per se* failure to comply with § 42.105(b)." Pet. Reply 1. Rather, Petitioner characterizes Patent Owner's argument as seeking a conclusion that next-day service was required for compliance with this rule. *Id.* Petitioner also requests that we "waive any procedural defects in the interests of justice since Petitioner acted in good faith." *Id.* at 3.

Patent Owner's arguments would have us read a next-day service requirement into 37 C.F.R. § 42.105(b). We decline to do that. Based on the particular facts of this case, we are satisfied that Petitioner's use of FedEx on a Friday evening followed by delivery on a Monday—the next business day—is sufficiently akin to Priority Mail Express to satisfy the service requirement § 42.105(b). Further, to the extent necessary, we waive regulatory requirements related to the timing of Petitioner's service based on the particular facts of this case. *See* 37 C.F.R. § 42.5(b). In particular, Patent Owner has not established any actual prejudice or harm arising from

Petitioner's next-business-day service. Finally, we do not agree with Patent Owner's implication (PO Sur-reply 1) that the timing of service is a statutory requirement under 35 U.S.C. § 312(a); the plain language of that statute does not address service deadlines.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition and the Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to its unpatentability challenges. Accordingly, we institute an *inter partes* review on all of the challenged claims and the ground presented in the Petition. At this stage of the proceeding, we have not made a final determination as to the patentability of these challenged claims.

IV. ORDER

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 314, *inter partes* review is instituted as to claims 1, 4, and 17–19 of the '490 patent with respect to the ground of unpatentability presented in the Petition; and

FURTHER ORDERED that *inter partes* review is commenced on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

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