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Paper 19
Entered: April 17, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELEKTA INC.,
Petitioner,

v.

BEST MEDICAL INTERNATIONAL, INC.,
Patent Owner.

IPR2020-00073
Patent 7,266,175 B1

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

SAINDON, *Administrative Patent Judge.*

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

I. INTRODUCTION

Elekta, Inc. ("Petitioner") filed a petition requesting *inter partes* review of claims 1, 8, 10–13, 17, 19, and 20 of U.S. Patent No. 7,266,175 B1 (Ex. 1001, "the '175 patent"). Paper 2 ("Pet."). Best Medical International, Inc. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition and the Preliminary Response shows that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.4(a) ("The Board institutes the trial on behalf of the Director."). Taking into account the arguments presented in the Petition and Preliminary Response, we conclude that the information presented in the Petition does not establish a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim. Accordingly, we do not institute an *inter partes* review.

A. Related Matters

The '175 patent is also the subject of Board proceedings IPR2020-00053 and IPR2020-00077, brought by a different petitioner, which are decided at the same time as this proceeding.

Petitioner also challenges related patents: U.S. Patent No. 7,015,490 ("the '490 patent") in IPR2020-00067, U.S. Patent No. 6,393,096 ("the '096 patent) in IPR2020-00074, and U.S. Patent No. 6,038,283 ("the '283 patent") in IPR2020-00070. The '490 patent is also the subject of

Board proceeding IPR2020-00076. The '096 patent is also the subject of Board proceedings IPR2020-00071 and IPR2020-00072. The '283 patent is also the subject of Board proceeding IPR2020-00075.

According to the parties, the '175 patent is involved in *Best Medical International, Inc.* v. *Elekta Inc.*, 1:19-cv-03409-MLB (N.D. Ga.) and *Best Medical International, Inc. v. Varian Medical Systems, Inc.*, 1:18-cv-01599 (D. Del.). Pet. 2; Paper 4, 1–2 (Patent Owner's Mandatory Notice).

B. Real Parties In Interest

The parties do not present any dispute over real parties in interest. Petitioner asserts that Elekta Limited (UK), Elekta Holdings U.S., Inc., and Elekta AB are the real parties in interest. Pet. 2. Patent Owner asserts that Best Medical International, Inc. is the real party in interest. Paper 4, 1.

C. The '175 Patent

The '175 patent is directed to a method for planning radiation therapy. Traditionally, planning systems attempt to find radiation intensity maps that result in the best calculated dose distribution for a tumor. Ex. 1001, 1:13–16. Although optimized intensity maps may provide the best dose distribution, they may not be practical to implement (i.e., inefficient). *Id.* at 1:16–20. For example, an inefficient intensity map may require a lot of machine on-time (i.e., "monitor units" or "MU") or may require setting up a large number of radiation beam configurations (e.g., "segments"). *Id.* at 1:21–26. The time required to both run the machine longer and to set up many different configurations may not be practically available—a patient can only sit perfectly still for so long, and other patients are also waiting for their turns. The '175 patent alleges that it provides a method to control the

tradeoff between delivery efficiency and dosimetric fitness in radiation treatment plans. *Id.* at 1:36–38.

D. Challenged Claims

Claims 1, 8, 10–13, 17, 19, and 20 in the '175 patent are challenged. Claims 1, 11, 13, and 19 are independent. Independent claim 1 is reproduced below:

> 1. A method of determining a radiation beam arrangement, the method comprising the steps of:
> receiving prescription parameters for a patient target; and
> evaluating a cost function for each of a set of a plurality of candidate intensity maps formed responsive to the prescription parameters to provide control of a trade-off between treatment plan delivery efficiency and dosimetric fitness within an optimizer to optimize a radiation treatment plan within a continuum between substantially optimal dosimetric fitness and enhanced delivery efficiency at an expense of dosimetric fitness, the cost function including a dosimetric cost term representing dosimetric cost and related to dosimetric fitness of the respective candidate intensity map and a delivery cost term representing delivery cost and related to delivery time to deliver radiation according to a beam arrangement represented by the respective candidate intensity map, the evaluation of the delivery cost term for each respective candidate intensity map having linear computational complexity with respect to size of the respective candidate intensity map.

Independent claim 11 is also reproduced below:

> 11. 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:

applying prescription parameters to each of a plurality of optimization algorithms within an optimizer, the plurality of optimization algorithms including a local optimization algorithm and a global optimization algorithm, the local optimization algorithm providing greater delivery efficiency than that of the global optimization algorithm, the global optimization algorithm providing greater dosimetric fitness than the local optimization algorithm; and

selecting one of the plurality of algorithms to be the optimizer responsive to a user selection between enhanced delivery efficiency and enhanced dosimetric fitness.

E. Prior Art and Asserted Grounds

Petitioner asserts the following grounds (Pet. 25):

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1	103	Webb[1]
13	103	Webb, Bar[2]
17	103	Webb, Bar, Shepard[3]
8	103	Webb, Bar, Siebers[4]
10, 19, 20	103	Webb, Bar, Siebers, Shepard
11, 12	103	Shepard, Que[5]

[1] Steve Webb, *A simple method to control aspects of fluence modulation in IMRT planning*, 46 Physics Med. & Biology N187–N195 (2001) (Ex. 1006).

[2] W. Bär, et al., *A variable fluence step clustering and segmentation algorithm for step and shoot IMRT*, 46 Physics Med. & Biology 1997–2007 (2001) (Ex. 1014).

[3] D. M. Shepard, et al., *Direct aperture optimization: A turnkey solution for step-and-shoot IMRT*, 29 Medical Physics No. 6, 1007–18 (2002) (Ex. 1010).

[4] Jeffrey V. Siebers, et al., *Incorporating multi-leaf collimator leaf sequencing into iterative IMRT optimization*, 29 Medical Physics No. 6, 952–59 (2002) (Ex. 1008).

[5] William Que, *Comparison of algorithms for multileaf collimator field segmentation*, 26 Medical Physics No. 11, 2390–96 (1999) (Ex. 1012).

II. PATENTABILITY ANALYSIS

A. Claim Construction

"[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). No terms require explicit construction to render our Decision.

B. Level of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have had an undergraduate degree in science, computer science, engineering or math, and an advanced degree in radiation dosimetry, physics, medical physics, medicine, or an equivalent field of study, with some clinical experience in radiotherapy treatment planning. Pet. 21 (citing Ex. 1003 ¶¶ 55–98).

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. Prelim. Resp. 12 (citing Ex. 2002 ¶¶ 58, 65).

The prior art references and the '175 patent were written with a highly skilled and technically proficient audience in mind. *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."). For purposes of this Decision, we see little practical difference between selecting Petitioner's or Patent Owner's proposed definitions; both suggest a

high level of skill in the intersection between mathematical modeling and radiology. Given the complex nature of the subject matter and relatively higher level of skill involved, we choose Patent Owner's proposed level of skill.

C. The Obviousness Grounds Based on Webb (Claims 1, 8, 10, 17, 19, and 20)

Petitioner asserts that claim 1 would have been obvious in view of Webb. Pet. 26–38. Most relevant to this Decision, claim 1 requires the evaluation of a cost function for a set of "intensity maps." Patent Owner's chief argument against this ground is that Webb does not disclose an intensity map. Prelim. Resp. 16–27.

Petitioner's key assertion as to the intensity map limitation is as follows:

> Also, the [person of ordinary skill in the art] would understand that Webb 2001 discloses **"**(*evaluating a cost function). . .* ***for each of a set of a plurality of candidate intensity maps formed responsive to the prescription parameters***." Webb 2001's hybrid cost function is used in an iterative optimization process in which the cost function is evaluated repeatedly, at each of potentially many iterations, for the intensity map being considered at that iteration, given the model parameters. The "3. Results" section of Webb 2001 discloses an evaluation of the cost function for each of a set of a plurality of candidate intensity maps formed responsive to the prescription parameters with reference to Table 1 (Ex. 1006. N190 ¶4 and N192-N193 (Figure 2):. "Table 1 shows the results. Five plans (labelled runs 4,1,8,10,9) were computed, each with nine equispaced IMBs." A [person of ordinary skill in the art] would understand that Table 1 shows, for each of 11 runs: the calculated value of the dose-space term, the calculated value of the beam-space term, the set values of the three weights, statistics for the calculated partial volumes (e.g. the target, an OAR), the calculated value of the two delivery

> cost component terms, and three DVH points. *See* Ex. 1003 ¶¶ 280-296.

Pet. 34–35.

In the above paragraph, Petitioner appears to be directing our attention to Table 1 and Figure 2 in Webb.[6] Table 1 is reproduced below:

Table 1. The parameters applied during the optimization and the consequent outcomes in dose-space and beam-space for 11 separate optimizations. All symbols and the results are discussed in the text.

	9 beams equispaced at 40° intervals					5 beams equispaced at 72° intervals					
Run	4	1	8	10	9	12	13	14	15	16	17
Cost in dose space	4329	4861	5725	7029	8800	5497	6334	6656	6867	7235	8134
Cost in beam space	—	—	−7.0	−16.2	−24.2	—	—	1.1	−1.0	−1.9	−6.1
w_1	—	—	0.1	0.1	0.1	—	—	0.1	0.1	0.1	0.1
w_2	—	—	1	1	1	—	—	1	1	1	1
w_3	0	0	10	20	30	0	0	10	20	30	50
MWF included?	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
OAR_{mean}	0.285	0.312	0.418	0.493	0.560	0.365	0.402	0.435	0.453	0.475	0.523
σ_{OAR}	0.238	0.257	0.216	0.202	0.191	0.240	0.259	0.244	0.239	0.233	0.214
PTV_{mean}	0.996	0.996	0.995	0.993	0.993	0.995	0.992	0.993	0.992	0.991	0.988
σ_{PTV}	0.026	0.024	0.023	0.021	0.023	0.025	0.026	0.026	0.025	0.023	0.024
S_x	364	273	250	228	218	330	274	241	240	231	219
F_{min}	11	27	32	39	46	7	19	23	25	25	28
V_{80}	0.067	0.076	0.087	0.115	0.132	0.078	0.102	0.121	0.123	0.128	0.147
V_{70}	0.094	0.110	0.125	0.179	0.216	0.126	0.149	0.165	0.176	0.189	0.232
V_{60}	0.124	0.149	0.182	0.242	0.313	0.178	0.215	0.237	0.247	0.261	0.294

Ex. 1006, 191.

Table 1 of Webb shows "[t]he parameters applied during the optimization and the consequent outcomes in dose-space and beam-space for 11 separate optimizations." Table 1 depicts the results of "9 beams equispaced at 40° intervals" and the results of "5 beams equispaced at 72° intervals." Values reported include a run number, cost in dose space, cost in beam space, various algorithm weights and values, and some output values of interest (e.g., doses to organs at risk and the target organ, and percent of organ receiving above a threshold dose).

[6] Petitioner also cites to its expert declaration, but that document largely mirrors the language of the Petition. *Compare* Pet. 30–35, *with* Ex. 1003 ¶¶ 280–296. Thus, we do not need to separately discuss that declaration.

Figure 2 depicts (i) nine beam profiles, (ii) a dose distribution, and (iii) a DVH. *Id.* at 192, 193. Figure 2(a) of Webb is reproduced below:

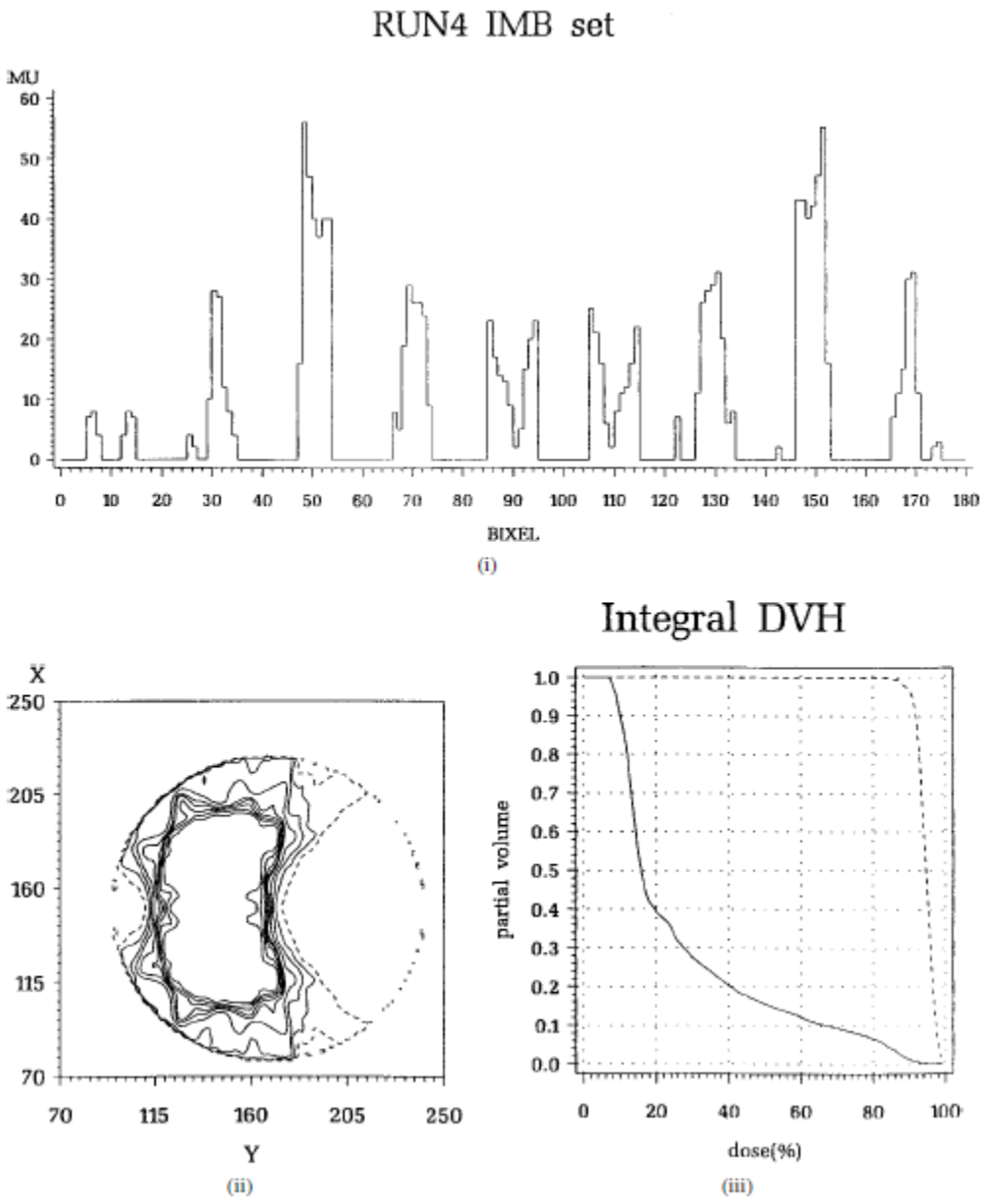

Figure 2(a) of Webb has three subparts. Part (i) shows "nine IMBs [(Intensity Modulated Beams)], each 20 bixels long displayed in a line." *Id.* at 192. Part (ii) shows the dose distribution. The x and y axes are labeled in millimeters and the isodoses are shown as various contour lines. *Id.* Part

(iii) shows the dose volume histogram. *Id.* at 190. There is also a Figure 2(b) that shows the same three subparts, but for a different set of beams. *Id.* at 193.

Although we do not require a petitioner to direct us to the exact words of a claim in a reference, we do require a petitioner to explain how the claim reads on the prior art. 37 C.F.R. § 42.104(b)(4) (requiring a petitioner to "specify where each element of the claim is found in the prior art"). The level of explanation required is situation-specific. Sometimes, little to no explanation is required, because of how apparent the limitation is met by the cited disclosures. In other situations, a claim construction will be required to bridge the gap between different words that describe the same concept. In still other situations, detailed technical analysis or reliance on other evidence may be required.

In this situation, Petitioner points to Table 1 and Figure 2 in Webb, alleging that the claimed intensity map is found among them. *See* Pet. 34–35. We have reproduced those portions of Webb above. But it is not readily apparent to us what Petitioner believes is the intensity map in them. The majority of the claim is directed to evaluating a cost function *for* intensity maps. Thus, it is critical to know which portion of Webb that Petitioner believes is an intensity map, in order to evaluate whether the claims are obvious. We will not perform our own independent analysis of Webb, nor will we infer Petitioner's position without being reasonably able to discern it.[7] Because Petitioner does not take a sufficiently clear position on how

[7] In IPR2020-00053, a related proceeding, a different petitioner asserted that the proposed dose distribution—D(*i*, *j*)—in Webb's optimization equation (*see, e.g.*, Ex. 1006, 189) is an intensity map. *Varian Med. Sys., Inc., v. Best Med. Int'l, Inc.*, IPR2020-00053, Paper 2, 36–37. None of the items in

Webb discloses an intensity map, we determine that Petitioner has not established a reasonable likelihood of success of showing that claim 1 would have been obvious in view of Webb. For the same reasons, we also determine that Petitioner has not established a reasonable likelihood of success for claims 8, 10, 13, 17, 19, and 20.

D. The Shepard-Que Ground (Claims 11, 12)

Independent claim 11 differs from the other independent claims addressed above. Primarily, there is no intensity map. Instead, claim 11 focuses on "a plurality of the optimization algorithms within an optimizer." The optimization algorithms must include both a local and a global optimization algorithm, each used for a particular purpose (delivery efficiency and dosimetric fitness, respectively). Petitioner asserts that Shepard and Que disclose the limitations of claim 11. Pet. 54–59. Petitioner asserts that Shepard discloses the local and global optimization algorithms. *Id.* at 56–57. Specifically, Petitioner points to a simulated annealing algorithm for the global optimization algorithm, and a gradient-based algorithm for the local optimization algorithm. *Id.* (citing Ex. 1010 at Abstract, 1012, and Fig. 6).

Reviewing the portions of Shepard cited by Petitioner, we find that the abstract states that simulated annealing is used for optimization. Ex. 1010, 1007. Figure 6 depicts a plot showing the results of simulated annealing. Shepard further states that simulated annealing is beneficial because of its

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Figure 2 or Table 1 of Webb lists D(i, j). In any event, we were not persuaded that D(i, j) in Webb was an intensity map in IPR2020-00053. *Id.*, Paper 14, 26 (Decision Denying Institution).

ability to avoid local minima (i.e., it is a global algorithm). *Id.* at 1012. Reviewing these portions of Shepard, we find that Petitioner has sufficiently established that Shepard discloses a global optimization algorithm for providing dosimetric fitness.

However, as Patent Owner argues, and we agree, Shepard only uses one optimization algorithm. Prelim. Resp. 57 ("there is only one optimization algorithm in Shepard") (citing Ex. 2002 ¶ 184). Petitioner directs our attention to Shepard's mention of a "gradient-based optimization algorithm," but Shepard merely talks about that algorithm, it does not use it as a second algorithm. Pet. 57 (citing Ex. 1010, 1012). Specifically, Shepard states it takes a feature from a different paper, one that uses a gradient-based optimization algorithm: "[w]ithin the context of *our* least squares objected function, DVH constraints are applied *using a technique first described by [another person] for* a gradient-based optimization algorithm." Ex. 1010, 1009 (emphasis added). In other words, Shepard is using a feature borrowed from another optimization procedure for the purpose of applying DVH constraints, but Shepard does not state that it is also adding a second, gradient-based algorithm. Thus, Petitioner has not sufficiently demonstrated that Shepard discloses an optimizer having a local optimization algorithm used for delivery deficiency in the manner required by claim 11.

Petitioner also asserts that Que discloses choosing among optimization algorithms. Pet. 57–59. We agree that it does. *See, e.g.*, Ex. 1012, Abstract ("it is desirable to have multiple algorithms available in a [system] which will search through all algorithms automatically and find the most efficient delivery sequence for a given treatment"). However, we

determine that Petitioner has not explained sufficiently how it would have been obvious to a person of ordinary skill in the art to modify Shepard in a manner that results in the claimed invention. Petitioner makes no attempt to explain how Que would provide the missing local optimization algorithm. *See* Pet. 56–57 (addressing the limitation requiring global and local optimizations but not citing Que). Petitioner does assert that Que shows different algorithms. *Id.* at 57–59 (quoting, e.g., Ex. 1012, 2395 ¶¶ 3–4). However, Petitioner merely asserts, without explanation, that "a [person] of ordinary skill in the art would take the recommendation of Que 1999 to characterize and select from a plurality of algorithms." *Id.* at 59. Thus, Petitioner provides neither an explanation of the proposed modification to Shepard, nor a sufficient reason for doing so.[8] For these reasons, we determine that Petitioner has not established a reasonable likelihood of success of showing that claim 11 or 12 would been obvious based on the proposed combination of Shepard and Que.

III. ORDER

We determine that Petitioner has not demonstrated a reasonable likelihood that it would succeed in demonstrating that one or more claims of

[8] Petitioner also makes several generic statements under a motivation to combine section later in its Petition (Pet. 61–63), but none of these statements sufficiently articulates how the proposed combination would result in the claimed invention nor why it would have been obvious to combine the prior art in the manner proposed to arrive at the claimed invention.

the '175 patent would have been unpatentable under any of the grounds asserted in its Petition.

In view of the foregoing, it is hereby

ORDERED that the Petition is *denied* and that we do not institute an *inter partes* review of the '175 patent.

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