IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BEST MEDICAL INTERNATIONAL, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. 18-1599 (MN)
VARIAN MEDICAL SYSTEMS, INC. and VARIAN MEDICAL SYSTEMS INTERNATIONAL AG,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 21st day of July 2020:

IT IS HEREBY ORDERED that the claim terms of U.S. Patent Nos. 6,038,283 ("the '283 Patent") and 6,393,096 ("the '096 Patent") with agreed-upon constructions are construed as follows (*see* D.I. 120, Exhibit A at A-1):

1. "approach correspondence of" means "improve agreement of" ('283 Patent, cl. 6-7; '096 Patent, cl. 18);

2. "correspondence to" means "agreement with" ('283 Patent, cl. 46);

3. "conform to" means "improve agreement with" ('096 Patent, cl. 31, 33);

4. "cost zone" means "region relative to a CDVH curve" ('096 Patent, cl. 21, 23); and

5. "zone" means "region relative to a CDVH curve" ('283 Patent, cl. 7, 12; '096 Patent, cl. 21, 23).

Further, as announced at the hearing on June 26, 2020, IT IS HEREBY ORDERED that the disputed claim terms of the '283 Patent, the '096 Patent, and U.S. Patent Nos. 7,266,175 ("the '175 Patent") and 7,015,490 ("the '490 Patent") are construed as follows:

1. "computer . . . to computationally":

    (A) "obtain a proposed beam arrangement" ('283 Patent, cl. 6-7, 12, 24-25, 27-28; '096 Patent, cl. 18, 31, 33),
    (B) "obtain a set of proposed beam weights" ('283 Patent, cl. 46),
    (C) "change the proposed radiation beam arrangement iteratively" ('283 Patent, cl. 6-7, 12, 24-25, 27-28; '096 Patent, cl. 18, 31, 33),
    (D) "change the set of proposed beam weights iteratively" ('283 Patent, cl. 46), and
    (E) "calculate [an/the] optimized radiation beam arrangement" ('283 Patent, cl. 42, 46; '096 Patent, cl. 44, 46),

    has its plain and ordinary meaning in each instance;

2. "objective cost function" means "mathematical function that determines a cost value based upon objective factors" ('175 Patent, cl. 13, 15, 19);

3. "optimizer" means "program or device that iteratively attempts to find a preferred solution" ('175 Patent, cl. 13, 15, 19);

4. "intensity map[s]" means "a representation of the variation across a defined area of radiation of a single beam" ('175 Patent, cl. 13, 15, 19);

5. "determine [a/the] collimator angle of [a/the] multi-leaf collimator" means "select [a/the] rotation angle of [a/the] multi-leaf collimator" ('490 Patent, cl. 4, 17-18).[1]

The parties briefed the issues (*see* D.I. 85), submitted an appendix containing both intrinsic and extrinsic evidence, including expert declarations[2] (D.I. 86, 87, 88), and a supplemental

[1] During the hearing, the parties reached agreement as to the construction of this term. In coming to that agreement, both sides agreed that a gantry angle is different from a collimator angle and that changing the gantry angle is not the same as changing the collimator angle. *See infra*.

[2] Defendants Varian Medical Systems, Inc. and Varian Medical Systems International AG (collectively, "Defendants" or "Varian") submitted declarations from Timothy D. Solberg, Ph.D., a Professor of Radiation Oncology and Vice Chair of the Division of Medical Physics at the University of California, San Francisco, and Kenneth P. Gall, Ph.D., an independent consultant in the field of medical devices, specifically radiation therapy, with their answering brief. (*See* D.I. 88, Ex. 29-30). Plaintiff Best Medical International, Inc. ("Plaintiff" or "Best") submitted the declaration of Chester R. Ramsey, Ph.D., Director of Medical Physics for the Thompson Cancer Survival Center, with its reply. (*See id.*, Ex.

appendix (D.I. 121). Each side also provided a tutorial describing the relevant technology. (*See* D.I. 115 & 116). The Court carefully reviewed all submissions in connection with the parties' contentions regarding the disputed claim terms, heard oral argument (*see* D.I. 132), and applied the following legal standards in reaching its decision.

I. LEGAL STANDARD

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). "[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Id.* at 1314. "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted).

The patent specification "is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at

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44-46). Additional declarations were also included in the IPR filings submitted. (*See, e.g., id.*, Ex. 21).

1316. "Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [(Patent and Trademark Office)] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, courts "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports

and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

II. THE COURT'S RULING

The Court's rulings regarding the disputed claim terms of the '283, '096, '175, and '490 Patents were announced from the bench at the conclusion of the hearing as follows:

> . . . Thanks, everyone. Thank you for getting back on the line promptly and thank you for the arguments that you made today.
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> At issue in this case, we have four patents[3] and, after the argument, we have four terms in dispute. I am prepared to rule on each of those disputes today. I will not be issuing a written opinion, but I will issue an order stating my rulings. I want to emphasize before I announce my decisions that, although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the '283, '096, '490 and '175 Patents, and the portions of the prosecution history and the IPR, as well as the other materials, in the joint appendices, including expert declarations. Both sides submitted tutorials about the technology at issue. There was full briefing on the disputed issues and there has been argument here today. All of that has been carefully considered.
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> Now, as to my rulings. I am not going to read into the record my understanding of claim construction law. I have a legal standard section that I have used earlier, including in my relatively recent order in *Quest Diagnostics Investments LLC v. Laboratory Corporation of America Holdings*, C.A. No. 18-1436(MN). I incorporate that law and adopt it into my ruling today and I will also set it out in the order that I issue.

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3 U.S. Patent Nos. 6,038,283, 6,393,096, 7,266,175, and 7,015,490.

As to the person of ordinary skill in the art, there are slight differences in the proposals[4] but there has not been any argument that proposed differences in who that person may be are relevant to claim construction.

The first disputed term is "computer . . . to computationally" obtain, change, or calculate specified aspects of the radiation beam arrangement or weights found in various claims of the '283 and '096 Patents.[5] Plaintiff proposes that the term "computer" should have its plain and ordinary meaning or, if a construction is required, that it means "a programmable electronic device that can store, retrieve, and process data." Defendants assert that the word "computer" should be construed pursuant to 35 U.S.C. § 112, ¶ 6 and then propose structures and functions for each of the variations of the term.

Here, I agree with Plaintiff and conclude that the "computer" terms are not subject to § 112, ¶ 6. First, I note that there is a rebuttable presumption that § 112, ¶ 6 does not apply in situations where, as here, the word "means" is absent from the claim term at issue. [*See Diebold Nixdorf, Inc. v. ITC*, 899 F.3d 1291, 1297-98 (Fed. Cir. 2018) (citations omitted)]. That presumption may be overcome if Defendants "demonstrate[] that the claim term fails to recite sufficiently definite structure" or if they demonstrate that the claim "recites function without sufficient structure for performing that function." [*Id.*] Defendants have failed to make that showing.

The inquiry here is whether the "computer" recited in the claims of the '283 and '096 Patents connotes sufficiently definite structure to a person of ordinary skill in the art. [*See TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, 920 F.3d 777, 785 (Fed. Cir. 2019) (citing *Diebold*, 899 F.3d at 1297); *see also Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1007 (Fed. Cir. 2018) ("When evaluating

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4 The parties define the person of ordinary skill for each patent via their experts. (*See* D.I. 88, Ex. 29 ¶¶ 16, 18 (Defendants' proposal for '175 and '490 Patents); *id.*, Ex. 30 ¶¶ 18-19 (Defendants' proposal for '283 and '096 Patents); *id.*, Ex. 46 ¶¶ 63-69 (Plaintiff's proposal for all four patents)).

5 Specifically, "computer . . . to computationally": (A) "obtain a proposed beam arrangement" ('283 Patent, cl. 6-7, 12, 24-25, 27-28; '096 Patent, cl. 18, 31, 33); (B) "obtain a set of proposed beam weights" ('283 Patent, cl. 46); (C) "change the proposed radiation beam arrangement iteratively" ('283 Patent, cl. 6-7, 12, 24-25, 27-28; '096 Patent, cl. 18, 31, 33); (D) "change the set of proposed beam weights iteratively" ('283 Patent, cl. 46); and (E) "calculate [and/the] optimized radiation beam arrangement" ('283 Patent, cl. 42, 46; '096 Patent, cl. 44, 46).

whether a claim limitation invokes § 112, ¶ 6, the essential inquiry remains 'whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure.'" (internal citations omitted)).] "That determination must be made under the traditional claim construction principles, on an element-by-element basis, and in light of evidence intrinsic and extrinsic to the asserted patents." [*Zeroclick*, 891 F.3d at 1007 (citations omitted); *see also Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1351 (Fed. Circ. 2015) ("At bottom, we find nothing in the specification or prosecution history that might lead us to construe that expression as the name of a sufficiently definite structure as to take the overall claim limitation out of the ambit of § 112, para. 6.").]

Here, the term "computer" as used in the claims is sometimes followed by functional language and sometimes not. There is no argument that the computer is a different computer at different points. And there has been no Federal Circuit case law cited to support the argument that the references to "computer" when it is not followed by functional language are subject to § 112, ¶ 6 or that such a "computer" is transformed into one subject to § 112, ¶ 6 when the computer is later given a function.

In addition, I find that there is sufficiently definite structure for the claims to avoid being subject to § 112, ¶ 6. In the claims themselves, there are references to "partial volume data . . . entered directly into the computer," [('283 Patent, cl. 23; '096 Patent, cl. 30),] data "graphically entered into the computer using a pointing device," [('283 Patent, cl. 24; '096 Patent, cl. 29),] "entering the desired partial volume data into a computer," [('283 Patent, cl. 33, 40; '096 Patent, cl. 37, 43),] and "a conformal radiation therapy apparatus in communication with the computer," [('283 Patent, cl. 27; '096 Patent, cl. 33)].

These references suggest components connected to or communicating with the computer, and evidence the structural nature of the computer. [*See Samsung Elecs. Am., Inc. v. Prisua Eng'g Corp.*, 948 F.3d 1342, 1353-54 (Fed. Cir. 2020).]

The specification also provides examples of physical structures for the claimed computer. For example, the '096 Patent refers to a "conventional computer or set of computers," [('096 Patent col. 5 l. 67 – col. 6 l. 1),] and also states that a "suitable computer is utilized" and gives as an example a "programmable 150 Mhz pentium computer with four symmetric multiprocessors,

running the Sun Solaris Operating System, and having 256 megabytes RAM," [(*id.* col. 8 ll. 52-59)].

And, finally, although not dispositive, I note that in its decision to institute review of the '096 Patent, the PTAB did not apply § 112, ¶ 6 to the term "computer" in the claims addressed, agreeing that "an ordinarily skilled artisan would have readily understood what a computer is."[6]

Thus, I will construe the "computer . . . to computationally" obtain, change, or calculate specified aspects of the radiation beam terms in the claims of the '283 and '096 Patents to have its plain and ordinary meaning.

The second disputed term is "objective cost function" in claims 13, 15, and 19 of the '175 Patent. Plaintiff asserts that the term has its plain and ordinary meaning, which is "mathematical function that determines a value based upon factors." Defendants propose that it means "mathematical function that determines a numerical value based on factors used to iteratively optimize a beam arrangement."

The crux of the dispute is whether the value determined must be "numerical" and whether the mathematical function in question must be based on factors used to iteratively optimize a beam arrangement.

Here, I will construe the term to mean a "mathematical function that determines a cost value based upon objective factors."

This is consistent with the ordinary meaning of the words themselves as understood by persons of skill in the art as we have seen in the declarations submitted.

This construction is also supported by the intrinsic evidence. The claims of the '175 Patent, including asserted claim 19, use the

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6 Similarly, the Federal Circuit has determined that a "computing unit" is not subject to § 112, ¶ 6 because it referred to a "commercially available personal computer or workstation." *Inventio v. ThyssenKrupp Elevator*, 649 F.3d 1350, 1359-60 (Fed. Cir. 2011), *overruled on other grounds by Williamson*, 792 F.3d 1339). It has furthered determined that a "digital processing unit" is not subject to §112, ¶6, because the term "clearly serves as a stand-in for a 'general purpose computer' or a 'central processing unit,' each of which would be understood as a reference to structure in this case, not simply a device that can perform a particular function." *Samsung*, 948 F.3d at 1353-55 (citing *Inventio*, 649 F.3d at 1359).

word "value" and correlate that "value" with cost. Additionally, the '096 Patent, which is incorporated into the '175 Patent by reference, states that "[e]xisting methods and apparatus utilize a computational method of establishing optimized treatment plans based on an objective cost function that attributes costs of radiation of various portions of both the tumor and surrounding tissues, or structures." ['096 Patent col. 3 ll. 17-21.]

I will not include in the construction the additional language proposed by Defendants. With the addition of that language, it appears that Defendants go beyond what the claimed objective cost function is to describe what the cost function is used for and how it is used.

Defendants assert that Plaintiff's construction is so broad as to describe any mathematical equation. As used in the claims, however, the objective cost function is not so unlimited. For example, the asserted claims require that the objective cost function include a "dosimetric cost term and the delivery cost term." All of the parties agree to that.

Defendants rely on Plaintiff's statements opposing institution of IPR. The statements that Defendants point to, however, generally discuss the claims and the patent. The statements do not clearly define what a cost function is. And indeed, in connection with the petition for IPR, the cost function term was never defined.

Defendants also rely on a declaration from the inventor Carol during prosecution of the '175 Patent. I do not view those statements as clearly defining a cost function to iteratively optimize a beam arrangement. The statements do not say that the cost function itself is iterative; rather, they focus on the process.

Finally, Defendants' citations to the specification are generally citations to embodiments of the invention rather than a definition of the invention. The Federal Circuit has cautioned against reading embodiments in the specification into the claims. [*E.g.*, *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002); *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).] I will heed that caution.

The third disputed term is "optimizer" also in claims 13, 15, and 19 of the '175 Patent. Plaintiff proposes that the word should be given its plain and ordinary meaning or, if a construction is required, that it means "program or device that attempts to find a

preferred solution." Defendants propose the construction "iterative optimization algorithm."

Here, I will construe "optimizer" to mean a "program or device that iteratively attempts to find a preferred solution."

This, again, is supported by the intrinsic evidence, which only ever addresses optimization as being iterative.[7] For example, at column 9, beginning at line 29, the '283 Patent, which is incorporated by reference into the '175 Patent, states: "The optimizer of the present invention computes an optimized treatment plan, or beam arrangement . . . . The optimal beam arrangement is arrived at by computationally increasing the proposed beam weight iteratively . . . ."

Similarly, during prosecution of the '175 Patent, the patentee described the delivery cost term as being "used by the optimizer to evaluate each potential intensity pattern to thereby determine the optima (best value) of the objective function to determine a beam arrangement . . . to be presented to the clinician during the iterative optimization process." ['175 Patent File History, Aug. 7, 2006 Amendment and Response to May 3, 2006 Office Action at 12 (D.I. 87, Ex. 12 at JA00154); *see also id.*, Jan. 30, 2007 Amendment and Response to Oct. 25, 2006 Office Action at 9 (D.I. 87, Ex. 13 at JA00172).]

The patentee also referred to the "optimizer" as "the optimization loop" that "optimize[s] a radiation treatment plan," further confirming the iterative operation of the optimizer. [*Id.*, Aug. 7, 2006 Amendment and Response to May 3, 2006 Office Action at 14 (D.I. 87, Ex. 12 at JA00156); *see also id.* at 16 (JA00158) (The "optimization loop or optimization process [is] performed by the optimizer."); *id.*, Jan. 30, 2007 Amendment and Response to Oct. 25, 2006 Office Action at 11 (D.I. 87, Ex. 13 at JA00174-75 (same); *id.*, Jan. 24, 2007 Declaration of Mark P. Carol at 8 (D.I. 87, Ex. 20 at JA00539-40) ("[A]n optimizer needs to computer a cost after each iteration . . . .").] And the patentee amended the claims to include the term "optimizer" in order to distinguish the prior art during prosecution, and successfully argued that the '175 invention pertains to "improvements within the optimization loop . . . performed by the optimizer" and not "mechanical improvements." [*Id.*, Aug. 7, 2006 Amendment and

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7 The Court is not convinced that this dispute is meaningful. The only optimization that either party could identify was iterative – whether in the patent or in the real world.

Response to May 3, 2006 Office Action at 16 (D.I. 87, Ex. 12 at JA00158).]

In recent filings, Plaintiff also referenced the iterative nature of the optimizer, stating that the '175 invention "utilize[s] a cost function that considers[,] at each iteration of an optimizer," both dosimetric fitness and delivery efficiency. [Jan. 22, 2020 Patent Owner's Preliminary Response to Petition for *Inter Partes* Review of U.S. Patent No. 7,266,175, Case No. IPR2020-00053 at 11 (D.I. 87, Ex. 18 at JA00412); *accord* Jan. 22, 2020 Patent Owner's Preliminary Response to Petition for *Inter Partes* Review of U.S. Patent No. 7,266,175, Case No. IPR2020-00077 at 13 (D.I. 87, Ex. 18 at JA00480).]

I will not limit the "optimizer" claimed to an algorithm. Certain claims, such as claim 11, specifically reference optimization algorithms. And thus it appears that when the patentee meant for the optimizer to be an algorithm, he stated that. He did not do so in the claims at issue here.

I also note that limiting the optimizer to an algorithm is not supported by the specification. Indeed, in the Summary of the Invention, it refers to three methods for enabling user control of the tradeoff between dosimetric fitness and delivery efficiency. Each of those references optimization, but only one – the third – references choosing an optimization algorithm.

The fourth disputed term is "intensity map[s]" again in claims 13, 15, and 19 of the '175 Patent. Plaintiff proposes this term means "a representation of the variation across a defined area of radiation of a single beam." Defendants originally proposed the construction "representation[s] of dose distribution." But during discussions aimed at narrowing the disputes, Defendants proposed the construction "a representation of the variation across a defined area of radiation of a single beam from a single gantry angle," thus adopting Plaintiff's construction with the addition of the words "from a single gantry angle."

Here, I agree with Plaintiff and will construe the term to mean "a representation of the variation across a defined area of radiation of a single beam."

This is consistent with the ordinary meaning of the term as recognized by the PTAB in denying the petition to institute IPR. [*See* Decision Denying *Inter Partes* Review of '175 Patent, IPR2020-00053 at 12 (D.I. 121, Ex. 48 at JA01233).]

Defendants have not cited anything in the specification, claims, or prosecution history that clearly requires that the language "from a single gantry angle" be added to the ordinary meaning.

The fifth and final disputed term is "determine [a/the] collimator angle of [a/the] multi[-]leaf collimator" in claims 4, 17, and 18 of the '490 Patent. During the hearing the parties reached agreement that this term means "select [a/the] rotation angle of [a/the] multi[-]leaf collimator." And in coming to that agreement, both sides agreed that a gantry angle is different from a collimator angle and that changing the gantry angle is not the same as changing the collimator angle.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge