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Paper 14
Date: April 17, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VARIAN MEDICAL SYSTEMS, INC.,
Petitioner,

v.

BEST MEDICAL INTERNATIONAL, INC.,
Patent Owner.

IPR2020-00053
Patent 7,266,175 B1

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

EASTHOM, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Varian Medical Systems, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet." or "Petition") pursuant to 35 U.S.C. §§ 311–319 to institute an *inter partes* review of claims 13–16, 18, and 19 (the "challenged claims") of U.S. Patent No. 7,266,175 B1 (Ex. 1001, the "'175 patent"). Best Medical Systems, Inc. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

The Board's authority under 35 U.S.C. § 314 to determine whether to institute an *inter partes* review requires a demonstration of "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the parties' contentions and the evidence of record, we determine that Petitioner does not establish a reasonable likelihood of prevailing in demonstrating the unpatentability of any of the challenged claims. Accordingly, we deny Petitioner's request and do not institute an *inter partes* review.

II. BACKGROUND

A. Real Parties in Interest

Petitioner contends "[i]n addition to Petitioner Varian Medical Systems, Inc., VMS International AG and its two Dutch parent companies, VMS International Holdings, Inc., VMS Netherlands Holdings, Inc., and VMS Nederland BV are real parties-in-interest." Pet. 1.

B. Related Matters

Patent Owner identifies the following as related matters involving the '175 patent: *Best Medical International, Inc. v. Accuray, Inc. et al.,* No. 2:10-cv-01043 (W.D. Pa.) (dismissed June 26, 2014); *Best Medical*

International, Inc. v. Elekta Inc. et al., No. 1:18-cv-01600-MN (D. Del.) (Complaint filed October 16, 2018) (transferred to N.D. Ga.); *Best Medical International, Inc. v. Elekta Inc. et al.* No. 1:19-cv-03409-MLB (N.D. Ga.); *Best Medical International, Inc. v. Varian Medical Systems, Inc. et al.*, No. 1:18-cv-01599 (D. Del.) (complaint filed October 16, 2018). Paper 4, 1–2.

Related PTAB *inter partes* proceedings include the following challenges to the ’175 patent: *Varian Medical Systems, Inc. v. Best Medical International, Inc.,* IPR2020-00077, Paper 2 (PTAB Oct. 18, 2019) (petition challenging claims 1, 3–5, 8, 9 13–16, 18, and 19 of the ’175 patent); *Elekta Inc. v. Best Medical International, Inc.,* IPR2020-00073, Paper 2 (PTAB Oct. 18, 2019) (petition challenging claims 1, 8, 10–13, and 17, 19, and 20 of the ’175 patent). *See* Paper 4, 2–3.

C. The ’175 Patent

The ’175 patent, titled “Planning Method for Radiation Therapy,” involves a “[m]ethod and apparatus for controlling the correlation between the factors of treatment plan efficiency and dosimetric fitness” to optimize a radiotherapy plan. Ex. 1001, code (57).

In the “Background of the Invention” section, the ’175 patent states “[t]raditional inverse intensity modulated radiation therapy (‘IMRT’) planning systems attempt to find radiation intensity maps resulting in the best calculated dose distribution for a specific tumor for a specific patient” using, “typically, a conventional linear accelerator provided with a multileaf, or multiple leaf, collimator (‘MLC’).” Ex. 1001, 1:13–20.

The ’175 patent seeks to provide control of a “tradeoff” between “dosimetric cost” (which measures how close a prescribed dose tracks the delivered dose) and efficiency (measured in the number of MUs or segments):

> For many treatment plans, the resultant intensity maps often cannot be efficiently delivered by the radiation therapy treatment equipment . . . . Inefficient intensity maps may require a large number of monitor units ("MU") or a large number of "MLC" segments for delivery. These inefficient treatment plans, or solutions, are undesirable because they might require a large amount of delivery time, radiation beam on time, and/or radiation leakage dose to the patient. It is also undesirable to uniformly preclude the discovery of less efficient treatment plans, which may also be dosimetrically superior plans. Thus, it would be desirable to provide user control of the tradeoff, or correlation, between the factors of treatment plan efficiency and dosimetric fitness to optimize a radiation therapy, or radiotherapy, plan.

Ex. 1001, 1:16–32. The number of "MUs" or "segments" corresponds or relates to the amount of radiation energy output by the treatment machine. *See id.*

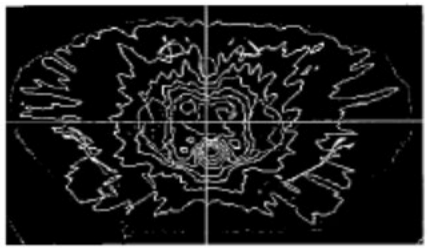
During prosecution of the '175 patent, in response to an office action, the patent applicant filed a declaration by Dr. Mark P. Carol shedding light on the background of the invention *See* Ex. 1007, 15 (citing Carol Declaration ¶¶ 6e1–6e2); Ex. 1009 ("Carol Declaration"). For example, Dr. Carol refers to beam segments as "small portions of a large beam" and relates an increase in monitor units and segments to an increase in inefficiency. *See* Ex. 1009 ¶ 6a1. He also describes a decrease in monitor units or "the use of a smaller number of simpler segments" as "requiring less radiation, and therefore less machine time." *Id.* ¶ 6a4.

Figures 4A–4C of the '175 patent, which follow, illustrate the results of three plan results showing a trade-off between dosimetric cost and monitor units:

(Efficiency becomes more important from top to bottom):

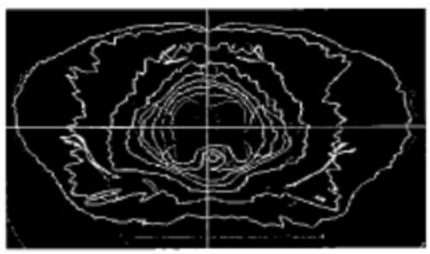
Dosimetric Cost = 0.132
Total Monitor Units = 22365

FIG. 4A.



Dosimetric Cost = 0.149
Total Monitor Units = 15624

FIG. 4B.



Dosimetric Cost = 1.94
Total Monitor Units = 6640

FIG. 4C.

Figures 4A–4C above represent "dose distribution intensity maps for three different radiotherapy plans" with the most efficient plan (lowest number of monitor units) and highest dosimetric cost represented by the radiotherapy plan of Figure 4C. *See* Ex. 1001, 2:3–5.

D. Illustrative Claims

Claims 14–16 and 18 depend from independent claim 13. Independent claims 13 and 19, reproduced below, illustrate the subject matter of the challenged claims:

> 13. A method of providing control of a trade-off between treatment plan delivery efficiency and dosimetric fitness to optimize a radiation treatment plan within a continuum between delivery efficiency and dosimetric fitness, the method comprising the steps of:

> assigning a delivery cost term within an optimizer to each of a plurality of intensity maps representing a potential radiation beam arrangement, the assignment based on complexity of each respective intensity map; and
>
> evaluating an objective cost function for each of the plurality of intensity maps, the objective function including a dosimetric cost term and the delivery cost term, the dosimetric cost term representing dosimetric fitness of the respective intensity map and the delivery cost term representing delivery efficiency.

Ex. 1001, 6:5–19.

> 19. A method of providing control of a trade-off between treatment plan delivery efficiency and dosimetric fitness to optimize a radiation treatment plan within a continuum between delivery efficiency and dosimetric fitness, the method comprising the steps of:
>
> evaluating an objective cost function within an optimizer for each of a plurality of intensity maps, the objective function including a dosimetric cost term and the delivery cost term, the delivery cost term representing total monitor units to deliver radiation according to a beam arrangement represented by the respective intensity map; and
>
> rejecting each intensity map resulting in the delivery cost term exceeding a preselected threshold value.

Id. at 6:48–62.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 13–16, 18, and 19 would have been obvious on the following grounds (Pet. 2–3):

Claims Challenged	35 U.S.C. §	References
13–15	103(a)[1]	Webb 2001,[2] Mohan[3]
16, 18, 19	103(a)	Webb 2001, Mohan, Webb 1993[4]
13–15	103(a)	Webb 2001, Mohan, Siebers[5]
16, 18, 19	103(a)	Webb 2001, Mohan, Webb 1993, Siebers

Petitioner relies on the "Declaration of Timothy D. Solberg, Ph.D." (Ex. 1002). Patent Owner relies on the Declaration of Daniel J. Chase (Ex. 2002).

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[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103 (effective March 16, 2013). However, because the filing date of the application from which the '175 patent issued antedates March 16, 2013, the pre-AIA version of § 103 applies.

[2] Steve Webb, "A Simple Method to Control Aspects of Fluence Modulation in IMRT Planning," PHYS. MED. BIO 46:N187–95 (2001) (Ex. 1003).

[3] Mohan et al., "The Impact of Fluctuations in Intensity Patterns on the Number of Monitor Units and the Quality and Accuracy of Intensity Modulated Radiotherapy," MED. PHYS. V.27, No. 6, 1226–37 (2000) (Ex. 1004).

[4] Steve Webb "The Physics of Three-Dimensional Radiation Therapy: Conformal Radiotherapy, Radiosurgery and Treatment Planning" (1993) (Ex. 1005).

[5] Siebers et al., "Incorporating Multi-leaf Collimator Leaf Sequencing into Iterative IMRT Optimization," MED. PHYS, V.29, No. 6, 952–59 (June 2002) (Ex. 1006).

III. DISCUSSION

A. Principles of Law Relating to Obviousness

The question of obviousness requires resolving 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) any objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, tribunals "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006)).

B. Level of Ordinary Skill

Petitioner contends

> [a] person of ordinary skill as of July 2003 would be a medical physicist with a Ph.D. (or similar advanced degree) in physics, medical physics, or a related field, and two or more years of experience in radiation oncology physics treatment planning, treatment plan optimization related to radiation oncology applications, and computer programming associated with treatment plan optimization (or equivalent degree or experience).

Pet. 3 (citing Ex. 1002 ¶ 13).

Patent Owner asserts that a person with ordinary skill in the art would have had a master's or doctoral degree in radiation dosimetry, physics, medical physics, or medicine, or equivalent disciplines, and three years of clinical experience in radiation treatment planning. *Id.* (citing Ex. 2002 ¶¶ 54, 61–64). Patent Owner also urges a flexible approach that trades some formal education with experience and vice versa. *See id.* at 12–13.

The prior art references and the ’175 patent reflect a highly skilled and technically proficient audience. *See, e.g.*, *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556 (Fed. Cir. 1983) (“Patents . . . are written to enable those skilled in the art to practice the invention.”). Petitioner’s and Patent Owner’s proposals similarly suggest a high level of skill in the intersection between mathematical modeling and radiology, with the prior art of record and the ’175 patent specification supporting each proposal. We adopt Patent Owner’s proposed level of skill.

C. Claim Construction

Under 37 C.F.R. § 42.100(b), claims in an *inter partes* review

> shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b), including construing the 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.

Petitioner construes an “intensity map” as recited in the challenged claims “to mean a ‘**representation of dose distribution**.’” Pet. 16. According to Petitioner, “[a]n ‘**intensity map**’ as used in the ’175 patent represents the resultant *dose distribution* created by *multiple beams* positioned.” *Id.* at 15–16 (citing Ex. 1002 ¶¶ 47–48). Petitioner acknowledges that “[i]n the traditional context, an intensity map is used to describe the properties of a single beam.” Pet. 13. Nevertheless, Petitioner contends the “’175 patent uses ‘**intensity map’** in a different way.” *Id.*

To support its claim construction, Petitioner annotates Figure 1 from a textbook by Dr. Carol's, reproduced below:[6]

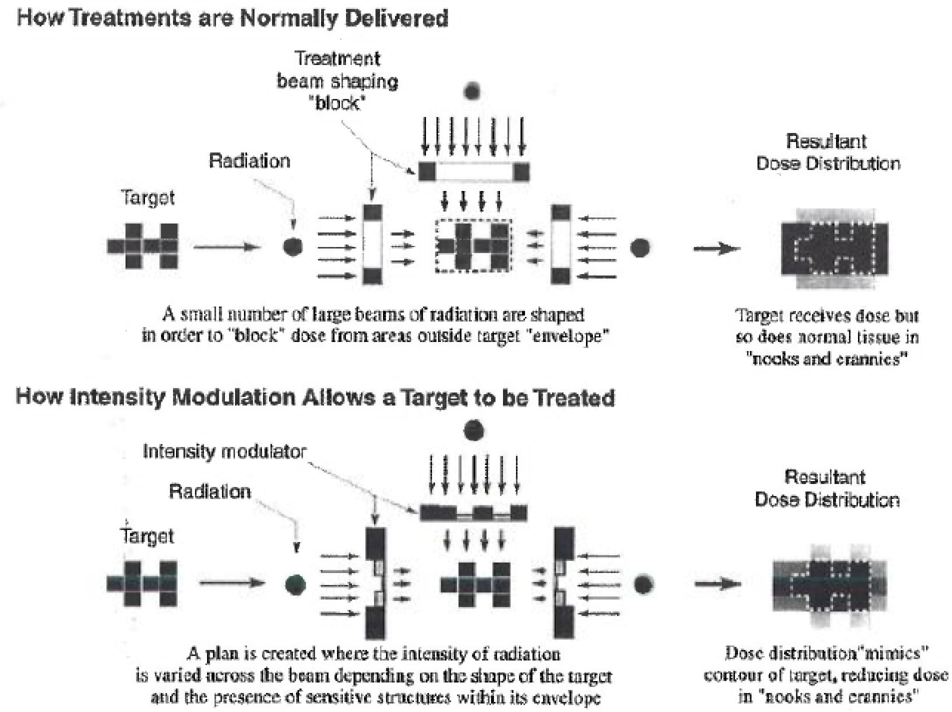

Figure 1. Conventional versus IMRT delivery.

Pet. 4 (citing Ex. 1013, Fig. 1; Ex. 1002 ¶ 27). Figure 1 above reveals a resultant dose distribution on the right-hand side that mimics the contour of the target, with the dose distribution created by three modulated radiation beams. *See* Ex. 1002 ¶¶ 27–29, 44–45 (citing Ex. 1013).

Petitioner does not explain sufficiently how Figure 1 from Dr. Carol's textbook as reproduced above supports a deviation from what Petitioner admits constitutes the customary, or "traditional" meaning of "intensity map" to a person of ordinary skill in the art. Pet. 13; *see also id.* at 16 (discussing the above-reproduced Figure 1). Figure 1 of the textbook

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[6] As indicated above (Section II.C), the patent applicant relied upon the Carol Declaration (i.e., by Dr. Carol) during prosecution of the '175 patent.

portrays a "[r]esultant [d]ose [d]istribution" that results from several radiation beams, and the figure also clearly shows an "intensity modulator" at each beam. Figure 1 also states "the intensity of radiation is varied across the beam depending on the shape of the target." Accordingly, Figure 1 supports the customary meaning of "intensity map" as a map used to modulate a single beam. Moreover, in describing Figure 1 of Dr. Carol's textbook, Dr. Solberg, Petitioner's declarant, quotes a statement in the textbook that also supports this customary meaning: "Unique to IMRT itself is the need to create <u>non-uniform fluence maps ***for each beam***</u> regardless of its location." Ex. 1002 ¶ 44 (quoting Ex. 1013, 19–20).

As discussed above (*supra* Section II.C), the '175 patent describes solving problems associated with inefficient delivery of radiation using traditional intensity maps. *See* Ex. 1001, 1:13–32. Patent Owner contends the claims recite the "common usage of the term 'intensity map'" based on an understanding gleaned through the '175 patent specification. *See* Prelim. Resp. 17. Patent Owner states the term "'intensity map' should be construed as *a representation of the variation of radiation across a defined area*." *Id.* at 14. Patent Owner also argues that per the "common[]" "meaning . . . as [used] in the claims of the '175 [p]atent, the term 'intensity map' refers to the varying fluence levels of radiation administered through a 2D cross-section of a modulated radiation beam." *Id.* at 17 (citing Ex. 2002 ¶ 72).

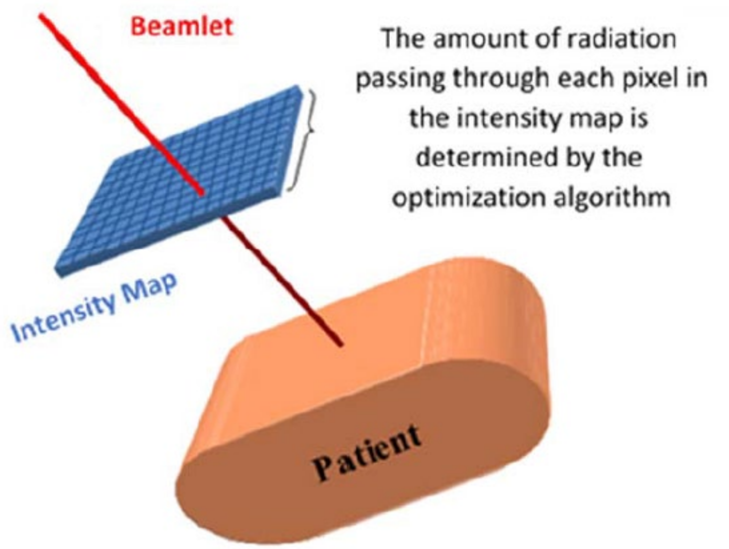
Mr. Chase, Patent Owner's declarant, provides the following background with respect to a traditional intensity map and the claims:

> Claims 13–15, 16, 18, and 19 of the '175 [p]atent are directed to 3D IMRT treatment planning. This can be seen, for example, in the recitations of "intensity maps" in the claims. *See, e.g.,* Ex. 1001, 6:10, 54. Treatment planning for 3D IMRT is

> based on 3D imaging and 3D dose calculation. *See, e.g.,* Ex. 1006, p. 954. The optimization process for IMRT treatment planning subdivides *each radiation treatment beam* into a 2D array of smaller beamlets called an intensity map. *See, e.g.*, Ex. 1006, p. 953. The intensity map is a mathematical tool used to optimize the weights of the individual beamlets during the optimization process. *See, e.g.,* Ex. 2008, p. 1007. The theoretical intensity map is then converted into a series of MLC shapes that can be delivered to the patient. *See* Ex. 1006, p. 954.

Ex. 2002 ¶ 90 (emphasis to text added, emphasis to citations removed). According to Mr. Chase's testimony quoted above, Mr. Chase agrees with Petitioner that a traditional intensity map represents a mathematical tool used to modulate and describe the radiation variation of individual beamlets of a single beam. Dr. Solberg agrees as to this customary meaning. Ex. 1002 ¶ 45 ("The typical use of an 'intensity map' to represent the intensity modulation of a single beam is also reflected in Bortfeld."). In our view, then, the parties agree that an "intensity map" carried a customary meaning to a person of ordinary skill in the art. Accordingly, we construe an "intensity map" in a way commensurate with that customary meaning, as "a representation of the variation across a defined area of radiation of a single beam." This construction takes Patent Owner's proposed construction but clarifies that the intensity map describes a given beam. Pet. 13 ("[i]n the traditional context, an intensity map is used to describe properties of a single beam"); Prelim. Resp. 17 (discussing how an intensity map corresponds to "a 2D cross-section of a modulated radiation beam").

As indicated above, a beam typically includes beamlets. Ex. 2002 ¶ 90 (discussing subdividing a beam into beamlets that, in sum, describe one intensity map); Ex. 1013, 8, Fig. 1; Ex. 1003, 3–4, Fig. 2ai, 2Bi (20 beam elements or bixels per beam). Mr. Chase provides the following heuristic illustration of an intensity map, signifying how the mathematical tool operates to modulate different beamlets of a single beam:



Ex. 2992 ¶ 90. The figure above portrays an idealized representation of an "[i]ntensity [m]ap," which actually consists of mathematical terms used to modulate the intensity of a group of beamlets from a single beam.

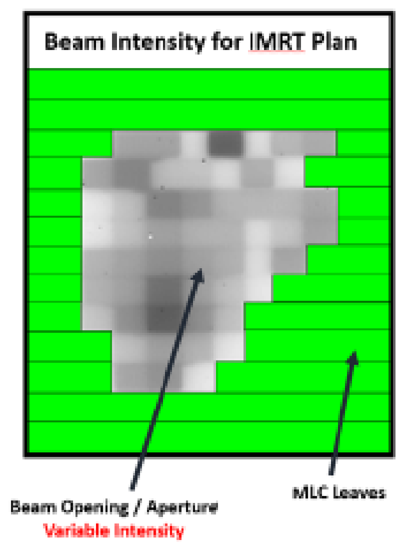
Notwithstanding the fact that an "intensity map" carried a customary meaning," Petitioner argues that the '175 patent dictates a different definition. To support its construction as deviating from the customary meaning identified by the parties, Petitioner points to the use of "dose distribution intensity maps" as described in the '175 patent in connection with Figures 2A–2C, 4A–4C, 7, and 8. Pet. 13–15 (citing Ex. 1001, 1:66–67, 2:3–4, 2:10–11, 2:11–12). Petitioner also points out that dependent claim 16 recites "***the*** respective ***dose*** intensity map," which may refer back to "the respective intensity map" recited in claim 13. *Id.* at 19. Petitioner sets forth other arguments in an attempt to support the argument that the ’175 patent deviates from the normal meaning of an “intensity map” and represents instead “the resultant dose distribution created by multiple beams.” *See id.* at 15, 13–20.

Patent Owner agrees “Figures 4A–4C in the ’175 [p]atent are characterized as ‘dose distribution intensity maps for three different radiotherapy plans.’” Prelim. Resp. 15 (citing Ex. 1001, 2:3–4; Ex. 2002 ¶ 70). But according to Patent Owner, “in reciting the term ‘intensity map’ – and not ‘dose distribution intensity map’ – the claims were referring to the common usage of the term ‘intensity map.’” *Id.* at 17. As Patent Owner argues, none of the claims, including claim 16, recites a “dose distribution intensity map.”

The ’175 patent supports the customary meaning of “intensity map.” For example, it describes a “first method” in which “[a] delivery cost term is assigned to an intensity map based [on] the complexity of the intensity map. Maps with more intensity [ ] generally require more segments to deliver, and thus are assigned a larger delivery cost term.” Ex. 1001, 2:51–55. The method “comprises controlling [s]egment [c]ount by use of a delivery cost term.” *Id.* at 2:50–51. This language does not indicate a deviation from the customary meaning of the term “intensity map.”

The ’175 patent also specifies “wherein a delivery cost term based on the complexity of the intensity maps may be utilized.” Ex. 1001, 1:39–41. Although this language indicates assessing “complexity of the intensity maps” in the plural, it indicates that the ’175 patent distinguishes between plural and single intensity maps. The passages that describe “dose distribution intensity maps” in connection with Figures 2A–2C, 4A–4C, 7, and 8 of the '175 patent, and other descriptions related to evaluating dosimetric fitness, relied upon by Petitioner, do not imply a clear deviation from the customary meaning of that term. *See* Pet. 16; Ex. 1001, 1:66–67, 2:3, 2:10, 2:12.

Patent Owner additionally explains that an intensity map must be "deliverable, typically using an MLC." *See* Prelim. Resp. 16. In this context, Patent Owner describes a "segment" as a "beam shape" via a window or aperture defined by leafs that shape the beam according to an intensity map, and produces the following annotated figure:



Id. at 8–9. Referring to the figure above, Patent Owner asserts "[i]n a leaf sequencing plan such as this, the MLC leaves will be repeatedly adjusted (either continuously or step-wise) throughout treatment to create a series of beam segments that are administered by the radiotherapy instrument, which, when combined, reproduce the shapes and intensities of the optimized intensity maps." *Id.* at 9 (emphases added).

Patent Owner's explanation supports segment counting for each intensity map of an individual beam with respect to typical MLC leaves.

The limited record does not reveal how a dose distribution, as ordinarily employed and as described in the ’175 patent, serves to provide a deliverable series of beam segments akin to what an intensity map provides under its customary meaning. Rather, as Patent Owner argues, a dose distribution typically represents the result of radiation from several beams, including in connection with the “dose distribution intensity map” or “maps” as represented in Figures 2A–2C, 4A–4C, 7, and 8 of the ’175 patent. *See* Ex. 1001, 1:66–67, 2:3, 2:10, 2:12; *see also* Pet. 18 (“dose depends on ‘[t]he cumulative effect of multiple beams passing through the treatment field’” (quoting Ex. 1010, 5:28–38)).

Nevertheless, as Petitioner argues, “a claim term may be clearly redefined without an explicit statement of redefinition and even when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents.” Pet. 16 (quoting *Trustees of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1364 (Fed. Cir. 2016) (brackets, quotation marks, and citation omitted by Petitioner).

On this record, however, Petitioner does not explain sufficiently how the ’175 patent re-defines an “intensity map” as a “representation of dose distribution” resulting from more than one beam “by implication such that the meaning may be found in or ascertained by a reading of the patent documents.” *See Symantec Corp.*, 811 F.3d at 1364. In contrast, in *Symantic Corp.*, the court found that the patent specification and its provisional application “defin[ed]” the disputed term in several places. *See id.* at 1365 (“These are not simply descriptions of the preferred embodiment but are statements defining ‘byte sequence feature.’ Further, the provisional application similarly defined byte sequence feature, stating that '[t]he byte sequence feature is the most informative because it represents the *machine code in an executable instead of resource information*' which is not made of machine code instructions.") (emphasis by the court).

Here, Petitioner does not point to similarly defining statements from the '175 patent specification. As this limited record shows and as Patent Owner argues, "[d]ose distribution is entirely different from an intensity map. . . . Indeed, intensity maps are the basis from which a dose distribution is created." Prelim. Resp. 17 (citing Ex. 2002 ¶ 69; Ex. 1001, 1:13–16).

Petitioner also asserts that other language in the claims support its claim construction. *See* Pet. 17. As an example, Petitioner asserts the following:

> [I]ndependent claim 13 recites "evaluating an objective cost function for each of the plurality of intensity maps, the objective function including a dosimetric cost term . . . the dosimetric cost term representing dosimetric fitness of the respective intensity map." *This limitation would be rendered nonsensical* if the "respective intensity map," as claimed, represents a single beam rather than the entirety of a multi-beam arrangement. . . . This is because the recited "dosimetric fitness" and "dosimetric cost" refer, respectively, to the fitness and quantified cost of a dose distribution, as the '175 specification itself makes clear.

Id. (citing Ex. 1002 ¶50) (omitted footnote reciting limitations in claim 1 and claim 19) (emphasis added).

As Petitioner argues, the '175 patent refers to dosimetric fitness and cost and thereby implies it includes evaluating radiation from more than one beam. *See* Pet. 17. However, the plain language of claim 13 specifies "evaluating an objective cost function for each of the plurality of intensity maps." The '175 patent describes evaluating delivery cost on a per beam basis at least with respect to segment count, as indicated above. *See* Ex. 1001, 2:51–55 ("A delivery cost term is assigned to an intensity map based upon the complexity of the intensity map."). This tracks the customary meaning with respect to counting deliverable segments of a single beam, as Patent Owner argues and as discussed above. *See* Prelim. Resp. 5, 8–9, 17. The '175 patent also generally describes a relationship between the conformality of a dose distribution and the segment count, which suggests at least some connection between delivery cost and a singular intensity map: "As the [s]egment [c]ount is decreased, the dose distribution becomes less conformal as the [d]osimetric [c]ost increases." *See* Ex. 1001, 3:34–36.

As Petitioner also notes, claim 1 recites "evaluating a cost function for each of a set of a plurality of candidate intensity maps . . . the cost function including a dosimetric cost term representing dosimetric cost and related to dosimetric fitness of the respective candidate intensity map." *See* Pet. 17 n.4. And independent claim 19 recites "evaluating an objective cost function . . . for each of a plurality of intensity maps, the objective function including a dosimetric cost term." *See id.* However, claims 1 and 19 respectively refer to evaluating "a set of a plurality of candidate intensity maps" and "each of a plurality of candidate intensity maps." Contrary to Petitioner's arguments, these claims do not require by implication or otherwise evaluating an intensity map that modulates the radiation of more than one beam.

Petitioner also contends "an interpretation that limits 'intensity map' to a representation of a single beam would render the claims nonsensical and therefore indefinite." Pet. 19. In addition, Petitioner contends "the patent neither describes nor enables the use of a 'dosimetric cost term representing dosimetric fitness,' as claimed, of a single-beam representation." *Id.* (citing *Trs. of Boston Univ. v. Everlight Elecs. Co.*, 896 F.3d 1357, 1362–65 (Fed. Cir. 2018)).

In the *Everlight* case relied upon by Petitioner, the court noted that the patent owner there "needed to successfully defend against an enablement challenge as to the claim's full scope," after "[h]aving obtained a [sought-after] claim construction." *Everlight*, 896 F.3d at 1365. Here, however, the Board does not resolve issues of definiteness, written description, and enablement in determining whether to institute an *inter partes* review.

In any event, claim 13 recites "the dosimetric cost term representing dosimetric fitness of the respective intensity map." For the reasons given above and on this limited record, the '175 patent supports the construction of an "intensity map" according to its customary meaning, even if the specification does not provide explicit details as to how "the dosimetric cost term represent[s] dosimetric fitness" on a per intensity map basis. *See Everlight*, 896 F.3d at 1365 ("This is not to say that the specification must expressly spell out every possible iteration of every claim [for enablement purposes]. For instance, 'a specification need not disclose what is well known in the art.'" (quoting *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339 (Fed. Cir. 2003)).

Accordingly, based on the foregoing discussion, we construe an "intensity map," according to its customary meaning in light of the '175 patent specification, as "a representation of the variation across a defined area of radiation of a single beam."

We need not resolve the construction of other terms. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed.

Cir. 2017) (noting that "we need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'") (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

D. Obviousness

Petitioner asserts that the combined teachings of Webb 2001 and Mohan would have rendered claims 13–15 obvious. Pet. 19–65. Petitioner also asserts that the combined teachings of Webb 2001, Mohan, and Webb 1993 would have rendered claims 16, 18, and 19 obvious. *Id.* at 61–69. Finally, Petitioner asserts that the combined teachings of those references with Siebers would have rendered claims 13–16, 18, and 19 obvious. *Id.* at 70–81. Patent Owner disagrees. *See generally* Prelim. Resp.

1. Overview of Webb 2001

Webb 2001 discloses a method for delivering intensity-modulated radiation beams (IMRT) to a patient seeking treatment for targeted radiation, using multiple beams or beam positions of a rotating gantry machine. *See* Ex. 1003, 2–3.[7] The system modulates the beams using multileaf collimators to create a set of beam profiles using leaf patterns, where each beam may comprise beamlets or bixels (smaller beam segments or elements of a beam). *See id.* at 2–4. "Modulated beams created by inverse-planning systems are 'interpreted' into MLC [(multileaf collimator)] leaf patterns which, when delivered, create a close approximation to the computed dose

[7] We cite the page numbers added by Petitioner to the Exhibits (with the exception of citing declaration paragraph (¶) numbers).

distribution." *Id.* at 3.

Webb 2001 describes "an iterative method which predetermines the number of coplanar gantry angles and creates the modulated 1D profiles which, when combined, lead to a conformal 2D dose distribution." *Id.* at 3. A gantry moves a beam around to encompass different angles surrounding a patient who receives radiation at each angle. *See id.*at Figs. 2ai, 2bi (illustrating the intensity of 9 intensity modulated beams (IMBs) in monitor units (MUs) and each of their 20 beamlets/bixels).

According to Webb 2001's method:

> At each iterative cycle, grains of beamweight are offered to one of the fields, randomly selected from the set, and to one randomly chosen beam element (bixel). The cost of the change in dose-space is computed and, if lower than the previous estimate, the grain is accepted. After a predetermined number of iterations (48,000), chosen so each bixel site is visited many times (at least 250), the outcome is a set of beam profiles and the corresponding dose distributions together with statistics characterizing the distribution including the appropriate dose-volume histograms. All this is fairly standard and includes a median-window filter (MWF) applied every 500 iterations to eliminate unwanted noise in the beam-space profiles (Webb et al 1998).

Id. at 3.

Webb 2001 initially describes a previous work that involves minimizing a "cost" in dose density according to Equation (1) below:

$$\chi = \sum_i \sum_j I_w(i, j)\,(D(i, j) - D^p(i, j))^2 \quad (1)$$

"where $I_w(i, j)$ is the importance factor attached to the (i, j)th dose element (i and j are labels on an x − y grid), $D(i, j)$ is the dose from the grains so far placed and $D^p(i, j)$ is the prescribed dose distribution." *Id.* at 2–4.

Webb 2001 then adds "beam space" modifier $w_3[w_1 S_+ - w_2 F_{min}]$ to Equation (1), creating Equation (2):

$$\chi = \sum_i \sum_j I_w(i,j)\,(D\,(i,j\,) - D^p(i,j))^2 \; + w_3[w_1 S_+ - w_2 F_{min}] \quad (2)$$

where "[t]he three weights w_1, w_2, w_3 control the relative contributions to the overall cost which is to be minimized." *Id.* at 4–5.

The term S_+ in Equation (2) represents a summation of "positive-going fluence changes" over N_B (e.g., 9) IMBs (intensity modulated beams), each with 20 beamlets or bixels, as follows:

$$S_+ = \sum_{n=1}^{N_B} \sum_{m=1}^{20} (\Delta_+ I)_{m,n}$$

Stated differently, the term S_+ above represents "the sum . . . of the positive-going fluence changes where N_B is the number of IMBs, each with 20 elements, and $(\Delta_+ I)_{m,n}$ is the change in fluence at the mth bixel of the nth beam if positive." *Id.* at 4. "S_+ has dimensions of fluence which scales to monitor units." *Id.* at 5. The number of monitor units represents the amount of radiation supplied. *See id.* at 3 ("[T]he efficiency of the DMLC technique is generally quite low, i.e. the number of monitor units required to deliver each field is generally much higher than the peak value in the field."). Webb 2001 relates treatment time in a radiation therapy plan to the sum S_+: "[T]he treatment time is directly given by the sum of the positive-going fluence changes added to the fixed time for a leaf[-]pair to sweep the field at maximum speed." *Id.* at 4.

The term F_{min} in Equation (2) also represents a summation, as follows:

$$F_{min} = \sum_{n=1}^{N_B} [\max(d_{min})]_n$$

F_{min} above represents a maximum of the sum over all N_B beams of the values of the minimum field size d_{min} of a window using the leaf-sweep method. *Id.* at 4. Webb 2001's method notes that at each iteration, an IMB "can be created in a very large number of ways," so it picks the maximum value of the minimum field size d_{min} of a window and sums those over all beams during each iteration. *See id.* Webb 2001 maximizes window/field size because small windows "lead[] to two problems: the delivery error from a known fixed leaf-position error is larger for smaller fields and the inclusion of smaller fields requires a detailed knowledge of output factors and careful dosimetry." *Id.* at 3.

Webb 2001 describes the tradeoff between dose-space and beam-space, and the goal to minimize the overall cost as follows:

> The three weights w_1, w_2, w_3 control the relative contributions to the overall cost which is to be minimized. So, for example, if w_3 is set to zero the iterations ignore beam-space constraints and proceed to minimize only the cost in dose-space as in [E]quation (1). For non-zero w_3 there is a contribution from the cost of beam-space. The larger the value of w_3 the more the iteration is weighted towards the demands in beam-space. It will be shown that as w_3 increases the IMBs become smoother and the maximum value of the minimum field size increases as desired. However, some conformality in dose-space is inevitably lost. The relative weights of w_1 and w_2 control whether beam smoothing or maximization of minimum fieldsize is the priority.

Ex. 1003, 5.

2. Overview of Mohan

Mohan provides background teachings related to IMRT and MLC systems. Ex. 1004, 1. Mohan teaches that complex intensity patterns (i.e., with more varying frequency and amplitude fluctuations in an intensity pattern as complexity arises) tend to involve smaller window widths. *Id.* Mohan also teaches "the number of MUs required to deliver the same maximum intensity increases as the amplitude (depth of valleys) and the frequency (number of valleys) of fluctuations increases." *Id.* at 6.

3. Independent Claims 13–15

Petitioner asserts that the teachings of Webb 2001 and Mohan would have rendered claims 13–15 obvious. Pet. 23–60, 70–81. Petitioner relies on Webb 2001 to disclose most of the limitations of claims 13–15, and relies on Mohan to supplement principles related to beam cost in Webb 2001's optimization algorithm. *See id.* at 19–57.

Claim 13 recites "assigning a delivery cost term within an optimizer to each of a plurality of intensity maps representing a potential radiation beam arrangement, the assignment based on complexity of each respective intensity map." Petitioner contends

> Webb 2001 teaches "assigning a delivery cost term within an optimizer to each of a plurality of intensity maps representing a potential radiation beam arrangement," and Mohan is cited for its explanation of the underlying physical principles that demonstrate how the "delivery cost term" in Webb 2001 in fact operates "based on the complexity" of each "intensity map."

Pet. 28 (emphasis omitted).

In order to read the claims onto Webb 2001 as supplemented by Mohan, Petitioner relies on the claim construction of an intensity map as "a representation of dose distribution." *See* Pet. 30–31. As indicated above, we do not adopt Petitioner's claim construction and instead adopt the customary meaning of an "intensity map," which does not include Petitioner's construction. *Supra* Section III.C (construing an "intensity map" as "a representation of the variation across a defined area of radiation of a single beam").

According to Petitioner, Webb 2001 "evaluates multiple . . . 'intensity maps,' one at each iteration, as it progresses through the optimization algorithm." Pet. 30–31 (citing Ex. 1003, 3). Petitioner explains "[a] new dose distribution is computed based on the new set of fields (or 'beam profiles')" and "[t]he cost of the new dose distribution is computed using a cost function." *Id.* at 31 (citing Ex. 1002 ¶94).

Petitioner produces an annotated version of Webb's Equation (2), which follows:

$$\chi = \left\{ \sum_i \sum_j I_w(i, j)(D(i, j) - D^P(i, j))^2 \right\} + w_3[w_1 S_+ - w_2 F_{\min}].$$

"intensity map" "delivery cost term"

Pet. 37 (annotating Ex. 1003, 4 (Equation (2)). As annotated above in Equation (2), Petitioner reads the claimed "intensity map" onto Webb 2001's dose distribution term $D(i, j)$. Further referencing Equation (2) above, Petitioner reads the claimed dosimetric fitness on the expression on the left-hand side in large brackets, "because it quantifies how closely dose distribution $\boldsymbol{D(i, j)}$ approximates the prescribed dose distribution $\boldsymbol{D^P(i, j)}$ (as weighted by importance factors $\boldsymbol{I_w(i, j)}$)." *Id.* at 57 (citing Ex. 1003, 3–4; Ex. 1002 ¶142). As the annotated version of Equation (2) also indicates, Petitioner reads the "delivery cost term" on the terms in the blue box of the annotated version of Equation (2). *See id.*

Claim 13 also recites "evaluating an objective cost function for each of the plurality of intensity maps, the objective function including a dosimetric cost term and the delivery cost term, the dosimetric cost term representing dosimetric fitness of the respective intensity map and the delivery cost term representing delivery efficiency." Petitioner refers to its showing summarized above and relies again on the annotated version of Webb 2001's Equation (2) as reproduced above. *See* Pet. 56–57.

In response, Patent Owner argues "Webb 2001 does not teach assigning an objective cost function to each of a plurality of intensity maps, being limited to evaluation of dosimetric fitness of 1D intensity profiles." Prelim. Resp. 33 (citing Ex. 1003; Ex. 1002 ¶ 128). Patent Owner also argues "the delivery terms are not applied to each individual beam" and "[t]he delivery term is summed together over all beams (N_B)." *Id.*

We agree with Patent Owner. As discussed above, Petitioner relies on each iteration of dose distribution term $D(i, j)$ as an intensity map. Under our claim construction of a intensity map according to its customary meaning, Petitioner does not show sufficiently how $D(i, j)$ represents an intensity map that corresponds to the radiation of a single beam. *See supra* Section III.C.

Claims 14 and 15 depend from claim 13. Upon a review of the evidence and arguments of record, for the aforesaid reasons, we determine that Petitioner does not establish a reasonable likelihood of prevailing with respect to its obviousness challenges to claims 13–15 based on the collective teachings of Webb 2001 and Mohan.

4. *Independent Claims 16, 18, and 19*

Petitioner contends that the combined teachings of Webb 2001, Mohan, and Webb 1993 render obvious claims 16, 18, and 19. Pet. 61–69.

Claims 16, 18, and 19 depend from claim 13. Petitioner relies on its showing with respect to Webb 2001 as teaching the claimed intensity map. *See id.* Accordingly, based on the foregoing discussion, we determine that Petitioner does not establish a reasonable likelihood of prevailing with respect to its obviousness challenges to claims 16, 18, and 19 based on the collective teachings of Webb 2001, Mohan, and Webb 1993.

5. *Claims 13–15, Webb 2001, Mohan, and Siebers; Claims 16, 18, and 19, Webb 2001, Mohan, Webb 1993, and Siebers*

Petitioner adds Siebers to the prior art addressed in the challenges discussed above. Pet. 70–81. Petitioner adds Siebers for the purpose of supplementing Webb 2001 to the extent the challenged claims or Petitioner's showing require a teaching related to three-dimensional treatment planning. *See, e.g., id.* at 74–75. Petitioner also relies on Siebers to teach "a method to incorporate constraints imposed by delivery systems used for intensity modulated radiation therapy (IMRT) into the IMRT treatment plan optimization process." *Id.* at 74. Petitioner contends it would have been obvious to modify Webb 2001's teachings based on the teachings of Siebers. *See id.* at 74–81.

Patent Owner relies, *inter alia*, on its claim construction arguments addressed above in connection with the claimed intensity map. *See* Prelim. Resp. 22 ("Webb 2001 lacks intensity maps."). Based on the foregoing discussion, Petitioner does not establish a reasonable likelihood of prevailing in showing that the teachings of Webb 2001, Mohan, and Siebers render obvious claims 13–15, and the teachings of Webb 2001, Mohan, Webb 1993, and Siebers render obvious claims 16, 18, and 19.

IV. CONCLUSION

For the reasons discussed above, we determine that Petitioner failed to demonstrate a reasonable likelihood of prevailing in establishing the unpatentability of the challenged claims of the '175 patent.

V. ORDER

In consideration of the foregoing, we hereby *deny* the Petition.

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