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Paper 54
Date: April 21, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VARIAN MEDICAL SYSTEMS, INC. and ELEKTA INC.,
Petitioner,

v.

BEST MEDICAL INTERNATIONAL, INC.,
Patent Owner.

IPR2020-00076[1]
Patent 7,015,490 B2

Before KARL D. EASTHOM, JOHN A. HUDALLA, and AVELYN M. ROSS, *Administrative Patent Judges*.

HUDALLA, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Petitioner's Motion to Exclude
35 U.S.C. § 318(a); 37 C.F.R. § 42.64

Varian Medical Systems, Inc. ("Varian") 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"). Patent Owner, Best

[1] Petitioner from IPR2020-00956 has joined this proceeding.

Medical International, Inc. ("Patent Owner"), filed a Preliminary Response (Paper 6, "Prelim. Resp."). Varian also filed a Preliminary Reply (Paper 8), and Patent Owner filed a Preliminary Sur-reply (Paper 9). Taking into account the arguments presented in these papers, we determined that the information presented in the Petition established that there was a reasonable likelihood that Varian would prevail with respect to its unpatentability challenges. Pursuant to 35 U.S.C. § 314, we instituted this proceeding on April 24, 2020, as to all challenged claims and all grounds of unpatentability. Paper 14 ("Dec. on Inst.").

Elekta Inc. ("Elekta") subsequently filed a similar petition and motion for joinder in IPR2020-00956. *See* IPR2020-00956, Papers 2, 3. We instituted an *inter partes* review and joined Elekta as a party to this proceeding in a limited capacity. *See* IPR2020-00956, Paper 8. Henceforth, we refer collectively to Varian and Elekta as "Petitioner."

During the course of trial, Patent Owner filed a Patent Owner Response (Paper 32, "PO Resp."), and Petitioner filed a Reply to the Patent Owner Response (Paper 37, "Pet. Reply"). Patent Owner also filed a Sur-reply. Paper 41 ("PO Sur-reply"). An oral hearing was held on January 28, 2021, and a transcript of the hearing is included in the record. Paper 52 ("Tr.").

Petitioner filed a Declaration of Timothy D. Solberg, Ph.D. (Ex. 1002) with its Petition and a Declaration of Sha Chang, Ph.D. (Ex. 1023) with its Reply. Petitioner also filed a Declaration of Sylvia Hall-Ellis, Ph.D. (Ex. 1011) with its Petition. Patent Owner filed declarations of Daniel J. Chase with its Preliminary Response (Ex. 2002) and with its

Response (Ex. 2035). The parties also filed transcripts of the depositions of Dr. Solberg (Ex. 2032) and Mr. Chase (Ex. 1025).

Petitioner filed a motion to exclude certain testimony from Mr. Chase. Paper 45 ("Exclude Mot."). Patent Owner filed an opposition (Paper 47, "Exclude Opp."), and Petitioner filed a reply (Paper 51, "Exclude Reply").

We have jurisdiction under 35 U.S.C. § 6. This decision is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of claims 1, 4, and 17–19 of the '490 patent. For the reasons discussed below, Petitioner has demonstrated by a preponderance of the evidence that claims 1, 4, and 17–19 of the '490 patent are unpatentable.

I. BACKGROUND

A. Real Parties-in-Interest

Varian 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. Elekta identifies Elekta Limited (UK), Elekta Holdings U.S., Inc., and Elekta AB as real parties-in-interest. IPR2020-00956, Paper 2, 1. 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; IPR2020-00956, Paper 2, 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. We denied institution in all of these cases except for IPR2020-00071 and IPR2020-00072, which are pending.

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."[2] *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 [MUs] required for delivery of the desired prescription." *Id.* at 2:35–40.

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

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:

> 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");
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> 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 in 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 Instituted Ground

We instituted *inter partes* review of claims 1, 4, and 17–19 of the '490 patent on the following ground (Dec. on Inst. 34), which is the only ground presented in the Petition (Pet. 3):

Claims Challenged	35 U.S.C. §	References
1, 4, 17–19	103(a)[3]	Otto, Chang, Webb, Mohan

[3] 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

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.[4] *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) (quoting *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)).

B. Level of Ordinary Skill in the Art

The level of ordinary skill in the art is "a prism or lens through which . . . the Board views the prior art and the claimed invention" to prevent hindsight bias. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). In determining the level of ordinary skill, various factors may be considered, including the "types of problems encountered in the art; prior art solutions to those problems; rapidity with which innovation are made; sophistication of

[4] The record does not contain any evidence of secondary considerations of nonobviousness.

the technology; and educational level of active workers in the field." *In re GPAC Inc.,* 57 F.3d 1573, 1579 (Fed. Cir. 1995) (internal quotation and citation omitted). Generally, it is easier to establish obviousness under a higher level of ordinary skill in the art. *Innovention Toys, LLC v. MGA Entm't, Inc*., 637 F.3d 1314, 1323 (Fed. Cir. 2011) ("A less sophisticated level of skill generally favors a determination of nonobviousness . . . while a higher level of skill favors the reverse.").

Citing testimony from Dr. Solberg, Petitioner contends a person having ordinary skill in the art (POSA) would have been "a medical physicist with a Ph.D. (or similar advanced degree) in physics, medical physics, or a related field," and would have had "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." 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." PO Resp. 12 (citing Ex. 2035 ¶ 81); *see also* Prelim. Resp. 16 (same definition). For purposes of our Decision on Institution, we adopted Patent Owner's definition. Dec. on Inst. 7.

The parties' proposed definitions do not differ greatly as to the level and type of formal education, and the parties have not raised any dispute related to formal education. Therefore, as to that aspect, we continue to apply Patent Owner's articulation that a person of ordinary skill in the art

would have "earned at least a master's or doctoral degree in radiation dosimetry, physics, medical physics, or medicine, or equivalent disciplines." *See* PO Resp. 12.

Nevertheless, we must resolve the parties' dispute regarding the type of experience that an ordinarily skilled artisan would have possessed.[5] At the outset, we note that in determining the level of ordinary skill in the art, we consider the inventions of the '490 patent as a whole, and not just inventions related to individual claims. *See Hologic, Inc. v. Minerva Surgical, Inc.*, 764 F. App'x 873, 879 (Fed. Cir. 2019) (considering broader teachings in a challenged patent's specification, and not just the more narrowly drawn claims, when evaluating the Board's determination of a level of ordinary skill).

The '490 patent "relates to a method and apparatus for intensity modulated radiation therapy treatment, and more specifically, a method and apparatus for optimization of collimator angles for multileaf collimators ('MLC') used in intensity modulated radiation therapy treatment." Ex. 1001, 1:27–31. This indicates that the relevant field of the invention includes apparatus, and not just methods, for intensity modulated radiation therapy treatment. Moreover, the specification of the '490 patent states that "the present method and apparatus for optimization of collimator angles in IMRT inverse treatment planning systems" include embodiments that "utilize a *new algorithm* to determine collimator angles in favoring, or

[5] We note that the parties' definitions do not differ meaningfully as to the number of years' experience that would have been possessed by an ordinarily skilled artisan, i.e., "two or more" for Petitioner versus "three" for Patent Owner. As mentioned below, we apply two years of experience.

enhancing, IMRT radiation therapy treatment plan delivery efficiency." *Id.* at 1:65–2:4 (emphasis added). The specification also states that "[e]mbodiments of the present invention also include a cost function obtained by *combining the prior algorithm* based upon Brahme's orientation theory *with the algorithm* utilized in the present invention." *Id.* at 2:7–11 (emphases added). These passages indicate that an ordinarily skilled artisan would have had familiarity with algorithm development in the context of an IMRT inverse treatment planning system, particularly with regard to treatment optimization using various algorithms.

Regarding the use of computers, the specification of the '490 patent states that one of its embodiments for determining an optimum collimator angle of the multi-leaf collimator "preferably [is] computer-implemented." *Id.* at 2:26–32. The specification also states that "[t]he computations associated with the cost function to determine the optimum collimator angle and related software . . . *can be processed on a computer or other computational device known to those skilled in the art* and which can be associated with the selected radiation delivery apparatus." *Id.* at 6:62–67 (emphasis added). The '490 patent additionally includes an embodiment in the form of

> *a computer readable medium that is readable by a computer* determining a collimator angle of a multi-leaf collimator having an opening and a plurality of multi-leaf collimator pair leafs 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 computer readable medium includes a set of instructions that, when executed by the computer, causes the computer to perform various operations . . . .*

Id. at 3:58–67 (emphases added). Given that it was known in the art to use computers for optimization calculations, and given that the '490 patent specification includes computer-implemented embodiments, we find that a person of ordinary skill in the art would have had experience programming computers with optimization algorithms like those disclosed in the '490 patent.[6] Thus, we adopt Petitioner's articulation of the experience that an ordinarily skilled artisan would have possessed.

For these reasons, and based on the entire trial record, we determine that an ordinarily skilled artisan (1) would have earned at least a master's or doctoral degree in radiation dosimetry, physics, medical physics, or medicine, or equivalent disciplines, and (2) would have had two 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.

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

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[6] Mr. Chase attempts to draw a distinction between "*formal* computer programming, *i.e.*, designing and writing underlying computer code" and "using computer programs associated with radiation therapy." Ex. 2035 ¶ 86. Given the disclosures about algorithm development discussed above, we interpret the requisite experience in computer programming to be formal computer programming. We reject Mr. Chase's suggestion that it might relate to merely using computer programs.

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; PO Resp. 13. 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. Mr. Chase's Testimony and Petitioner's Motion to Exclude

Patent Owner submits a declaration of Mr. Chase as an expert witness in the field of the '490 patent. *See* Ex. 2035. Petitioner moves to exclude the entirety of Mr. Chase's declaration (*id.*) under Federal Rule of Evidence 702 "because it is improper expert testimony on nonobviousness by a witness that does not meet the minimum qualifications of a person ordinarily skilled in the art." Exclude Mot. 1. In particular, Petitioner cites its assertion that a person of ordinary skill in the art would have had experience

in "computer programming associated with treatment plan optimization." *Id.* at 3 (citing Pet. 4). Petitioner further notes Mr. Chase's cross-examination testimony in which he conceded that he did not "have the ability to design and write computer code that implements the claimed cost function of the '490 patent." *Id.* at 1 (citing Ex. 1025, 63:4–8). In the alternative, Petitioner moves to exclude certain enumerated paragraphs from Mr. Chase's declaration that "express opinions specific to issues of treatment planning system design, which is outside Mr. Chase's area of expertise." *See id.* at 1, 14–15. Petitioner bases its alternative motion on Mr. Chase's cross-examination testimony from IPR2020-00072 in which he states he is "not an expert in the design of treatment planning systems." *Id.* at 11 (quoting IPR2020-00072, Ex. 1044, 68:4–5).[7]

Petitioner argues that "only one of ordinary skill in the art who is qualified as a technical expert under Rule 702 of the Federal Rules of Evidence may offer expert testimony on technical matters." Exclude Mot. 2 (quoting *Byrne v. Wood, Herron & Evans, LLP*, 450 F. App'x 956, 962–63 (Fed. Cir. 2011) (non-precedential)) (citing *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008)) (emphasis by

[7] Based on this testimony, Petitioner asks us to "take judicial notice of Mr. Chase's admission that he is not an expert in the design of treatment planning systems." Exclude Mot. 11 n.9. In its reply in support of the motion to exclude, Petitioner further notes that "Patent Owner makes no objection to Petitioner's request for judicial notice . . . , nor does it dispute Mr. Chase's admitted lack of expertise in treatment planning system design." Exclude Reply 5. Under these circumstances, we take official notice of Mr. Chase's statement that he is "not an expert in the design of treatment planning systems." *See* Fed. R. Evid. 201; 37 C.F.R. § 42.62 ("*Judicial notice* means official notice"). We consider this to be a factor in the weight we accord Mr. Chase's opinions.

Petitioner). Petitioner acknowledges, but seeks to distinguish, certain guidance in our Consolidated Trial Practice Guide that there is "no requirement of a perfect match between the expert's experience and the relevant field." *Id.* at 8–9 (quoting Patent Trial and Appeal Board Consolidated Trial Practice Guide 34 (Nov. 2019), *available at* https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf) (citing *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360 (Fed. Cir. 2010)). Petitioner contends the case cited in support of this guidance, *SEB*, "is inapposite" because the testimony at issue in *SEB* "did not relate to invalidity . . . and did not include opinions on the disclosure of particular art references, the motivation to combine those prior art references, or any other issue that requires interpretation from the perspective of one having at least ordinary skill in the art." *Id.* at 9 (quoting *Morpho Detection, Inc. v. Smiths Detection, Inc.*, No. 2:11-cv-498, 2012 WL 6004085, at *1 (E.D. Va. Nov. 30, 2012)) (emphasis by Petitioner). According to Petitioner, Mr. Chase does not qualify as a person of ordinary skill in the art, so "his opinions purportedly undertaken from the perspective of a person skilled in the pertinent art cannot be 'based on sufficient facts or data,' nor can they be 'the product of reliable principles and methods.'" *Id.* at 10 (quoting Fed. R. Evid. 702).

Patent Owner contends there is an "'adequate relationship' between Mr. Chase's experience and the claimed inventions disclosed in the '490 patent." Exclude Opp. 8 (quoting *SEB*, 594 F.3d at 1373); *see also id.* at 7–8 (discussing Mr. Chase's experience as a medical physicist with "extensive clinical experience including extensive work with linear accelerators ('LINACs'), treatment planning systems and their associated

software," among other things). Patent Owner also seeks to distinguish the holding of *Sundance*, a case Petitioner cites in support of its motion, based on the fact that the proffered expert in that case was an expert in patent law who did not have relevant experience in the pertinent art of the patent-in-suit. *Id.* at 8 (citing *Sundance*, 550 F.3d at 1362). In contrast, Patent Owner contends that Mr. Chase does possess the relevant expertise. *See id.* at 8–9.

As stated above, the '490 patent relates to, *inter alia*, a method and apparatus for intensity modulated radiation therapy treatment. Ex. 1001, 1:27–31. We agree with Patent Owner (Exclude Opp. 7–8) that Mr. Chase's background in nuclear engineering and experience with treatment planning systems is adequately related to the disclosed methods and apparatus for intensity modulated radiation therapy treatment in the '490 patent. *See SEB*, 594 F.3d at 1373; Ex. 2035 ¶¶ 12–16. In addition, Mr. Chase is not required to have the exact experience in our adopted definition of the level of ordinary skill, namely "computer programming associated with treatment plan optimization." *See* Consolidated Trial Practice Guide 34; *see also Mytee Prods., Inc. v. Harris Research, Inc.*, 439 F. App'x 882, 886–87 (Fed. Cir. 2011) (nonprecedential) (upholding admission of the testimony of an expert who "had experience relevant to the field of the invention," despite admission that he was not a person of ordinary skill in the art). Thus, Mr. Chase is qualified to provide expert testimony in this proceeding under Federal Rule of Evidence 702.

We also note that the Board acts as both the gatekeeper and the weigher of evidence. Similar to a district court in a bench trial, the Board, sitting as a non-jury tribunal with administrative expertise, is well positioned to determine and assign appropriate weight to evidence presented, including

giving it no weight. *See, e.g.*, *Donnelly Garment Co. v. NLRB*, 123 F.2d 215, 224 (8th Cir. 1941) ("One who is capable of ruling accurately upon the admissibility of evidence is equally capable of sifting it accurately after it has been received . . . ."). For these reasons, we *deny* Petitioner's motion to exclude the entirety of Mr. Chase's declaration. Rather than excluding evidence that is allegedly confusing, misleading, unsupported, and/or irrelevant, we will simply assign the weight that we consider to be appropriate in our analysis.

Regarding Mr. Chase's concession that he is "not an expert in the design of treatment planning systems" (IPR2020-00072, Ex. 1044, 68:4–5), we view this is an issue affecting the weight we accord Mr. Chase's testimony, rather than its admissibility. As such, we *deny* Petitioner's alternative motion to exclude certain enumerated paragraphs from Mr. Chase's declaration.

Despite our denial of Petitioner's motion to exclude, we consider the facts underlying Petitioner's motion to be significant in our weighing of Mr. Chase's testimony vis-à-vis the testimony of Petitioner's declarants Dr. Solberg and Dr. Chang. According to Mr. Chase, a person of ordinary skill in the art would have been a mere clinician who did not have the ability to design and write computer code that implements the cost function of the '490 patent. *See* Ex. 1025, 54:17–56:3, 61:12–63:14; Ex. 2035 ¶ 81. Yet it strains credulity to say that a person working in the art of the '490 patent would not have had such fundamental capability that is relevant to methods and systems like those disclosed in the '490 patent itself. Moreover, Mr. Chase's analysis is distorted insofar as he testified about the improbability of an ordinarily skilled artisan implementing the claimed cost

function in a treatment planning system using *existing commercial systems* in 2003 in a clinical setting. Ex. 1025, 61:23–63:3. He additionally considered FDA approval restrictions and liability issues. *Id.* In our view, these restrictions on the perspective of a person of ordinary skill in the art do not square with the notion that the ’490 patent allegedly advanced the existing art. Ex. 1001, 1:51–61 (noting that “the art ha[d] sought a method and apparatus for determining the collimator angle before optimization in an inverse treatment planning system which favors, or enhances, the delivery efficiency by reducing the number of segments and MUs” and that no such method or apparatus had existed before the ’490 patent). In addition, the asserted prior art is not necessarily limited to commercial methods and systems. *See, e.g.*, Ex. 1004, 7:58–65 (Chang comparing optimization results of its disclosed method with those of “the IMFAST™ algorithm by Siemens” and “conventional methods”); Ex. 1005, 233–35 (Webb describing mathematical calculations behind Brahme’s theory); Ex. 1006, 1227–29 (Mohan describing mathematical algorithms for calculating beam-on time). This indicates that an ordinarily skilled artisan would not have been confined to commercialized systems as suggested by Mr. Chase. *See, e.g.*, Ex. 1025, 55:7–56:3 (deposition testimony of Mr. Chase). For these reasons, we discount Mr. Chase’s testimony related to system development in our obviousness analysis below.

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; Pet. Reply 1–24. Patent Owner disputes Petitioner's contentions. PO Resp. 13–64; PO Sur-reply 1–12.

1. Otto

Otto is a U.S. patent application publication directed 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.

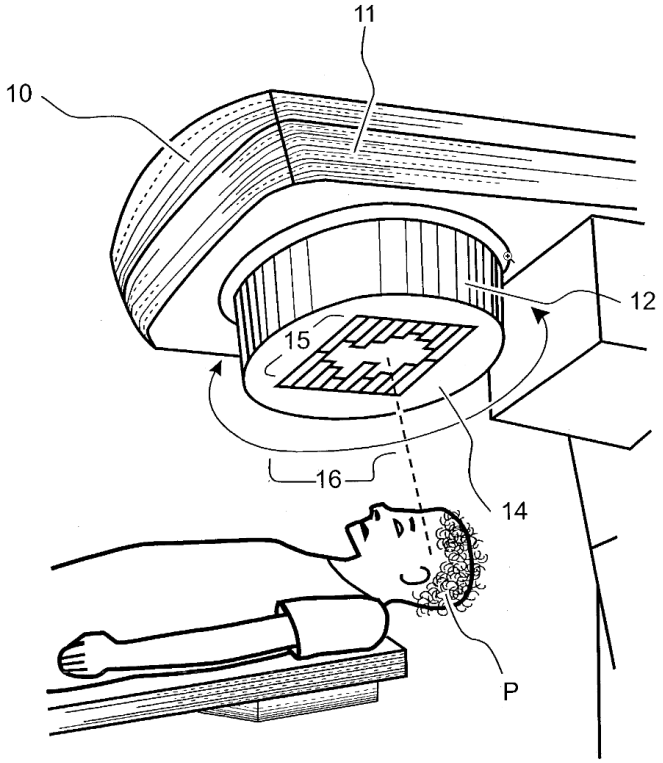

Figure 1 depicts the radiation emitting portion of a radiation treatment device with a rotating MLC. *Id.* ¶ 17. Patient P is positioned to receive radiation from radiotherapy device 10. *Id.* ¶ 25. Radiation exits through multi-leaf collimator 14 within collimator 12 and impinges onto patient P. *Id.* 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.

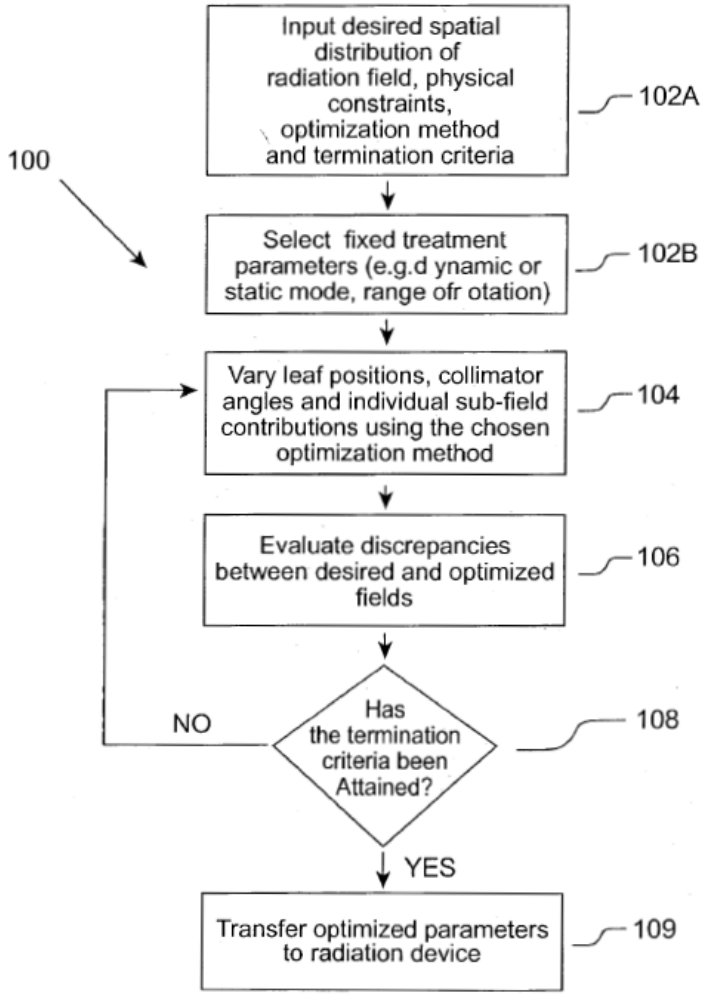

FIGURE 5

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,[8] 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

[8] Although the flowchart of Figure 5 includes separate blocks 102A and 102B, the specification otherwise refers to these blocks as a single block 102.

be delivered statically or dynamically, the maximum range of rotation of the 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.

We have no evidence of an invention date other than the earliest possible effective filing date of the challenged claims. Thus, 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" 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 intensity-modulated (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.

We have no evidence of an invention date other than the earliest possible effective filing date of the challenged claims. Thus, 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.

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 distributions on 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 the following:

> 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 (brackets and parentheses omitted).

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)). According to Dr. Solberg, "$x_{i_{\text{start}}}$ refers to

the starting position of the leaf pair," "$x_{i_{\text{last}}}$refers to the terminal position of the leaf pair," and "Ω_e refers to the radiation intensity to be delivered at each discrete point in the path of leaf travel." Ex. 1002 ¶ 89. Dr. Solberg further explains that "the left term in equation (7) is proportional to the leaf travel distance for the leaf pair, $x_{i_{\text{start}}} - x_{i_{\text{last}}}$," whereas "[t]he right term captures the amount of 'complexity' or fluctuation in radiation intensity in the direction of leaf travel." *Id.* ¶ 90 (citing Ex. 1006, 1229). "The total beam-on time *M* is the maximum of the beam-on times of individual leaf pairs," as set forth below:

$$M = \max\{M_l\}$$

Ex. 1006, 1229 (equation (10)).

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.

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

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."[9] *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).

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 Otto teaches the preamble, we need not determine whether the preamble is limiting. *See Nidec*, 868 F.3d at 1017.

b. "calculating an initial radiation beam arrangement according to a desired prescription"

Claim 1 further recites "calculating an initial radiation beam arrangement according to a desired prescription." Ex. 1001, 10:18–19. Petitioner cites Otto's optimization method in Figure 5 for teaching the recited "calculating." Pet. 25–26 (citing Ex. 1003 ¶¶ 21, 44, Fig. 5). Regarding the recited "desired prescription," Petitioner cites Otto's teaching

[9] 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).

in block 102A of Figure 5 that a "desired overall radiation field" is an input to the optimization method. *Id.* at 26 (citing Ex. 1003 ¶ 44, Fig. 5). Petitioner acknowledges that Otto does not disclose the format of the desired radiation field, so Petitioner relies on Chang's teaching of generating a "continuous, smooth intensity maps representing the ideal treatment for a patient afflicted with a tumor" for this implementation detail. *Id.* at 28–31 (quoting Ex. 1004, 7:66–8:5) (citing, *inter alia*, Ex. 1002 ¶ 72) (emphasis omitted). Petitioner further contends that an ordinarily skilled artisan would have understood that, as part of Otto's optimization method performed in block 104 of Figure 5, an "initial radiation beam arrangement" would be calculated based on the desired radiation field (and further optimized thereafter). *Id.* at 27–28 (citing Ex. 1002 ¶ 70; Ex. 1003 ¶ 53, Fig. 5).

Patent Owner does not dispute Petitioner's analysis of the "calculating an initial radiation beam arrangement" limitation. We are persuaded that Otto's Figure 5 method teaches using a desired prescription (block 102A) to calculate an initial beam arrangement, which is optimized thereafter (block 104). *See, e.g.*, Ex. 1002 ¶ 70; Ex. 1003 ¶¶ 21, 44, 53, Fig. 5. Chang also teaches a smooth intensity map for specifying the desired prescription. *See, e.g.*, Ex. 1004, 7:66–8:5. Based on Petitioner's analysis, we are persuaded that Otto and Chang teach "calculating an initial radiation beam arrangement according to a desired prescription," as recited in claim 1.

c. "changing the radiation beam arrangement" 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. 1002 ¶ 76[10]; 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 also cites Chang's teaching of choosing a single, optimal collimator angle to increase delivery efficiency. *Id.* (citing Ex. 1004, 11:10–12).

Claim 1 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

[10] Petitioner mistakenly cites to paragraph 70, but the context makes clear Petitioner intended to cite to paragraph 76.

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 . . . 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.* at 36 (citing Ex. 1002 ¶¶ 32–33, 49, 82) (emphasis by Petitioner). 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 and internal citations 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) (internal citations omitted) (emphasis by Petitioner). As such, Petitioner maps the recited "second cost function" to Mohan's equation (10), which incorporates equation (7), and Petitioner maps the recited "third cost function" to Brahme's theory, which is described in Webb. *Id.* 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) (internal citation omitted). Petitioner contends the relationship between MUs and segments is confirmed by the three different intensity patterns shown in Figure 3 of Mohan. *Id.* According to Petitioner, Figure 3 shows that window widths decrease and exhibit greater variation as the number of MUs increase, which "reflect[s] an increased number of MLC configurations implemented as the leaf pair travels from its starting to end points." *Id.* (citing Ex. 1002 ¶ 94). Thus, 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.* at 45 (citing Ex. 1002 ¶ 94).

As a further evidence of the relationship between MUs and segments, Petitioner notes that claim 5 of the '490 patent (not challenged here) specifies the recited second cost function of claim 1 can take the form of "$\max[l_e(\theta)]$," which "outputs a single value 'describing the maximum effective length'" of a leaf pair. Pet. 46–47 (citing Ex. 1001, 11:33–36). According to Petitioner, the fact that this single value fulfills the limitation "reducing a number of radiation beam segments and reducing a number of radiation beam monitor units" in claim 1 "confirms that the number of beam segments is directly correlated with the number of MUs." *Id.* at 47; Ex. 1002 ¶ 95. Furthermore, Petitioner notes that "[t]he '490 [patent] specification . . . discloses no separate mathematical function or algorithm for reducing beam segments as distinguished from reducing MUs." Pet. 47 (citing Ex. 1001, 4:35–53).

We are persuaded that Otto's discussion with respect to block 104 of Figure 5 teaches "changing the radiation beam arrangement . . . to determine the collimator angle of the multi-leaf collimator." *See, e.g.*, Ex. 1003 ¶ 53,

Fig. 5 ("Vary . . . collimator angles . . . using the chosen optimization method."). Webb teaches the use of an overall cost function for optimization, i.e., "a first cost function." *See, e.g.*, Ex. 1005, 344 (stating that a cost function is a "[m]athematical function parametrizing the effect of arranging beams in some particular way" and that "[t]he aim of optimization would be to minimize the cost function"). Chang teaches the objectives of the "third cost function" and the "second cost function," respectively: (1) "find[ing] the collimator angle that conforms to the contour as closely as possible" (*see, e.g.*, Ex. 1004, 10:34–36), while (2) factoring in "the influence of such solution . . . on treatment delivery efficiency" (*see, e.g., id.* at 11:10–12). Webb also teaches a "third cost function to enhance conformity" based on Brahme's theory. *See, e.g.,* Ex. 1005, 234. Finally, Mohan's equation (10), which incorporates equation (7), teaches the recited "second cost function to enhance delivery efficiency." *See, e.g.*, Ex. 1005, 1229, 1237. In particular, Mohan's equation (10) is described as a cost function to reduce monitor units (or "beam-on time") (*see, e.g.*, *id.* at 1227, 1229), and we are persuaded that an ordinarily skilled artisan would have known of a correlation between reduced monitor units and reduced radiation beam segments. *See, e.g.*, Ex. 1002 ¶¶ 94–95; Ex. 1023 ¶¶ 66–71. We further discuss Petitioner's analysis for the "changing the radiation beam arrangement" limitation in the context of Patent Owner's arguments below.

(1) Patent Owner's Arguments Based on Otto

Patent Owner disputes that Otto teaches an iterative optimization algorithm to optimize collimator angle. PO Resp. 18–24. According to Patent Owner, Otto "explicitly teaches that each segment has a ***pre-***

determined collimator angle." *Id.* at 18 (citing Ex. 1003 ¶ 11; Ex. 2035 ¶ 109); *see also id.* at 19 (discussing embodiments of Otto where collimator angles are "pre-determined and fixed" and "spaced apart equally over a suitable angular range"), 21 (citing testimony from Dr. Solberg about "the collimator angle for each segment [being] fixed at an angle manually selected by the user'); PO Sur-reply 4 (same argument). Patent Owner further disputes that Otto's Figure 5 embodiment teaches the use of an optimization algorithm for collimator angle. PO Resp. 19–24. In particular, Patent Owner notes that Otto does not teach specific criteria to determine when optimization has been achieved. *Id.* at 19–20 (citing Ex. 1002 ¶ 77).

Nevertheless, we agree with Petitioner (Pet. Reply 5–6) that the plain language shown within Otto's Figure 5 contradicts Patent Owner's arguments. Specifically, block 102B of Figure 5 states "[s]elect fixed treatment parameters (e.g. dynamic or static mode, range of rotation)," whereas block 104 states "[v]ary leaf positions, collimator angles and individual sub-field contributions using the chosen optimization method." Ex. 1003, Fig. 5. Otto further explains: "Block 104 determines a set of configurations for delivering a number of sub-fields. Each configuration specifies leaf positions, collimator angles and sub-field contributions. All the parameters that are not fixed may be varied according to the chosen optimization method." *Id.* ¶ 53. Thus, Otto teaches that the collimator angle may be varied as part of a chosen optimization method. These teachings also support Petitioner's argument that an ordinarily skilled artisan "would have understood and found it obvious that as part of the optimization step shown in block 104, the radiation beam arrangement would be 'chang[ed]' by varying its parameters until an optimal collimator angle is determined."

Pet. 33 (citing Ex. 1002 ¶ 76) (emphasis omitted). Furthermore, to the extent Otto does not teach particular optimization criteria (*see* PO Resp. 19–20), Petitioner relies on Chang, not Otto, for teaching such criteria. *See* Pet. 33–34. Thus, we find Petitioner's argument to be persuasive.

Patent Owner also refers to a different reference, "Otto Paper," in an attempt to draw distinctions with the Otto reference asserted here. PO Resp. 24–26 (citing Ex. 2033). Based on Otto Paper, Patent Owner contends an ordinarily skilled artisan "would not have concluded that Otto taught or suggested the use of an iterative algorithm to optimize collimator angle." *Id.* at 26 (citing Ex. 2035 ¶ 134). We agree with Petitioner (Pet. Reply 7), however, that Otto Paper does not undermine or change the cited portions of Otto on which Petitioner relies. *See EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985) ("A reference must be considered for everything it *teaches* by way of technology").

Patent Owner additionally argues that Otto does not disclose dynamic delivery using a single collimator angle. *See* PO Resp. 27–30; PO Sur-reply 5–6. Specifically, Patent Owner contends an ordinarily skilled artisan "would not have read paragraph [0006] of Otto as teaching or suggesting a dynamic system in which leaves moved while the beam is on" because this paragraph pertains to general background, not the invention of Otto. PO Resp. 29 (citing Ex. 2035 ¶¶ 151–155). Rather, Patent Owner points to an embodiment of Otto where radiation is delivered "dynamically (with the collimator rotating while radiation is being delivered)." *Id.* at 29; PO Sur-reply 5 (both quoting Ex. 1003 ¶ 35). Thus, Patent Owner concludes that it would have been "impossible to practice Otto's invention involving

multiple collimator angles without rotating the collimator." *Id.* at 30 (citing Ex. 2035 ¶ 156).

We do not agree with Patent Owner's arguments. Petitioner is entitled to rely on Otto "for what it fairly teaches in combination with the prior art as a whole," and not just "in isolation." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Nor are the teachings from Otto limited to "the particular *invention* it is describing and attempting to protect." *See EWP*, 755 F.2d at 907. Paragraph 6 of Otto states that "[i]n dynamic [delivery] methods[,] the leaves are moved while the beam is on." Ex. 1003 ¶ 6. Otto also mentions that "[a]ny desired overall radiation field can be made by applying any of many possible combinations of sub-fields." *Id.* ¶ 43. As such, Petitioner is entitled to rely on Otto for teaching dynamic delivery where just the leaves of a collimator move.[11] *See Merck*, 800 F.2d at 1097. The fact that Otto may additionally describe embodiments with a rotating collimator does not limit how Petitioner (and an ordinarily skilled artisan) may rely on Otto. *See EWP*, 755 F.2d at 907. This is supported by Mr. Chase's testimony that "Otto adds *the possibility* of rotating the MLC in addition to moving the leaves during treatment." Ex. 2002 ¶ 68 (emphasis added). Moreover, Dr. Solberg mentions a suggestion in Otto of

[11] Indeed, Petitioner's combination relies only 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"). Correspondingly, 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.

> computational advantage (in addition to the delivery efficiency advantage taught by Chang) that would be gained by using a single optimized collimator angle to deliver an entire beam: "It is not trivial to identify a combination of sub-fields which will produce a desired overall radiation field when collimator 14 is permitted to rotate between sub-fields."

Ex. 1002 ¶ 108 (quoting Ex. 1003 ¶ 39) (emphasis by Dr. Solberg). This also supports Petitioner's reliance on Otto's teaching of dynamic movement of the leaves without collimator rotation.

Patent Owner makes other arguments related to Otto that do not address the particular combination asserted by Petitioner. *See* PO Resp. 16–18 (arguments regarding Otto's objective being dosimetric fit, though Petitioner relies on Chang for teaching the objective of "enhanc[ing] delivery efficiency"), 26–27 (arguments regarding the application of Otto's algorithm to the combination, though Petitioner relies on Chang's algorithm). These arguments do not undermine Petitioner's persuasive showing.

(2) Patent Owner's Arguments Based on Chang

Patent Owner contends "Chang's primary and secondary solutions to select a collimator rotation angle are both directed to maximizing dosimetric fitness." PO Resp. 35 (citing Ex. 2035 ¶ 175); *see also* PO Sur-reply 6 (same argument). As such, Patent Owner contends an ordinarily skilled artisan would not have read Chang as "disclosing or suggesting a collimator angle optimization cost function or algorithm to determine collimator angle based on any measurement of deliver efficiency, much less by decreasing the number of segments and MU[s]." PO Resp. 38 (citing Ex. 2035 ¶ 190); *see also* PO Sur-reply 7 (citing Ex. 2035 ¶¶ 182–183) (same argument). Yet

Chang expressly states that "[a]n optimal collimator angle can also be selected for all segments of the same IM field to increase treatment delivery efficiency" and that "the final solution or solutions is chosen based [on] the influence of such solution or solutions on treatment delivery efficiency." Ex. 1004, 11:7–12. Thus, Chang does not support Patent Owner's suggestion that Chang's teachings are limited to improving conformity or that Chang does not teach optimization based on efficiency considerations. Moreover, we agree with Petitioner (Pet. Reply 11–12) that Chang teaches initially identifying collimator angles based on conformity, and then evaluating the angles on the basis of efficiency, which results in a final optimized angle that accounts for both conformity and efficiency. *See* Ex. 1002 ¶¶ 46, 77–80; Ex. 1004, 10:34–36, 10:65–11:12; *see also* Pet. 16, 34–35 (citing same).

To the extent that Patent Owner argues that Chang does not disclose an iterative algorithm to reduce segments and MUs (*see* PO Resp. 37–40), Petitioner relies on Mohan for teaching this limitation. *See* Pet. 40–48. As such, these arguments do not undermine the combination proposed by Petitioner.

(3) Patent Owner's Arguments Based on Mohan

Patent Owner disputes that Mohan teaches "enhanc[ing] delivery efficiency by reducing a number of radiation beam segments and reducing a number of radiation beam monitor units required." *See* PO Resp. 47–48. In particular, Patent Owner takes issue with Mohan's statement that it may be possible to reduce indirect radiation contributions by "optimiz[ing] the collimator angle for each beam in order to find orientations which minimize

fluctuations," which Mohan states is "possible but not trivial." Ex. 1006, 1237. Patent Owner characterizes Mohan's statement as something the author had not done, and that an ordinarily skilled artisan would not have interpreted this as guidance on how to accomplish the optimization of a collimator angle with respect to any parameter. PO Resp. 48 (citing Ex. 2035 ¶¶ 236–237).

In reply, Petitioner argues that Patent Owner's argument ignores Mohan's express teaching of "optimiz[ing] the collimator angle for each beam in order to find orientations which minimize fluctuations." Pet. Reply 16 (citing Ex. 1006, 1237). According to Petitioner, "Mohan makes clear that the (synonymous) concepts of 'complexity' and 'fluctuation' is [sic] quantified by equation (7), which Petitioner cited to supply the delivery efficiency portion of the '**cost function**' as claimed." *Id.* at 17 (citing Ex. 1002 ¶¶ 90–91, 100–101). Petitioner also argues that it need not show absolute predictability in order to establish a reasonable expectation of success in making its proposed combination. *Id.* at 14–16 (citing, *inter alia*, *Soft Gel Techs., Inc. v. Jarrow Formulas, Inc.*, 864 F.3d 1334, 1342 (Fed. Cir. 2017)).

We agree with Petitioner. Mohan expressly teaches that it is possible to optimize the collimator angle for each beam in order to find orientations that minimize fluctuations. Ex. 1006, 1237. Mohan also provides an equation (*see id.* at 1229, equation (7)) that quantifies "the amount of 'complexity' or fluctuation in radiation intensity in the direction of leaf travel." Pet. 42–43; *see also* Ex. 1006, 1229 ("the contribution of the second term [of equation (7)] depends upon the complexity of the opening density profile"). We agree with Petitioner that, in light of these teachings, an

ordinarily skilled artisan would have been motivated to implement Mohan's equations as part of a cost function. Pet. 43 (citing Ex. 1002 ¶¶ 91, 107).

Patent Owner also disputes that Mohan teaches "how [to] enhance delivery efficiency by reducing both the number of segments required and the number of MUs required." PO Resp. 52 (citing Ex. 2035 ¶ 255). In particular, Patent Owner questions Dr. Solberg's testimony about "a general correlation between the number of MUs and the number of segments" (Ex. 1002 ¶ 94) as being unsupported and based merely on a "loose correlation." PO Resp. 52–54 (citing, *inter alia*, Ex. 2032, 163:22–18, 165:6–19). Patent Owner also cites two references in support of its contention that "the lack of a direct correlation between MU[s] and treatment time was well known in the art to a POSA." *Id.* at 54–55 (citing Ex. 2037 ("Potter"), 275, 282; Ex. 2034 ("Herman"), 7); *see also* Ex. 2035 ¶ 264 (citing same).

In reply, Petitioner argues that it only needs to prove that its proposed combination is "'reasonably capable' of operating so as to reduce segments as claimed, even if it would not ***necessarily*** reduce segments in all instances of its operation." Pet. Reply 21 (quoting *ParkerVision, Inc. v. Qualcomm Inc.*, 903 F.3d 1354, 1361 (Fed. Cir. 2018)). Petitioner reiterates the testimony of Dr. Solberg and cites additional testimony from Dr. Chang about a "general correlation" between the number of MUs and the number of segments. Pet. Reply 21 (citing Ex. 1002 ¶¶ 94–96; Ex. 1023 ¶¶ 66–71).

As noted by Petitioner (Pet. Reply 21), Mr. Chase apparently concedes that "higher complexity is associated with higher MUs" and that Mohan's cost function would work to reduce complexity and reduce the number of MUs. Ex. 2035 ¶¶ 214, 246–247. Thus, the only remaining

question is whether an ordinarily skilled artisan would have known of a correlation between Mohan's teaching of reducing the number of MUs and the recited "reducing the number of radiation beam segments" of claim 1. We are persuaded by Petitioner's showing that an ordinarily skilled artisan would have known about this general correlation based on Mohan's teachings. In particular, Figure 3 of Mohan shows that as the number of MUs increases, "corresponding window widths not only decreased but exhibited greater variation – reflecting an increased number of MLC configurations implemented as the leaf pair travels from its starting to end points." Ex. 1002 ¶ 94; Ex. 1006, 1232. This supports Petitioner's contentions because Mohan teaches that "radiation is delivered through a sequence of windows formed by the leaves" (Ex. 1006, 1226), which Petitioner likens to segments. *See* Pet. 45.

Nor do we agree with Patent Owner's argument that an ordinarily skilled artisan would have understood Mohan's teachings—particularly with regard to equation (7)—to be "specific to the physics of a dynamic sliding windows system" such that they would not be "applicable to segment based systems (either dynamic or static), and would not be material to the calculation of MUs, segment count, or treatment time of segment-based systems." PO Resp. 50–51 (Ex. 2035 ¶¶ 250–251). Although Patent Owner contends that Mohan does not address how to extend Mohan's equation (7) to "a non-sliding dynamic system" (*see id.* at 51), Mohan discusses both dynamic and static systems. *See* Ex. 1006, 1226. Record evidence also establishes that the sliding window technique to which Mohan's equation (7)

corresponds is equally applicable to both dynamic and static delivery.[12] Ex. 1023 ¶¶ 76–79; Ex. 1025, 72:19–73:7; Ex. 2032, 16:20–21, 17:6–20. For example, an ordinarily skilled artisan would have known that "segments" as applied to step-and-shoot delivery correspond to "control points" in the context of dynamic sliding window delivery. Ex. 1023 ¶ 81 & n.11; Ex. 2032, 112:22–113:22; Ex. 2035 ¶ 58. With this in mind, we do not agree that differences between dynamic and static delivery undermine Petitioner's contentions regarding "segments" based on Mohan, i.e., that the use of Mohan's cost function would result in reduced MUs and reduced segments ("windows formed by the leaves"). *See* Pet. 45–46 (citing Ex. 1002 ¶ 94; Ex. 1006, 1226, 1232). Dr. Chang also provides detailed testimony on how Mohan's equation would reduce MUs and segments for both dynamic and static sliding window delivery, which we credit. *See* Ex. 1023 ¶¶ 80–97.

We also agree with Petitioner (Pet. Reply 21) that Petitioner need not establish perfect correlation between Mohan's teaching of reduced MUs and the resulting reduced segments. Rather, Petitioner need only show that its proposed combination "is reasonably capable of operating so as to meet the claim limitations, even if it does not meet the claim limitations in all modes of operation." *ParkerVision*, 903 F.3d at 1361. As discussed above, Petitioner has established as much via its citations to Mohan. We additionally note that exemplary implementations of the cost function disclosed in the '490 patent sometimes resulted in decreased segments but increased MUs. *See* Ex. 1001, Fig. 8 (showing, for IMFAST software, a

[12] We further discuss Patent Owner's arguments regarding static versus dynamic delivery below. *See infra* § II.E.5.e.

93% ratio for segments but a 110% ratio for MUs), Fig. 9 (showing, for the STANDARD algorithm, a 92% ratio for segments but a 101% ratio for MUs); *see also* Ex. 1023 ¶ 73 (Dr. Chang's testimony regarding the same). As such, Patent Owner is wrong to suggest that Petitioner must show more than is disclosed in the '490 patent itself, which reflects less-than-perfect correlation between reduced segments and reduced MUs.

Furthermore, as noted by Petitioner (Pet. 46–47), the only efficiency cost function disclosed in the '490 patent ($\max[l_e(\theta)]$) results in a single value (the "value of the maximum effective length"). Ex. 1001, 6:35–44, 11:33–36 (claim 5). By virtue of claim 5 depending from claim 1, the '490 patent links this function with both reducing a number of segments and reducing a number of monitor units. *Id.* at 11:33 (claim 5 reciting that "$\max[l_e(\theta)]$ is the second cost function"). The single-value "second cost function" of the '490 patent thus confirms a direct correlation between reduced segments and reduced monitor units. *See* Ex. 1002 ¶ 95.

We additionally have considered Patent Owner's arguments related to certain references cited by Patent Owner (PO Resp. 54–55), Potter and Herman, in light of the testimony from Dr. Chang. *See* Ex. 1023 ¶¶ 68–70. We are persuaded by Dr. Chang's testimony that (1) Potter, for which she is a co-author, "does not demonstrate the absence of a general correlation between the number of MUs and segments" based on a very limited sample size (*id.* ¶ 68); and (2) Herman "refer[s] to a lack of an observed relation between MUs and treatment time, and not MUs and segment count" (*id.* ¶ 69). Thus, these references do not undermine Petitioner's contentions relating to Mohan.

d. Conclusion Regarding Preamble and Claim Limitations

On the entire trial record, Petitioner has established that the combination of Otto, Chang, Webb, and Mohan teaches all limitations of claim 1.

e. 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 optimal 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) (internal citations omitted). Petitioner additionally points to Chang's teaching that "[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).

We are persuaded by Petitioner's showing that an ordinarily skilled artisan would have had reasons to combine Chang, Webb, and Mohan with Otto in the manner proposed by Petitioner. Petitioner's reasons are rooted in the references themselves: (1) Chang touts that its "smooth" intensity map provides a better representation of the desired treatment than "discrete" intensity maps (Ex. 1004, 1:43–57, 8:8–15), a desirable improvement for Otto's method, which does not provide this implementation detail (i.e., the format in which the desired radiation field is provided); (2) Chang also teaches dual optimization objectives of enhancing conformity and enhancing delivery efficiency (*id.* at 10:32–11:12), which provides a missing detail

from Otto regarding criteria for evaluating optimal collimator angles; (3) Webb teaches cost functions (Ex. 1005, 344), which provides a computational technique that would be used to achieve Chang's dual objectives; (4) Webb also teaches Brahme's theory (*id.* at 233–35), which provides a specific mathematical technique to determine a collimator angle that best achieves the objective of enhancing conformity to a radiation target; and (5) Mohan teaches a mathematical function for minimizing the number of MUs (Ex. 1006, 1227–29, 1237), which quantifies delivery efficiency.

We also credit Dr. Solberg's testimony (*see, e.g.*, Ex. 1002 ¶¶ 72–74, 97–108) and Dr. Chang's testimony (*see, e.g.*, Ex. 1023 ¶¶ 41–46, 59–64) regarding the rationale for Petitioner's combination. To the extent Mr. Chase's testimony conflicts with Dr. Solberg's and Dr. Chang's testimony regarding this rationale, we find Dr. Solberg's and Dr. Chang's testimony more persuasive and consistent with the record (as discussed in greater detail below). In particular, Mr. Chase's testimony is flawed because it is based on the perspective of a clinician using commercially available systems rather than a person having two years' experience in computer programming associated with treatment plan optimization, among other things. *See supra* § II.D. As such, Mr. Chase's testimony does not "take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). We also are mindful of the high level of ordinary skill in the art (*see supra* § II.B), which may favor a determination of obviousness. *See Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011) ("A less sophisticated level of skill generally favors a determination of

nonobviousness . . . while a higher level of skill favors the reverse.”). We further discuss Petitioner’s rationale for the combination in the context of Patent Owner’s arguments below.

Patent Owner characterizes Chang as being directed to a step-and-shoot delivery system, and not dynamic delivery as in Petitioner’s proposed combination. PO Resp. 40 (citing Ex. 1004, 2:5–3:16), 59–60 (citing Ex. 2035 ¶ 297). Patent Owner contends that, although “Chang does not affirmatively say that it would be impossible to use [the disclosed] invention with a delivery system other than step-and-shoot,” Chang “certainly does not disclose or suggest how to do so, or even the desirability of trying.” *Id.* at 41 (citing Ex. 2035 ¶ 201). As such, Patent Owner contends an ordinarily skilled artisan would have understood “Chang’s disclosed invention to be specific to step-and-shoot delivery.” *Id.* Patent Owner additionally argues that an ordinarily skilled artisan would not have combined Otto’s dynamic mode with “Chang’s static step-and-shoot delivery method.” *Id.* at 59–60 (citing Ex. 2035 ¶¶ 297–300). Rather, Patent Owner argues an ordinarily skilled artisan would have combined “the two innovations on the step-and-shoot delivery system common to both.” *Id.* at 60 (citing Ex. 2035 ¶ 298).

We do not agree with Patent Owner’s arguments. 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 to 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. Thus, we do not agree that Chang's step-and-shoot teachings, which the Petition does not rely upon, undermine Petitioner's combination.

In addition, we do not agree that Chang's teachings are limited necessarily to step-and-shoot delivery. Even if Patent Owner were correct that Chang's disclosed invention is implemented with step-and-shoot delivery, Patent Owner admits that Chang discusses dynamic delivery. *See* PO Resp. 40 (citing Ex. 1004, 2:14–18, 2:38–55).

We also agree with Petitioner (Pet. Reply 19) that dynamic and static step-and-shoot delivery each can involve similar movements of the collimator leaves. *See* Ex. 1025, 72:9–73:7 (Mr. Chase testifying that, in step-and-shoot delivery, collimator leaves can move "side to side and make a series of static segments and have the beams turn off between the segments"); Ex. 2032, 94:4–95:14 (Dr. Solberg testifying sliding window and step-and-shoot delivery are "not exclusive of one another" and that "[s]ome linear accelerators can do dynamic, some can only do step-and-shoot, some can do both"); *see also* Ex. 1029,[13] 771 (2003 Williams paper explaining "there are many similarities between segmented and dynamic MLC treatments" and that "[d]ynamic delivery can be seen as an extension of segmented delivery to the limit where the segments are so small that their delivery without interruption becomes possible"); Ex. 2009, R373 (2006 Bortfeld paper explaining that "[i]f many segments are used the distinction

[13] Patent Owner notes that the 2003 Williams paper at Exhibit 1029 is not prior art to the '490 patent because it was published three months after the earliest possible effective filing date of the challenged claims. PO Sur-reply 9 & n.2. Nevertheless, we find the 2003 Williams paper to be probative of the state of the art around the time of the '490 patent.

between dynamic and step-and-shoot delivery becomes somewhat blurry"). Thus, even if we were to agree with Patent Owner that Chang's teachings are limited to step-and-shoot delivery, the evidence of record does not support that Patent Owner's purported distinction would make a difference to Petitioner's combination.

Patent Owner also argues that Mohan's equations "are specific to the physics of a dynamic sliding windows system, and are not applicable to segment based systems (either dynamic or static), and would not be material to the calculation of MUs, segment count, or treatment time of segment-based systems." *Id.* at 50–51 (citing Ex. 2035 ¶¶ 250–251). Patent Owner also criticizes Petitioner for relying on conclusory statements and for failing to detail how Mohan's equations would have been modified for segment based systems, such as step-and-shoot. *Id.* at 51 (citing Ex. 2035 ¶ 252). Patent Owner also disputes that an ordinarily skilled artisan would have expected success in combining Mohan's equations pertaining to unidirectional collimator leaves with Otto's and Chang's systems in which the leaves move bidirectionally. *Id.* at 62 (citing Ex. 1006, 1228–29; Ex. 2035 ¶ 304); *see also* PO Sur-reply 8 (same argument).

As discussed above, dynamic and step-and-shoot delivery both involve similar movements of the collimator leaves. *See* Ex. 1025, 72:9–73:7. Moreover, Petitioner cites testimony from both sides in its Reply (Pet. Reply 19) supporting Petitioner's contention that "the cited sliding or sweeping window technique from Mohan, in which the leaves move unidirectionally from one side to another, was commonly implemented with both dynamic and static delivery." Ex. 2032, 16:8–17:20; Ex. 1025, 72:19–73:7; Ex. 1023 ¶¶ 76–78 (citing Exs. 1028, 1029, 2009, 2037). Given the

common nature of both dynamic and static delivery in which the leaves move in the same direction, we do not agree that the various technological differences highlighted by Patent Owner would have meaningfully affected Petitioner's proposed combination. Moreover, as stated above, we credit Dr. Chang's testimony on how Mohan's equation would reduce MUs and segments for both dynamic and static sliding window delivery "without modification." *See* Pet. Reply 22; Ex. 1023 ¶¶ 80–97.

Patent Owner disputes that an ordinarily skilled artisan would have had a motivation to combine Otto, Chang, and Mohan because Otto and Chang "were seeking solutions to improve dosimetric fit." PO Resp. 57. As such, Patent Owner argues that Otto and Chang are "not about improving delivery efficiency, nor were they about reducing the number of segments required." *Id.* at 57 (citing Ex. 2035 ¶¶ 289–290). Rather, Patent Owner argues that the "subject and object" of Otto, Chang, and Mohan is dosimetric fitness. *Id.* at 58–59. Patent Owner further contends that the fact that Otto and Chang generally relate to improving dosimetric fitness would not have motivated an ordinarily skilled artisan to combine these references. *Id.* (citing Ex. 2035 ¶ 292). As discussed above, however, Chang also discusses delivery efficiency. *See* Ex. 1004, 11:7–12. We also find above that Mohan teaches how to reduce the number of segments and monitor units required, which results in efficiency improvements. *See supra* § II.E.5.c.(3). And, even if the "goal" of these references were to achieve dosimetric fitness, we do not agree that a reference's "goal" prevents its application for other aspects it teaches by way of technology. *See EWP*, 755 F.2d at 907. Thus, we do not agree with Patent Owner's arguments.

Patent Owner further argues that Petitioner's proposed combination is "the direct result of impermissible hindsight." PO Resp. 61–62. Patent Owner focuses on the following testimony from Dr. Solberg regarding his drafting process for his declaration: "It starts at the — well, I'm aided in understanding what claims to assess." *Id.* at 61 (quoting Ex. 2032, 63:20–64:12); *see also* PO Sur-reply 10–11. In light of this comment, Patent Owner argues that "Dr. Solberg's method . . . started with the claims at issue," which is "classic hindsight." PO Resp. 61; *see also id.* at 62 (argument regarding improper use of the claims as a roadmap); PO Sur-reply 11 (same argument). Yet we do not read Dr. Solberg's isolated statement about "understanding what claims to assess" as an indication that he impermissibly used the challenged claims as a roadmap. It does not strike us as unusual that a declarant would need to understand the claims at issue—and the particular inventions they recite—when he is asked to opine about the obviousness of those very claims. Moreover, as discussed above, we find Petitioner's rationale for the combination to be rooted in the references themselves, which disproves the existence of hindsight bias.

Patent Owner argues that Petitioner has failed to establish a reasonable expectation of success in implementing its proposed combination. PO Resp. 56–57; PO Sur-reply 1–3. In particular, Patent Owner criticizes Dr. Solberg's testimony that "[t]he precise computational techniques that would be used to evaluate the cost function of [Petitioner's] proposed combination would have been well within the capabilities and creativity of persons of ordinary skill." PO Resp. 56 (quoting Ex. 1002 ¶ 100 n.9). Patent Owner contends this statement is conclusory and unsupported by evidence. *Id.* at 56–57; *see also* PO Sur-reply 1 (same

argument). Patent Owner also argues that it has "submitted *unrebutted* expert opinion demonstrating that a POSA would not have had a reasonable expectation of success." PO Sur-reply 2 (citing PO Resp. 62; Ex. 2035 ¶¶ 304, 306).

Yet Patent Owner's arguments focus on a single statement about general computational techniques and do not address the totality of evidence on expected success. We note that the first term of Petitioner's proposed cost function pertains to Brahme's theory for determining an optimal collimator angle to enhance conformity. *See* Pet. 38–39, 44–45, 49. As acknowledged by Patent Owner, Brahme's theory was well known in the art, and Patent Owner does not dispute Petitioner's descriptions of Brahme's theory based on Webb. PO Resp. 55–56 n.9. Given that Brahme's theory was conventional at the time of the '490 patent, we find there would have been a reasonable expectation of success in implementing a conformity cost term based on Brahme's theory. As such, we turn to the issue of expected success as it pertains the efficiency cost term in Petitioner's combination.

In particular, Mohan's equation (10), which incorporates equation (7), supplies the delivery efficiency portion of the recited "cost function" in Petitioner's analysis. *See* Pet. 40–45, 49. As asserted by Dr. Solberg and Dr. Chang, this equation—along with Mohan's teaching of "optimiz[ing] the collimator angle for each beam in order to find orientations which minimize fluctuations" (Ex. 1006, 1237)—would have motivated an ordinarily skilled artisan to implement equation (10) in order to minimize complexity as a function of the collimator angle. Ex. 1002 ¶¶ 91, 93, 97, 100–102; Ex. 1023 ¶¶ 41–45; Ex. 2032, 206:20–207:2. Dr. Chang further testifies about a 2001

study by Williams[14] (Ex. 1024, "2001 Williams study") (after Mohan but before the time of the '490 patent) that "confirms that a POSA in 2003 would have been motivated to, and successful in, combining Mohan's teachings as part of an 'exemplary implementation' of collimator angle optimization described by Dr. Solberg." Ex. 1023 ¶ 47 (citing Ex. 1002 ¶¶ 97–102; Ex. 1024). In light of the 2001 Williams study (*see* Ex. 1023 ¶¶ 47–50; Ex. 1024), Dr. Chang concludes that "a POSA in 2003 would have had a high expectation that optimizing the collimator angle would successfully produce beneficial results, which as demonstrated by the 2001 Williams study, includes the potential of reducing total MUs by as much as 40%." Ex. 1023 ¶ 50. We credit the 2001 Williams study as evidence of expected success for the efficiency cost term. *See* Ex. 1023 ¶¶ 47–50; Ex. 1024. We also are persuaded of expected success by the fact that Mohan discloses a ready algorithm for reducing complexity. Ex. 1006, equations (7), (10); *see also* Ex. 2032, 206:20–207:2 (Dr. Solberg testifying that "the algorithm is essentially there; it's the right-hand part of equation 7.").

As mentioned above, we find Dr. Solberg's testimony on the rationale for the combination more persuasive and consistent with the record than Mr. Chase's testimony. For example, Mr. Chase testifies that "Mohan's equations would not be efficiently applied to the bidirectional dynamic motion of Otto or Chang" because "different mathematics" would have

[14] Patent Owner calls the 2001 Williams study improper reply evidence. PO Sur-reply 9. We find it to be directly responsive to Patent Owner's arguments about reasonable expectation of success and supportive of Petitioner's arguments made in the Petition. *See* Pet. 40–48.

made the combination difficult or impossible. Ex. 2035 ¶ 304. Yet Dr. Solberg testifies that Mohan's teachings "allow[] 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." Ex. 1002 ¶ 101. In light of one of Chang's stated goals, i.e., treatment delivery efficiency (Ex. 1004, 11:10–12), and its teaching of optimizing the collimator angle to improve efficiency (*id.* at 9:52–67), we are persuaded that an ordinarily skilled artisan would have expected success in implementing Mohan's function to minimize "beam-on time" and minimize MUs as part of an overall cost function. *See* Ex. 1002 ¶¶ 104–108. And, even if Petitioner's proposed combination used only one direction of leaf movement in Otto's (or Chang's) system, we view an ordinarily skilled artisan's choice in this regard to be the type of creative step a person of ordinary skill would have taken to attain efficiency. *See id.* ¶ 101; *see also* Ex. 1025, 72:19–73:7 (Mr. Chase testifying about the ability to implement step-and-shoot delivery with unidirectional leaves). Thus, we credit Dr. Solberg's testimony.

Based on the entire trial record, we are persuaded that an ordinarily skilled artisan would have had reasons to combine Otto, Chang, Webb, and Mohan and would have reasonably expected success in doing so.

f. Conclusion Regarding Claim 1

Petitioner has persuasively shown that the combination of Otto, Chang, Webb, and Mohan teaches all limitations of claim 1. Petitioner also has also put forth persuasive reasons for combining these references and has established that an ordinarily skilled artisan would have had a reasonable

expectation of success in making the combination. On the entire trial record, we determine Petitioner has shown, by a preponderance of the evidence, that the subject matter of claim 1 would have been obvious over the combination of Otto, Chang, Webb, and Mohan.

6. Claim 4

Claim 4 depends from claim 1 and further recites the step of

> rejecting the change in the radiation beam arrangement if the change of the radiation beam arrangement significantly leads to a lesser correspondence to the desired prescription and accepting the change of the radiation beam arrangement if the change of the radiation beam arrangement both leads to more radiation delivery efficiency and does not lead to significantly less correspondence to the desired prescription.

Ex. 1001, 10:66–11:8. Petitioner relies on its proposed combination from claim 1, which results in an overall cost function that outputs lower values when an evaluated collimator angle leads to greater conformity and enhanced delivery efficiency. Pet. 56 (citing Ex. 1002 ¶¶ 101, 110; Ex. 1004, 10:34–36, 11:10–12; Ex. 1005, 234; Ex. 1006, 1229). Petitioner notes that changes in collimator angle would be accepted only if the change leads to a lower value for the overall cost function. *Id.* (citing Ex. 1002 ¶ 111; Ex. 1005, 344). Petitioner contends that, under its proposed cost function, a proposed arrangement would be not be accepted (i.e., rejected) where it results in significantly less conformity, because it would lead to a significantly higher cost value. *Id.* at 56–57 (citing Ex. 1002 ¶ 111).

The second part of claim 4 concerns a situation where a proposed arrangement "leads to more radiation delivery efficiency" and "does not lead to significantly less correspondence to the desired prescription." Petitioner

notes that greater efficiency lowers the value of the overall cost function, whereas a slight decrease in conformity would not increase the overall cost function by much, if at all. Pet. 57 (citing Ex. 1002 ¶ 112). As a result, the overall cost function would be lower, which results in accepting the proposed arrangement. *Id.*

Patent Owner relies on the same arguments discussed above with respect to claim 1. Given that the aim of optimization is to minimize a cost function (*see* Ex. 1005, 344), we are persuaded that Petitioner's proposed overall cost function discussed in claim 1 would (1) reject radiation beam arrangements leading to significantly less conformity and (2) accept radiation beam arrangements that do not lead to significantly less conformity but increase efficiency. *See, e.g.*, Ex. 1002 ¶¶ 110–112. Thus, we determine Petitioner has shown by a preponderance of the evidence that the subject matter of claim 4 would have been obvious over the combination of Otto, Chang, Webb, and Mohan.

7. Claim 17

Independent claim 17 is an apparatus claim with limitations similar to those of claim 1. Ex. 1001, 14:13–32. Petitioner relies mostly on its analysis of claim 1, though Petitioner adds a few citations and explanations to address the additional limitations of claim 17. *See* Pet. 57–61. For example, claim 17 recites "a multi-leaf collimator having a plurality of selectable discrete collimator angles." Ex. 1001, 14:15–16. Petitioner cites Otto's Figures 2A and 2B, which "depict two exemplary MLC configurations that have different collimator angles." Pet. 58–59 (reproducing Ex. 1003, Figs. 2A, 2B) (citing Ex. 1002 ¶¶ 18, 28). Claim 17

also recites "a computer in communication with the multi-leaf collimator." Ex. 1001, 14:21–22. Petitioner cites Otto's teaching of a control system that "typically comprises a computer processor" and that "receives parameters specifying the leaf positions and rotation angle for a sub field and actuates the mechanism to cause the leaves to move to the desired positions and to cause the multi-leaf collimator to be rotated to the desired angle." Pet. 60 (citing Ex. 1003 ¶ 26). Petitioner additionally notes that claim 17 recites two different "parameters" in the same way that claim 1 recites a "second cost function" and a "third cost function." *Id.* Petitioner contends its analysis of claim 1's "second cost function" and "third cost function" applies equally to claim 17's "parameters" because "[i]t is fundamental knowledge to persons of ordinary skill that mathematical functions can be expressed using parameters." *Id.* at 60–61 (citing Ex. 1002 ¶ 119; Ex. 1013, 1683).

Patent Owner relies on the same arguments discussed above with respect to claim 1. To the extent claim 17 differs from claim 1, we are persuaded by Petitioner's analysis regarding the recited "plurality of selectable discrete collimator angles" (*see* Ex. 1003, Figs. 2A, 2B), "computer" (*see id.* ¶ 26), and "parameters" (*see* Ex. 1002 ¶ 119) as set forth above. Thus, based on this additional analysis and Petitioner's analysis for claim 1, we determine Petitioner has shown by a preponderance of the evidence that the subject matter of claim 17 would have been obvious over the combination of Otto, Chang, Webb, and Mohan.

8. Claim 18

Claim 18 depends from claim 17 and further recites that "the parameters to enhance delivery efficiency include a value of a maximum

effective length for a multi-leaf collimator leaf pair of the plurality of multi-leaf collimator leaf pairs having the maximum effective length." Ex. 1001, 14:33–37. Petitioner contends M^l in equation (7) of Mohan (*see supra* § II.E.4) is a value of "effective length." Pet. 62–63 (citing Ex. 1002 ¶ 123; Ex. 1006, 1229). Petitioner further contends the value *M* in equation (10) of Mohan (*see supra* § II.E.4) "is a value of the maximum effective length for the MLC leaf pair in an MLC (which has multiple leaf pairs) that ha[s] the maximum effective length, M^l." Pet. 63–64 (citing Ex. 1002 ¶ 124; Ex. 1006, 1229) (internal quotations and emphases omitted). Petitioner additionally notes that "the equation for *M* would be adapted as the mathematical function for enhancing delivery efficiency in the overall cost function of the proposed combination." *Id.* at 64.

Patent Owner contends that "Mohan does not evaluate 'maximum effective length for a multi-leaf collimator leaf pair of the plurality of multi-leaf collimator leaf pairs having the maximum effective length.'" PO Resp. 63 (citing Ex. 2035 ¶ 265). According to Patent Owner, Dr. Solberg "asserted that a term 'M' in one of Mohan's equations was 'similar' to a 'maximum effective length.'" *Id.* (citing Ex. 2032, 167:3–169:2).

In reply, Petitioner cites Mr. Chase's testimony that "maximum effective length" refers to "the furthest traveled distance of all the MLC pairs involved in the treatment. It would be the MLC pair that has traveled the furthest, in essence." Pet. Reply 23–24 (citing Ex. 1025, 42:2–10). According to Petitioner, "[t]he beam-on time equation for each individual leaf pair M^l . . . incorporates the term $x_{i_{\text{start}}} - x_{i_{\text{last}}}$, which captures the distance traveled by the leaf pair." *Id.* at 24 (citing Ex. 1002 ¶¶ 88–89). Petitioner further notes "the total beam-on time, *M*, incorporates the beam-

on times of all leaf pairs in order to identify the maximum value ('max{M_l}')," so "*M* 'includ[es] a value of a maximum effective length.'" *Id.* (citing Ex. 1002 ¶¶ 93, 123; Ex. 1023 ¶ 42).

We are persuaded by Petitioner's arguments. Based on the plain language of claim 18, "the parameters to enhance delivery efficiency" need only "*include* <u>*a*</u> *value* of a maximum effective length for a multi-leaf collimator leaf pair." Ex. 1001, 14:33–36 (emphases added). This does not mean that the parameters need to directly evaluate maximum effective length, as Patent Owner's argument seems to imply. *See* PO Resp. 63. We are persuaded that Mohan's total beam-on time, *M*, "includes a value of maximum effective length" by virtue of including the term $x_{i_{\text{start}}} - x_{i_{\text{last}}}$ for the furthest traveled leaf pair as part of the calculation of max{M_l}. *See* Ex. 1002 ¶¶ 122–125; Ex. 1006, 1229. The value of *M* also represents an efficiency term in Petitioner's mapping. *See* Pet. 40–43. Thus, we determine Petitioner has shown by a preponderance of the evidence that the subject matter of claim 18 would have been obvious over the combination of Otto, Chang, Webb, and Mohan.

9. Claim 19

Claim 19 depends from claim 18 and recites

> the parameters to enhance conformity of the radiation beam arrangement include an area difference between an area of an opening in the multi-leaf collimator which the multi-leaf collimator can define when approaching correspondence with a target shape in a beams eye view of the multi-leaf collimator and an area of the target shape in the same beams eye view of the multi-leaf collimator, a view from the perspective of the opening in the multi-leaf collimator along an axis of the

> radiation beam defining the beams eye view of the multi-leaf collimator.

Ex. 1001, 14:38–48. Petitioner contends this is nothing more than a recitation of Brahme's orientation theory, which is in the prior art. Pet. 64–65 (quoting Ex. 1001, 1:33–46); *see also* Ex. 1002 ¶ 127 (Dr. Solberg's testimony regarding the same). As such, Petitioner cites Webb's teachings of Brahme's orientation theory, which seeks to "minimize the volume (represented by an area 'seen' in the beam's-eye-view) of normal tissue outside the target volume." Pet. 65 (quoting Ex. 1005, 234) (emphasis omitted); *see also* Ex. 1002 ¶ 128 (Dr. Solberg's testimony regarding the same).

Patent Owner relies on the same arguments discussed above with respect to claims 1 and 18. We are persuaded that Webb teaches enhancing conformity using Brahme's theory by minimizing the difference in area between the collimator opening and the target shape in the beam's eye view. *See, e.g.*, Ex. 1002 ¶¶ 127–128; Ex. 1005, 234. Thus, we determine Petitioner has shown by a preponderance of the evidence that the subject matter of claim 19 would have been obvious over the combination of Otto, Chang, Webb, and Mohan.

III. CONCLUSION

Petitioner has shown, by a preponderance of the evidence, that the subject matter of claims 1, 4, and 17–19 would have been obvious over the combination of Otto, Chang, Webb, and Mohan.[15]

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[15] 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*

IV. ORDER

Accordingly, it is

ORDERED that claims 1, 4, and 17–19 of the ’490 patent are unpatentable;

FURTHER ORDERED that Petitioner’s motion to exclude 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.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1, 4, 17–19	103(a)	Otto, Chang, Webb, Mohan	1, 4, 17–19	

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).

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