UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VARIAN MEDICAL SYSTEMS, INC.
Petitioner

v.

ELEKTA LIMITED
Patent Owner

Case IPR2017-00885
Patent No. 7,961,843

# PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,961,843

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**TABLE OF CONTENTS**

I. INTRODUCTION AND RELIEF REQUESTED (37 C.F.R. §42.22(a)) ......1

II. OVERVIEW OF THE TECHNOLOGY ......1

III. THE ’843 PATENT ......4

A. Overview ......4

B. Level of Ordinary Skill in the Art ......6

C. Claim Construction ......6

1. Means-Plus-Function Limitations ......7

2. “Specified rate per degree” (Claim 7) ......19

3. “The rotation speed” (Claim 8) ......21

IV. OVERVIEW OF THE PRIOR ART ......21

V. IDENTIFICATION OF CHALLENGE (37 C.F.R. §42.104(b)) ......23

VI. Ground 1: Earl renders obvious claims 7, 9-11, and 14. ......24

A. Earl renders claim 7 obvious ......25

1. Earl teaches or suggests limitation [7.P]: “a treatment planning apparatus, for a radiotherapeutic apparatus of the type” ......25

2. Earl teaches or suggests limitation [7.1.A]: “a source able to emit a beam of therapeutic radiation along a beam axis” ......25

3. Earl teaches or suggests limitation [7.1.B]: “rotate about a rotation axis that intersects with the beam axis thereby to describe an arc around the rotation axis” ......26

4. Earl teaches or suggests limitation [7.2]: “a multi-leaf collimator arranged to collimate the beam to a desired shape” 26

5. Earl teaches or suggests limitation [7.3]: "a control means able to control dose rate of the source, rotation of the source, and the multi-leaf collimator" ....27

6. Earl teaches or suggests limitation [7.4]: "the treatment planning apparatus being arranged to divide the arc into a plurality of arc-segments and to prepare a treatment plan which includes" ....28

7. Earl teaches or suggests limitation [7.4.A]: "a first arc-segment adapted to deliver a first specified dose during which the source rotates a first specified angle and the multi-leaf collimator changes shape at a first specified rate per degree" ....29

8. Earl teaches or suggests limitation [7.4.B]: "a second arc segment adapted to deliver a second specified dose during which the source rotates a second specified angle and the multi-leaf collimator changes shape at a second specified rate per degree, such that at least the first and second specified rates per degree differ as between the first and second arc-segments" ...31

B. Earl renders claim 9 obvious: "the first arc-segment and the second arc-segment are consecutive" ....34

C. Earl renders claim 10 obvious: "an output means for transmitting the treatment plan to the radiotherapeutic apparatus" ....34

D. Earl renders claim 11 obvious: "arranged to calculate an irradiation time for each arc-segment apt to deliver a required dose and to infer a rotation speed from the irradiation time" ....35

E. Earl renders claim 14 obvious: "the beam axis and the axis of rotation of the source are substantially orthogonal" ....37

VII. Ground 2: Earl in view of Bjärngard renders obvious claims 12-13. ....37

A. The combination of Earl and Bjärngard renders claim 12 obvious: "prescribe a treatment plan that includes motion of a patient positioning system during the treatment in a manner correlated with motion of the source" ....37

1. Earl ....................................................................................37

2. Bjärngard............................................................................38

B. The combination of Earl and Bjärngard renders claim 13 obvious: "prescribe a treatment plan that includes motion of a patient positioning system during the treatment in a manner correlated with delivery of the dose".......................................................................39

1. Earl ....................................................................................39

2. Bjärngard............................................................................39

C. *KSR* Rationale and Motivation to Combine Earl and Bjärngard. .......40

VIII. Ground 3: Earl in view of Yu renders obvious claims 7, 9-11 and 14.........42

A. Earl in view of Yu renders claim 7 obvious.......................................42

1. Earl teaches or suggests limitation [7.P]: "a treatment planning apparatus, for a radiotherapeutic apparatus of the type comprising.........................................................................42

2. Earl teaches or suggests limitations [7.1.A], [7.1.B], and [7.2]42

3. The combination of Earl and Yu teaches or suggests limitation [7.3]: "a control means able to control dose rate of the source, rotation of the source, and the multi-leaf collimator"..............43

4. The combination of Earl and Yu teaches or suggests limitation [7.4]: "the treatment planning apparatus being arranged to divide the arc into a plurality of arc-segments and to prepare a treatment plan which includes"................................................44

5. The combination of Earl and Yu teaches or suggests limitation [7.4.A]: "a first arc-segment adapted to deliver a first specified dose during which the source rotates a first specified angle and the multi-leaf collimator changes shape at a first specified rate per degree" ........................................................................46

6. The combination of Earl and Yu teaches or suggests limitation [7.4.B]: "a second arc segment adapted to deliver a second specified dose during which the source rotates a second specified angle and the multi-leaf collimator changes shape at a second specified rate per degree, such that at least the first and second specified rates per degree differ as between the first and second arc-segments" ............ 48

B. The combination of Earl and Yu renders claim 9 obvious: "the first arc-segment and the second arc-segment are consecutive" ............ 50

1. Earl ............ 50

2. Yu ............ 50

C. Earl renders claim 10 obvious: "an output means for transmitting the treatment plan to the radiotherapeutic apparatus" ............ 51

D. The combination of Earl and Yu renders claim 11 obvious: "arranged to calculate an irradiation time for each arc-segment apt to deliver a required dose and to infer a rotation speed from the irradiation time" ............ 51

1. Earl ............ 51

2. Yu ............ 51

E. The combination of Earl and Yu renders claim 14 obvious: "the beam axis and the axis of rotation of the source are substantially orthogonal" ............ 53

1. Earl ............ 53

2. Yu ............ 53

F. KSR Rationale and Motivation to Combine Earl and Yu. ............ 54

IX. Ground 4: The combination of Earl, Yu, and Otto renders obvious claim 8. ............ 55

A. The combination of Earl, Yu, and Otto renders claim 8 obvious: "the rotation speed and the dose rate are both constant during an arc-segment, and at least one thereof is different as between the first arc-segment and the second arc-segment" ....................56

1. Yu....................56

2. Otto....................57

B. Motivation to Combine Earl, Yu, and Otto....................58

X. Ground 5: Earl in view of Yu and Bjärngard renders obvious claims 12-13. ....................60

A. Claims 12-13 ....................60

B. *KSR* Rationale and Motivation to Combine Earl, Yu, and Bjärngard.60

XI. CONCLUSION....................62

XII. STANDING (37 C.F.R. §42.104(a)) ....................62

XIII. MANDATORY NOTICES (37 C.F.R. §42.8(a)(1))....................62

A. Real Parties-In-Interest (37 C.F.R. §42.8(b)(1))....................63

B. Related Matters (37 C.F.R. §42.8(b)(2))....................63

C. Designation of Lead and Back-Up Counsel (37 C.F.R. §42.8(b)(3)) .63

D. Service Information (37 C.F.R. §42.8(b)(4)) ....................64

## EXHIBIT LIST

| Exhibit No. | Description |
|---|---|
| **1001** | U.S. Patent No. 7,961,843 to Brown et al. ("'843 Patent") |
| **1002** | Prosecution File History of U.S. Patent No. 7,961,843. |
| **1003** | Declaration of Kenneth P. Gall, Ph.D. |
| **1004** | *Curriculum Vitae* of Kenneth P. Gall, Ph.D. |
| **1005** | Dynamic Beam Delivery (DBD) Toolbox User's Manual. ("DBDToolbox") |
| **1006** | DMLC Implementation Guide. ("DMLCIG") |
| **1007** | Yu et al., "Clinical Implementation of Intensity-Modulated Arc Therapy," Int. J. Radiation Oncology Biol. Phys., Vol. 53, No. 2 at 453-463, 2002. ("Yu Article" or "Yu") |
| **1008** | Reserved |
| **1009** | U.S. Patent Publication No. 2004/0071261 to Earl et al. ("Earl") |
| **1010** | Reserved |
| **1011** | Declaration of Samuel Castellino. ("Castellino Declaration") |
| **1012** | Declaration of Gikas S. Mageras, Ph.D. ("Mageras Declaration") |
| **1013** | Declaration of William R. Wedding. ("Wedding Declaration") |
| **1014** | Declaration of Steve Harrell. ("Harrell Declaration") |
| **1015** | Reserved |
| **1016** | Shinji Takahashi, "Conformation Radiotherapy: Rotation Techniques As Applied To Radiography and Radiotherapy of Cancer," ACTA Radiologica Supplementum 242, Stockholm 1965. ("Takahashi") |
| **1017** | Chin et al., "Dose Optimization With Computer-Controlled Gantry Rotation, Collimator Motion and Dose-Rate Variation," Int. J. Radiation Oncology Biol. Phys., Vol. 9 at 723-729, 1983. ("Chin") |

| | |
|---|---|
| **1018** | Reserved |
| **1019** | Reserved |
| **1020** | Xia et al., "Communication and sampling rate limitations in IMRT delivery with a dynamic multileaf collimator system," Med. Phys., Vol. 29(3) at 412-423, 2002. ("Xia") |
| **1021** | Duan et al., "Dosimetric effect of respiration-gated beam on IMRT delivery," Med. Phys., Vol. 30(8) at 2241-52, 2003. ("Duan") |
| **1022** | Kumar et al., "QA of intensity-modulated beams using dynamic MLC log files," Med. Phys., Vol. 31(1) at 36-41, 2006. ("Kumar") |
| **1023** | Bjärngard et al., "Computer-Controlled Radiation Therapy," Proceedings of the Annual Symposium on Computer Application in Medical Care, 1978 at 86-92. ("Bjärngard") |
| **1024** | Chang et al., "Developments in megavoltage cone beam CT with an amorphous silicon EPID: Reduction of exposure and synchronization with respiratory gating," American Association of Physicists in Medicine in Medical Physics, Vol. 32, No. 3, March 2, 2005. ("Chang") |
| **1025** | Digital Imaging and Communications in Medicine (DICOM), Supplement 11, Radiotherapy Objects, Final Text, 4 June 1997 ("DICOM Standard") |
| **1026** | U.S. Patent No. 7,906,770 to Otto ("Otto") |
| **1027** | U.S. Provisional Patent Application No. 60/701,974 to Otto ("Otto Provisional") |

## I. INTRODUCTION AND RELIEF REQUESTED (37 C.F.R. §42.22(a))

Varian Medical Systems, Inc. ("Petitioner" or "Varian") hereby petitions for *inter partes* review of claims 7-14 of U.S. Patent No. 7,961,843 to Brown et al. ("the '843 Patent" or "Exhibit 1001") now assigned to Elekta Limited ("Patent Owner", "PO", or "Elekta"). Claims 7-14 are unpatentable under 35 U.S.C. §103.

This Petition provides (1) **ground 1:** claims 7, 9-11, and 14 are obvious under §103 in view of Earl (Ex. 1009); (2) **ground 2:** claims 12 and 13 are obvious under §103 in view of Earl and Bjärngard (Ex. 1023); (3) **ground 3:** claims 7-11 and 14 are obvious under §103 in view of Earl and the Yu Article (Ex. 1007, hereinafter "Yu"); (4) **ground 4:** claim 8 is obvious under §103 in view of Earl, Yu, and Otto (Ex. 1026); and (5) **ground 5:** claims 12 and 13 are obvious under §103 in view of Earl, Yu, and Bjärngard.

Claim construction, reasons for unpatentability, and specific evidence supporting this request are detailed herein.

## II. OVERVIEW OF THE TECHNOLOGY

The technology at issue generally relates to a radiation treatment planning apparatus for treating cancer. ('843 Patent, Abstract, 4:5-12; Gall Declaration, ¶39.)

Radiotherapy works by directing high energy ionizing radiation beams at a patient to kill cancer cells. (Earl, [0007].) The clinical goal of radiation therapy is to deliver as much radiation as possible to a tumor to destroy its cancerous cells, while minimizing radiation exposure (and consequent damage) to the cells of healthy tissue. (*Id*.)

One device for delivering the radiation to a patient is a linear accelerator, a machine that generates a high-energy beam of radiation that can be controlled and directed onto specified locations. (*Id*.) The terms "linac," "linear accelerator," and "accelerator" are used interchangeably in the industry to refer to either the specific component that generates the high energy ionizing radiation beams or to the entire radiotherapy system. (*Id.*; Gall Declaration, ¶41.) For nearly as long as linacs have been used, so too have been treatment planning computers arranged to plan a radiation treatment for the linacs. (Gall Declaration, ¶52.)

Since as early as 1965, linear accelerators have commonly implemented a multi-leaf collimator (MLC), a device that shapes each individual beam of radiation to minimize radiation exposure to healthy tissue. (Earl, [0007].) As shown in Earl's Figure 2, reproduced below, an MLC has multiple individually-controlled metal alloy leaves that work together to shape the beam of radiation. (*Id.*, [0027].) When radiation is delivered using an MLC, a series of beam shapes are delivered at each beam angle either dynamically, where the leaves of the MLC move during irradiation, or in a step-and-shoot fashion, where the radiation is paused during the movement of MLC leaves. (*Id.*, [0012].)

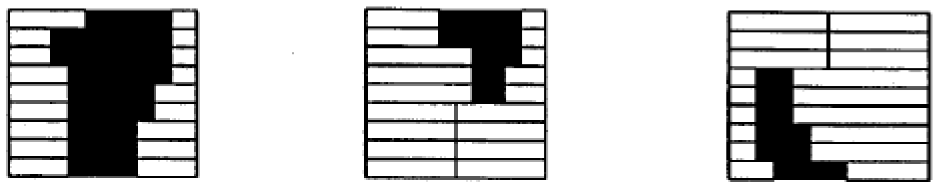

**Figure 2**

(Earl, FIG.2.)

Since as early as the 1960's, linear accelerators have commonly implemented a gantry to rotate a therapeutic radiation source around a patient. (Gall Declaration, ¶45.) A gantry directs the high energy ionizing radiation beams to the precise location of a tumor by rotating around a patient. (Yu, p.454; Gall Declaration, ¶45.) The gantry speed and position may be controlled by the radiotherapy apparatus based on a treatment plan received from a radiation planning computer or apparatus. (Earl, [0042].)

As MLC and gantry movements were implemented into linac treatments in the 1960's, treatment planning systems began prescribing treatment plans for the coordination of MLC movement and gantry rotation while administering a dose. (*Id.*, ¶52.) A treatment plan is an accumulation of geometric and dosimetric information defining the path of a beam during radiation treatment. (DICOM Standard, 3.) At least as early as 1997, it has been common practice to prepare radiation therapy treatment plans including MLC movement and gantry rotation over an arc-segment while delivering a dose. (*Id.*, 65, 74, and 78.) The standard further provides that a treatment plan can be established "by manual entry," i.e., by inputting the data into a text editor. (*Id.*, 19.)

## III. THE '843 PATENT

### A. Overview

As explained herein, the '843 Patent is merely a combination of technologies commonly used well before April 27, 2005. (Gall Declaration, ¶55.) Specifically, radiation treatment planning systems have been used to prepare treatment plans involving the coordinated movement of multiple factors since at least the 1990's. (*Id.*) The '843 Patent describes preparing a treatment plan using a combination of the methods described above, including the control of gantry rotation and MLC leaf speed. (*Id.*)

The '843 Patent discloses a treatment planning apparatus capable of planning radiation therapy treatments. ('843 Patent, 3:42-51.) The treatment planning apparatus defines a sequence of segments. (*Id.*, 4:5-7.) Each segment defines a position of the gantry, the dose that is to be delivered over the segment, and the shape of the MLC at the beginning and end of the segment. (*Id.*, 4:7-10.) As described in the '843 Patent, in the treatment plan, "the arc is divided into a plurality of arc-segments, the treatment plan specifying the total dose for the arc-segment and a start and end MLC position…" (*Id.*, 4:34-37.) The control means "control[s] the source in accordance with that plan" over an arc-segment. (*Id.*, 4:37-38.)

FIG. 6, reproduced below, illustrates the relationship between the '843 Patent's radiotherapeutic apparatus and its treatment planning apparatus. For example, the "treatment planning computer develops a treatment plan which defines the treatment and passes this to a treatment control computer." (*Id.*, 8:31-33.) The treatment plan provides instructions for "the MLC control computer, gantry control computer, and radiation control computer as to the operation of their specific item" for execution during treatment. (*Id.*, 8:33-38.)

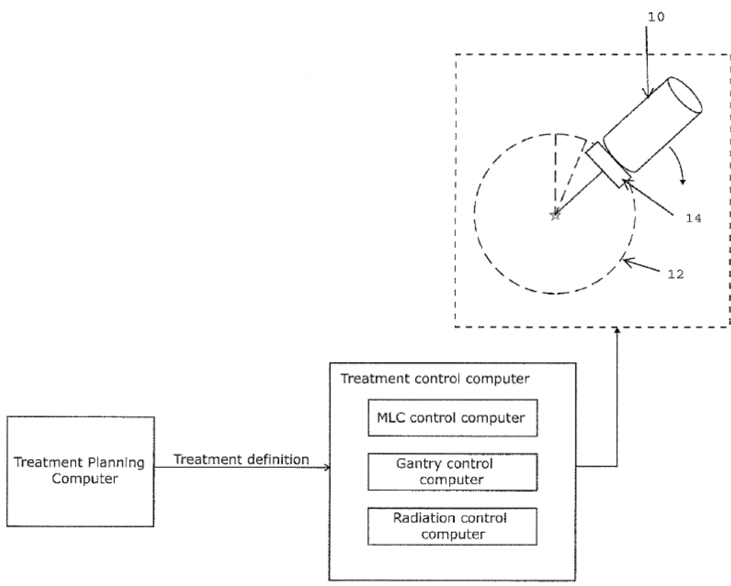


Fig 6

(*Id.*, FIG. 6.)

### B. Level of Ordinary Skill in the Art

The ’843 Patent claims priority to international patent application number PCT/EP2006/003901, filed on April 27, 2006. A person of ordinary skill in the art (“POSA”) at that time would be a person with a graduate degree (MS or PhD) in physics or a related field (e.g., Engineering or Computer Science), and either 2-3 years of work in radiation oncology beyond the completion of their degree or 2-3 years of experience programming radiation treatment systems. (Gall Declaration, ¶18.)

### C. Claim Construction[1]

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable interpretation (“BRI”) in light of the specification of the patent in which they appear. 37 C.F.R. §42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48766 (Aug. 14, 2012). *See also*, *Cuozzo Speed Technologies, LLC v. Lee*, 579 U.S. 13 (2016).

[1] Petitioner reserves the right to pursue different claim constructions, including that certain claim terms are indefinite, during this and related proceedings and in litigation, at least because of the different standards of claim interpretation used by the Patent Trial and Appeal Board and district courts.

**1. Means-Plus-Function Limitations**

There is a rebuttable presumption that 35 U.S.C. §112(f) applies to a claim element when the claim language uses "means" for performing a recited function. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015). Conversely, there is a rebuttable presumption that 35 U.S.C §112(f) does not apply to a claim element when the claim language does not use "means" for performing a recited function. *Id*.

Section 112(f) provides that a claim expressed in means-plus-function language "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. §112(f). Thus, the specification must provide "an adequate disclosure showing what is meant by that [claim] language." *Noah Sys. Inc. v. Intuit Inc.*, 675 F.3d 1302, 1311 (Fed. Cir. 2012). Under 35 U.S.C. §112(b) and (f), "a means-plus-function clause is indefinite if a person of ordinary skill in the art would be unable to recognize the structure in the specification and associate it with the corresponding function in the claim." *Noah Sys.*, 675 F.3d at 1312.

With computer-implemented inventions, the corresponding structure must be an algorithm. *Noah Sys.*, 675 F.3d at 1312. The structure disclosed in the specification must "be more than simply a general purpose computer or microprocessor." *Aristocrat Techs. Austl. PTY Ltd. v. Int'l Game Tech.*, 521 F.3d

1328, 1333 (Fed. Cir. 2008) ("Because general purpose computers can be programmed to perform very different tasks in very different ways, simply disclosing a computer as the structure designated to perform a particular function does not limit the scope of the claim to 'the corresponding structure, material, or acts' that perform the function….") The algorithm must transform the general purpose computer to a special purpose computer programmed to perform the disclosed algorithm. *Id*. at 1338. The algorithm can be expressed "in any understandable terms including as a mathematical formula, in prose, or as a flow chart, or in any other manner that provides sufficient structure." *Noah Sys.*, 675 F.3d at 1312. If no algorithm is disclosed, then the means-plus-function clause is indefinite. *Aristocrat*, 521 F.3d at 1337–38.

When the Board cannot construe some or all the claims, the Board will either deny institution altogether or only institute on those claims it can adequately construe. *See, e.g.*, *RPX Corp. v. Applications in Internet Time, LLC*, IPR2015-01751, Paper 62 (P.T.A.B. May 12, 2016); *see also Micron Tech., Inc. v. Innovative Memory Sys., Inc.*, IPR2016-00324, Paper 11, at *8-9 (P.T.A.B. June 13, 2016).

**a) "A treatment planning apparatus arranged to divide ... prepare… calculate… [and] prescribe…" (Claims 7 and 11-13)[2]**

Claim 7 recites "the treatment planning apparatus being arranged to divide the arc into a plurality of arc-segments and to prepare a treatment plan..." By using the word "apparatus," Claim 7 recites functional language without sufficiently describing corresponding structure for each recited function. Thus, §112(f) applies even though the claim language does not recite the word "means." *Williamson*, 792 F.3d at 1348. In *Williamson*, the Federal Circuit provided the following standard for determining whether §112(f) applies: "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." *Id*. at 1349. Thus, without the word "means," §112(f) may still apply if "the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.'" *Id*. The Federal Circuit additionally held that other "nonce" words that can "operate as a substitute for 'means,'" also fail to provide "any indication of structure because it sets forth the same black box recitation of

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[2] By providing a claim construction for this term and the other means plus function terms set forth herein, Petitioner does not admit that these "means" can be construed. Petitioner reserves the right to raise arguments regarding these term under 35 U.S.C. §112 in this and related proceedings and in litigation.

structure for providing the same specified function as if the term 'means' had been used." *Id*. at 1350. Here, like in *Williamson*, claim 7 of the '843 Patent uses a nonce word, "apparatus," and recites the functions of dividing and preparing but fails to recite structure in support thereof. Thus, §112(f) applies. Similarly, claim 11 recites the function of calculating, and claims 12 and 13 recite the function of prescribing, but all fail to recite any structure in support thereof. Thus, §112(f) applies to these claims as well.

Construing a means-plus-function limitation is a two-step process: first, identifying the claimed function, and second, ascertaining the corresponding structure. *Omega Eng'g, Inc. v. Raytek Cor*, 334 F.3d 1314, 1331 (Fed. Cir. 2003).

#### *(1) The claimed functions*

The treatment planning apparatus is *arranged to*:

- divide the arc into a plurality of arc-segments (claim 7);
- prepare a treatment plan which includes… (claim 7);
- calculate an irradiation time for each arc-segment (claim 11); and
- prescribe a treatment plan that includes motion of a patient positioning system… (claims 12 and 13).

#### *(2) Recited structure*

With respect to the recited structure, the '843 Patent describes the treatment planning apparatus to be a "treatment planning computer." ('843 Patent, FIG. 6, 8:31-33.) The ’843 Patent, however, does not provide any detail for the structure of the treatment planning computer. A POSA would understand that such a computer or computers would be general purpose computers. (Gall Declaration, ¶89.)

Because the ’843 Patent merely discloses a general purpose computer, the structure disclosed in the specification must be an algorithm that transforms such a general purpose computer to a special purpose computer programmed to perform the disclosed algorithm. *Aristocrat*, 521 F.3d at 1338. As explained above, a POSA must be able to recognize the structure and associate it with the corresponding function of the claim. *See Noah Sys.*, 675 F.3d at 1312.

In the following sections III.C.1.a.2.a-d, Petitioner addresses the algorithm and/or the lack of an algorithm for (a) dividing the arc into arc-segments, (b) preparing a treatment plan, (c) calculating an irradiation time, and (d) prescribing a treatment plan that includes motion of a patient positioning system.

***(a)* The treatment planning apparatus arranged to divide the arc into a plurality of arc-segments (claim 7)**

The ’843 Patent provides an algorithm for dividing the arc into a plurality of arc-segments. For example, the ’843 Patent recites that a “desired treatment is described by a Treatment Planning computer in terms of a sequence of ‘control points’.” (’843 Patent, 6:13-14.) Control points are typically “spaced regularly around the arc such as every degree, every few degrees, or every fraction of a degree." (*Id.*, 6:21-25.) Thus, a POSA would understand that dividing the arc into a plurality of arc-segments means dividing the arc using control points spaced around the arc. (Gall Declaration, ¶91.)

**(b) The treatment planning apparatus arranged to "prepare a treatment plan which includes… (claim 7)**

The '843 fails to provide an algorithm for preparing the recited treatment plan. As provided above, the treatment planning apparatus divides an arc into a plurality of arc-segments. This limitation, recites the preparation of a plan for the arc-segments. For example, the '843 Patent provides that the treatment plan which includes "the delivery of a certain number of mu," the source "rotates a certain number of degrees," and "the multi-leaf collimator changes shape" over an arc segment. ('843 Patent 5:19-23.)

As provided in the '843 Patent, the term "mu" is an "abbreviation for 'monitor units', which is "equivalent to a unit of dose delivered to the patient." (*Id.*, 1:29-32.) "One of the tasks of a Treatment Planning computer is to ascertain the mu that need to be delivered by the apparatus in order to achieve a specific dose within the patient, both in terms of a sufficiently high dose in the tumour site and a sufficiently low dose in other parts of the patient." (*Id.*, 1:36-42.) It is unclear from the '843 Patent how the computer could ascertain the total mu needed or how the total mu might be divided among the arc-segments. (Gall Declaration, ¶93.)

Given these ambiguities, claim 7 is indefinite, because a POSA would be unable to determine from the patent the algorithm for specifying the dose (*i.e.*, total mu) to be delivered over an arc-segment. (*Id*.)

For purposes of this Petition, Petitioner will assume that this claim language covers any structure/algorithm that performs the recited function for "preparing a treatment plan which includes a… specified dose."

As described above, the treatment planning apparatus provides an algorithm for dividing the arc into a plurality of arc-segments. Claim 7, further recites that "the source rotates a first [and second] specified angle." A POSA would have understood that the angle of source rotation would coincide with the beginning angle of the arc-segment and the ending angle of the arc-segment. (*Id.*, ¶95.) Therefore, the specified angle of rotation is the angle traveled as the gantry rotates over the arc-segment. (*Id*.)

As is described in greater detail below (*See* Section III.C.1.2), the '843 Patent fails to provide a sufficient algorithm/structure for preparing a treatment plan which includes "the multi-leaf collimator changes shape at a first specified rate per degree."

#### *(c)* The treatment planning apparatus arranged to calculate an irradiation time for each arc-segment (claim 11)

The ’843 Patent is silent with respect to an algorithm performed at the treatment planning computer for performing this function. For example, the ’843 Patent states that calculating “an irradiation time for each arc-segment” is performed at the radiotherapeutic apparatus**,** a distinctly separate computer from the treatment planning apparatus. (Gall Declaration, ¶97.) For example, the ’843 Patent provides for the control means of the radiotherapeutic apparatus “being arranged to receive a treatment plan in which the arc is divided into a plurality of arc-segments, the treatment plan specifying the total dose for the arc-segment ***and a start and end MLC position,*** and to control the source in accordance with that plan… by calculating [at the control means of the radiotherapeutic apparatus] the total time required for the arc segment for a plurality of factors…” (’843 Patent, 4:34-53, emphasis added.[3])

The ’843 Patent further states that the “treatment planning [apparatus] develops a treatment plan which ***defines the treatment*** and passes this to a treatment control computer. [The treatment control computer] determines, for each arc-segment, which factor is the time-limiting factor and is thereby able to instruct each of the MLC control computer, gantry control computer, and radiation control

[3] Unless otherwise noted, any emphasis in a citation has been added.

computer as to the operation of their specific item during that arc-segment." (*Id.*, 8:31-38.) Thus, calculating "an irradiation time," as described by the '843 Patent, occurs at the treatment control computer.

However, claim 11 recites that the treatment planning apparatus is arranged to "calculate an irradiation time." The specification only describes calculating "an irradiation time" as being performed at the treatment control computer (i.e., radiotherapeutic apparatus). And the '843 Patent is silent with respect to an algorithm performed at the treatment planning computer for performing this function.

For purposes of this Petition, however, Petitioner imports into the functional capabilities of the treatment planning apparatus the algorithm of the treatment control computer (i.e., radiotherapeutic apparatus) for calculating the irradiation time for each arc-segment using the following equations:

Minimum dose time=inter-control point dose/Maximum dose rate,

Minimum gantry time=Distance of gantry move/Maximum gantry speed,

Minimum leaf time=Distance of leaf move/Maximum leaf speed,

('843 Patent, 7:13-24; Gall Declaration, ¶100.) Using the foregoing equations an irradiation time for each arc-segment apt to deliver a required dose may be calculated and a rotation speed may be inferred from the irradiation time. (Gall Declaration, ¶100.)

#### *(d)* The treatment planning apparatus arranged to prescribe a treatment plan that includes motion of a patient positioning system (claims 12 and 13)

Claims 12-13 each recite prescribing a motion of a patient positioning system during the treatment, however, the ’843 Patent fails to disclose a structure/algorithm for performing such functions. The ’843 Patent only provides that the “treatment planning apparatus can further prescribe a treatment plan that includes motion of a patient positioning system during the treatment, in a manner correlated with motion of the source and/or delivery of the dose.” (’843 Patent, 5:50-53.) Therefore, claims 12-13 are indefinite, because a POSA would be unable to recognize the structure/algorithm in the specification and associate it with the corresponding function in the claims. *Noah Sys.*, 675 F.3d. at 1312; (Gall Declaration, ¶101).

Nonetheless, for purposes of this petition, Petitioner construes these claim limitations to cover any structure/algorithm that performs the prescribing functions, as recited in claims 12-13.

**b) "Control means" (Claim 7)**

Claim 7 recites a radiotherapeutic apparatus comprising "***a control means*** able to control dose rate of the source, rotation of the source, and the multi-leaf collimator."

With respect to a recited structure, the '843 Patent provides that "the control means will ***typically*** comprise a treatment control computer and an actuator." ('843 Patent, 4:54-55.) The '843 Patent further explains that "the Treatment Control Computer can be considered to contain a Radiation Control Computer which controls the radiation generation, an MLC Control computer which controls the shape of the MLC and a Gantry Control Computer which controls the position of the Gantry. These computers may physically be one or more computers but in this text are considered as distinct functional elements of the system." ('843 Patent, 1:21-28.) The '843 Patent, however, does not provide any detail for the structure of the treatment control computer, the radiation control computer, the MLC control computer, or the gantry control computer. A POSA would understand that such a computer or computers would be general purpose computers. (Gall Declaration, ¶104.)

Because the '843 Patent discloses only general purpose computers, the structure disclosed in the specification must be an algorithm that transforms such general purpose computers to special purpose computers programmed to perform the disclosed algorithm. *Aristocrat*, 521 F.3d at 1338. As explained above, a POSA must be able to recognize the structure and associate it with the corresponding function of the claim. *See Noah Sys.*, 675 F.3d at 1312.

The ’843 Patent discloses that the treatment control computer *i.e.*, the control means, instructs “each of the MLC control computer, gantry control computer, and radiation control computer as to the operation of their specific item during that arc-segment.” (’843 Patent, 8:35-38.) However, the ’843 Patent is silent with respect how the “dose rate of the source, rotation of the source, and the multi-leaf collimator” are controlled, as recited in claim 7. For purposes of this Petition, Petitioner will assume that the functional language of the claim covers any structure/algorithm that performs the recited function for controlling the dose rate of the source, rotation of the source, and the multi-leaf collimator.

#### c) “Output means” (Claim 10)

Claim 10 recites “an output means for transmitting the treatment plan to the radiotherapeutic apparatus.” The ’843 Patent is silent as to any structure to perform the recited function of transmitting the treatment plan to the radiotherapeutic apparatus. Therefore, claim 10 is indefinite, because a POSA would be unable to recognize the structure in the specification and associate it with the corresponding function in the claims. *Noah Sys.*, at 1312; (Gall Declaration, ¶107).

Nonetheless, for purposes of this petition, Petitioner construes this claim limitation to cover any structure that performs the recited function of transmitting the treatment plan to the radiotherapeutic apparatus.

**2. "Specified rate per degree" (Claim 7)**

The term "rate per degree" is mentioned but not defined in the '843 Patent. (Gall Declaration, ¶109.) The "specified rate per degree" at which the MLC changes shape could have multiple distinct meanings. (*Id*.) For example, the '843 Patent describes an MLC as having "80 leaves." ('843 Patent, 6:46-47.) Claim 7 recites that the multi-leaf collimator changes shape at a first specified rate per degree, which seems to imply that all MLC leaves travel at the same speed, or rate per degree. (Gall Declaration, ¶109.) However, requiring each of the MLC leaves to travel at the same speed would not make sense to a POSA. (*Id*.)

The "rate per degree" at which the MLC changes shape could also refer to the rate at which the area of the beam changes per degree of rotation of the gantry. (*Id*., ¶110.) However, it is unclear from the '843 Patent how one would measure the rate of change in shape of an MLC, as the MLC leaves shift between arbitrary shapes with arbitrary areas. (*Id*.)

The "rate per degree" at which the MLC changes could further indicate the travel speed of each of the MLC leaves per degree of rotation of the gantry. (*Id*., ¶111.) However, the '843 Patent does not provide a reasoned basis on which a

POSA could determine whether this limitation is meant to indicate a rate of change in area of the beam or a rate of change in the speed of leaf travel for a single leaf or for all leaves. (*Id*.) Further, the ’843 Patent fails to identify how the rate per degree is “specified.” Given these ambiguities, claim 7 is indefinite, because a POSA would be unable to determine the meaning of the term “specified rate per degree.” (*Id*.)

Given the ambiguities described above, the rate of change per degree could pertain to leaf speed rather than the rate of change in area. (*Id.*, ¶112.) In that case, the leaf speed could be specified using the following equation:

Expected leaf speed=Distance of leaf move/Expected arc-segment time

(’843 Patent, 7:42-45; Gall Declaration, ¶112.)

For purposes of this Petition, changing the shape of the MLC at a first and a second “specified rate per degree” should be construed to mean the “rate of any change in MLC aperture shape per degree of gantry rotation.” One way to measure a change in aperture shape per degree of gantry rotation is to determine the travel speed of an MLC leaf per degree of gantry rotation. (Gall Declaration, ¶113.) One way to specify the rate per degree is to specify a starting MLC shape, an ending MLC shape, and an arc-segment time. (*Id*.)

### 3. "The rotation speed" (Claim 8)

Claim 8 of the '843 Patent recites "[t]he treatment planning apparatus according to claim 7 in which the rotation speed [is] constant during an arc-segment…" However, claim 7 does not recite a "rotation speed." This lack of antecedent basis renders claim 7 indefinite under 35 U.S.C. §112. *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 n.6 (2014); *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1291-92 (Fed. Cir. 2006).

In the event that the Board finds that claim 7 is not indefinite, for purposes of this petition, "the rotation speed" should be construed to mean "a rotation speed."

## IV. OVERVIEW OF THE PRIOR ART

The earliest priority date for the '843 Patent is based on the filing date of International patent application number PCT/EP2006/003901, filed on April 27, 2006.

**Earl** (Ex. 1009), U.S. Patent Application Publication No. 2004/0071261 to Earl et al., titled "Novel Method for the Planning and Delivery of Radiation Therapy," was filed December 3, 2001, and published April 15, 2004. Therefore, Earl is prior art under 35 U.S.C. §102(b).

**Bjärngard** (Ex. 1023), titled "Computer-Controlled Radiation Therapy" by Bjärngard et al., was published in the AMIA Annual Symposium Proceedings, November 9, 1978. Therefore, Bjärngard is prior art under 35 U.S.C. §102(b).

**Yu** (Ex. 1007), titled "Clinical Implementation of Intensity-Modulated Arc Therapy," by Yu et al., was published in the International Journal of Radiation Oncology * Biology * Physics in June 2002. Therefore, Yu is prior art under 35 U.S.C. §102(b).

**Otto** (Ex. 1026), U.S. Patent No. 7,906,770 to Otto titled "Methods and apparatus for the planning and delivery of radiation treatments," was filed July 25, 2006 and issued March 15, 2011. Otto claims priority to U.S. Provisional Patent Application No. 60/701,974 (Ex. 1027) which was filed July 25, 2005[4]. Therefore, Otto is prior art under 35 U.S.C. §102(e).

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[4] Otto is entitled to a July 25, 2005 §119(e) prior art date, the filing date of its earliest provisional application. *See, e.g., Dynamic Drinkware, LLC v. National Graphics Inc*., 800 F. 3d 1375 (Fed. Cir. 2015) (holding that a §102(e) reference is prior art as of the filing date of its provisional application under §119(e), if that provisional provides proper written description support for a claim and the relevant text was carried forward from the provisional). The claims of Otto are fully supported by the Otto Provisional (Ex. 1027) and the relevant teachings in Otto are carried forward from the Otto Provisional. (Gall Declaration, Footnote 1.)

## V. IDENTIFICATION OF CHALLENGE (37 C.F.R. §42.104(b))

Obviousness is a question of law that is resolved based on underlying factual determinations: (1) the prior art's scope and content, (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. *Graham v. John Deere Co. of Kansas City,* 383 U.S. 1, 17-18 (1966).[5] As the Supreme Court explained, "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results," and "[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of

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[5] Petitioner reserves the right to provide a full rebuttal to any secondary consideration evidence provided during this proceeding. Petitioner cannot address such evidence now because Patent Owner has not yet provided any. Petitioner notes, however, that "[f]or objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010). Moreover, a strong showing of obviousness, as in this case, overcomes secondary considerations. *See, e.g., Leapfrog Enters, Inc.. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

ordinary skill can implement a predictable variation, 35 U.S.C. §103 likely bars its patentability." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416, 417 (2007). Indeed, a prior art combination is obvious to try "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *Id.* at 421.

Petitioner identifies how the prior art teaches or suggests each challenged claim element, as well as element-specific motivations as to why and how to combine the references. Given the similarity of the challenged claims, some explanations below refer to earlier discussions of the same or similar elements to avoid repetition.

## VI. Ground 1: Earl renders obvious claims 7, 9-11, and 14.

As will be explained in greater detail below, Earl renders obvious claims 7, 9-11, and 14 directed toward a treatment planning apparatus. (Gall Declaration, ¶271.)

### A. Earl renders claim 7 obvious

#### 1. Earl teaches or suggests limitation [7.P]: "a treatment planning apparatus, for a radiotherapeutic apparatus of the type"

Earl provides that the "present invention covers the method of planning and delivery of the radiation treatment plan for IMRT, IMAT, and [a hybrid thereof]." (Earl, [0033]-[0034].) Thus, Earl teaches or suggests this limitation. (Gall Declaration, ¶273.)

#### 2. Earl teaches or suggests limitation [7.1.A]: "a source able to emit a beam of therapeutic radiation along a beam axis"

The '843 Patent does not provide a definition for a beam axis. However, a POSA would have understood that a beam axis is the axis, or line, directed from the radiation source toward a target upon which a beam travels. (Gall Declaration, ¶274.)

Referring to Figure 4, Earl describes "a linear accelerator … which is a device capable of controlled ***delivery of radiation to a patient*** in need of radiation therapy. The radiation exits through the end of the treatment head which is mounted on the gantry…" (Earl, [0025].) Earl's radiation is emitted from the linac and delivered to a patient along a beam axis. (Gall Declaration, ¶275.) Thus, Earl teaches or suggests this limitation. (*Id*.)

### 3. Earl teaches or suggests limitation [7.1.B]: "rotate about a rotation axis that intersects[6] with the beam axis thereby to describe an arc around the rotation axis"

Earl describes a linear accelerator with a gantry that can "rotate about a horizontal axis H of rotation around the patient who is lying on the bed." (Earl, [0025].) A POSA would have understood that Earl's horizontal axis H of rotation teaches or suggests a rotation axis. (Gall Declaration, ¶277.)

Further, during treatment, Earl's radiation beam is "directed on a part of the treatment area on the patient. The gantry can rotate about a horizontal axis of rotation; thus allowing for a change in the angle of treatment." (Earl, [0026].) A POSA would have understood that Earl's rotation about a horizontal axis of rotation teaches or suggests an arc around the rotation axis that intersects with the beam axis. (Gall Declaration, ¶278.) Thus, Earl teaches or suggests this limitation. (*Id*.)

### 4. Earl teaches or suggests limitation [7.2]: "a multi-leaf collimator arranged to collimate the beam to a desired shape"

Earl provides that in some linacs, "the treatment head is equipped with ***a multi-leaf collimator (MLC) which shapes the radiation field***." (Earl, [0025].) Further, Earl provides that in an MLC, "there are opposing banks of leaves. Each

[6] On July 10, 2012 the USPTO issued a Certificate of Correction that inserted the term "intersects" into claim 7.

opposing leaf is attached to a drive unit. The drive units drive the leaves, in and out of the treatment field, thus ***creating the desired field shape***." (*Id.*, [0029].) Thus, Earl teaches or suggests this limitation. (Gall Declaration, ¶¶280-281.)

#### 5. Earl teaches or suggests limitation [7.3]: "a control means able to control dose rate of the source, rotation of the source, and the multi-leaf collimator"

Earl discloses a Linac Control System (LCS) that controls the linear accelerator. (Gall Declaration, ¶283.) For example, Earl provides that the "LCS coordinates ***radiation delivery*** and ***MLC leaf movement*** in order to achieve the desired intensity patterns. The LCS controls ***execution of the prescription generated*** by the present invention and transferred to the linac control system from the treatment planning system." (Earl, [0032].)

By executing Earl's prescription plan, the LCS must deliver a plan that accounts for a number of geometric constraints, as directed by the prescription. (*See* Earl, [0032]-[0035].) The geometric constraints include, "the ***MLC leaf positions*** for the particular linear accelerator, the linac ***gantry speed***, the ***dose rate***, and MLC ***leaf travel speed***." (Earl, [0042].)

As described in Section III.c.1.b, the '843 Patent does not provide a structure or algorithm for the function of controlling the dose rate of the source, rotation of the source, and the multi-leaf collimator. For purposes of this Petition, this claim language covers any structure/algorithm that performs the recited functions, as described in Section III.c.1.b. Accordingly, a POSA would have understood that Earl's LCS is a structure (i.e., control means) able to perform the function of controlling the dose rate of the source, rotation of the source, and the multi-leaf collimator, as claimed. (*Id.*; Gall Declaration, ¶285.) Further, to the extent that the Board finds that the '843 Patent implies some algorithm, a POSA would have understood that the prescription, executed by the LCS, would also have included some algorithm to perform the recited functions. (*Id*.) Thus, Earl teaches or suggests the function of controlling the dose rate of the source, rotation of the source, and the multi-leaf collimator. (*Id.*) A POSA would have understood that Earl's LCS is capable of performing these functions. (*Id.*)

A POSA would have understood that an LCS is "a computer to control treatment" based on a prescription generated by a treatment planning system. (Gall Declaration, ¶286.) Thus, Earl teaches or suggests this limitation. (*Id.*)

### 6. Earl teaches or suggests limitation [7.4]: "the treatment planning apparatus being arranged to divide the arc into a plurality of arc-segments and to prepare a treatment plan which includes"

This claim element recites functionality performed by the treatment planning apparatus structure described above. Earl discloses a treatment planning apparatus being arranged to divide the arc into a number of evenly spaced arcs and to prepare a prescription file. (Gall Declaration, ¶287.) For example, Earl provides a treatment planning system that is "distinct from the LCS..." (Earl, [0034].)

Earl teaches that a user must select the "***number of arcs and the range for each arc***." (Earl, [0037].) Then, after the "consideration factors (the delivery angles and number of apertures assigned to each angle… or the number of arcs and range for each arc for IMAT) are entered… the treatment planning system automatically calculates ***evenly spaced radiation beams to approximate the range of rotation of the gantry***." (Earl, [0037].) As described, Earl divides the total radiation arc into a number of arc-segments. (Gall Declaration, ¶288.)

A POSA would have understood that Earl's treatment planning system performs the recited functions. (Gall Declaration, ¶289.) A POSA would have further understood that Earl's process for calculating the arcs and range for each arc would have included an algorithm for dividing the arc into a plurality of arc-segments and preparing a treatment plan, because Earl teaches the creation of treatment plans for all available linacs. (*Id*.) Thus, Earl teaches or suggests this limitation. (Gall Declaration, ¶290.)

**7. Earl teaches or suggests limitation [7.4.A]: "a first arc-segment adapted to deliver a first specified dose during which the source rotates a first specified angle and the multi-leaf collimator changes shape at a first specified rate per degree"**

This claim element recites functionality performed by the treatment planning apparatus. Earl's arc delivery is divided up into a plurality of segments, each segment having a range of gantry rotation. (Gall Declaration, ¶292.) Specifically, Earl teaches that a user must select the "***number of arcs and the range for each***

***arc***." (Earl, [0037].) Then, after the "consideration factors (the delivery angles and number of apertures assigned to each angle… or the number of arcs and range for each arc for IMAT) are entered… the treatment planning system automatically calculates evenly spaced radiation beams to approximate ***the range of rotation of the gantry***." (*Id*.) As described, Earl divides the total radiation arc into a number of arc-segments, each segment having a range of gantry rotation. (Gall Declaration, ¶292.)

Earl's treatment planning system further provides that in step 66, the system "assigns an initial aperture shape ***for each beam angle***… the treatment planning system also assigns a relative weight (intensity) to each aperture shape… [and] ***calculates the radiation dose***, the radiation dose distribution, and the dose distribution quantity (objective function)." (*Id.*, FIG 1, [0040].) Earl's treatment planning system also "calculates the radiation dose applied to the treatment area." (*Id.*, [0043].) A POSA would have understood that Earl teaches or suggests "specifying a total dose for an arc-segment," as claimed. (Gall Declaration, ¶293.)

Further, Earl's MLC has a start and end position. (*Id.*, ¶294.) "During delivery, the MLC leaves move in order to achieve the desired treatment." (*Id.*, [0032] and [0007] (the MLC "shapes each individual beam of radiation").)

Furthermore, Earl's optimization process considers a number of variables, including: "the ***positions of the MLC leaves*** used to shape each aperture for each beam angle." (*Id.*, [0041].) Earl's delivered beams generally require "very high accuracy in the positions of the MLC leaves." (*Id.*, [0053].) Further, "there are limitations on the ***speed at which the leaves of the multileaf collimator can travel***." (Earl, [0015].) Taken together, the speed at which Earl's MLC leaves change the beam shape within an arc teaches or suggests an MLC changing shape at a first specified rate per degree. (Gall Declaration, ¶294.)

A POSA would have understood that Earl's treatment planning system performs the recited functions. To the extent that the Board finds that the '843 Patent implies some algorithm, a POSA would have further understood that Earl's optimization process would have also included some algorithm to perform the function of preparing a treatment plan in which a first arc-segment adapted to deliver a first specified dose during which the source rotates a first specified angle and the multi-leaf collimator changes shape at a first specified rate per degree, because Earl describes the creation of a treatment plan having the recited capabilities. (*Id.*, ¶295.) Thus, Earl teaches or suggests this limitation. (*Id.*, ¶296.)

#### 8. Earl teaches or suggests limitation [7.4.B]: "a second arc segment adapted to deliver a second specified dose during which the source rotates a second specified angle and the multi-leaf collimator changes shape at a second specified rate per degree, such that at least the first and second specified rates per degree differ as between the first and second arc-segments"

This claim element recites additional functionality performed by the treatment planning apparatus. As described in Section VI.A.6, Earl teaches or suggests multiple arc-segments adapted to deliver a specified dose within that arc-segment. Thus, Earl teaches or suggests both a first arc-segment and a second-arc segment. (Gall Declaration, ¶¶297-298.)

Additionally, as described in Section VI.A.7, Earl teaches a gantry rotating a specified angle. Earl discloses multiple gantry angles over a prescribed treatment. (Earl, [0040]; Gall Declaration, ¶299.) Thus, Earl teaches or suggests both a first specified rotation angle and a second specified rotation angle. (Gall Declaration, ¶299.)

Yet further, as described in Section VI.A.7, Earl teaches or suggests a multi-leaf collimator that changes shape at varying speeds based on the prescribed shape. (*Id*., ¶300.) In each of the embodiments described above, Earl discloses multi-leaf collimator changes over a prescribed treatment. (*Id*.)

Earl further teaches or suggests that the specified rates per degree differ as between the first and second arc-segments. (Gall Declaration, ¶301.) For example, Earl provides that "[r]otational delivery would have additional constraints imposed by the speed of the gantry rotation and speed of the MLC leaves." (Earl, [0017].) Accordingly, each angle has a different beam shape, and therefore, could require a different MLC leaf speed. (Gall Declaration, ¶301.)

Earl additionally provides that:

> [I]t is understood that different MLC's can have widths ranging from 2 mm to 12 mm, range of travel ranging from 1 cm to over 32 cm, and different restrictions. Dynamic constraints include, but not limited to, the ***speed of leaf travel,*** the acceleration and deceleration. These static and dynamic geometric constraints ***determine the kind of aperture shapes that a particular MLC can form***.

(Earl, [0027].) The speed of leaf travel directly affects the kind of aperture shape that an MLC can form. (Gall Declaration, ¶302.) Changing the shape at a second specified rate per degree, such that at least the first and second specified rates per degree differ as between the first and second arc-segments would have been obvious in view of Earl's process (*Id*.) And a POSA would understand from the teachings of Earl that MLC leaf travel speed would vary from arc-segment to arc-segment depending on how much movement is required to change the MLC aperture shape over the arc segment. (*Id*., 303) An arc-segment having less shape change would use slower MLC leaf travel speeds as compared to an arc-segment having greater shape change. (*Id*.)

At least for the reasons described in Section VI.A.7, a POSA would have understood that Earl teaches or suggests the structure and would have included some algorithm for performing the recited functions. (Gall Declaration, ¶304.) Thus, Earl teaches or suggests this limitation. (Gall Declaration, ¶305.)

### B. Earl renders claim 9 obvious: "the first arc-segment and the second arc-segment are consecutive"

Earl teaches or suggests that the first arc-segment and the second arc-segment are adjacent. For example, Earl provides:

> With IMAT, the radiation is delivered while the gantry rotates continuously. Current inverse-planning algorithms fail to take the gantry's continuous movement into account. One feature of IMAT treatment plans is that the aperture shapes for ***adjacent angles within an arc*** must not differ significantly. This constraint exists because there are limitations on the speed at which the leaves of the multileaf collimator can travel.

(Earl, [0015].) A POSA would have understood that Earl's adjacent angles within an arc teach or suggest the consecutive first and second arc-segments, as claimed. (Gall Declaration, ¶307.) Thus, Earl teaches or suggests this claim. (*Id*.)

### C. Earl renders claim 10 obvious: "an output means for transmitting the treatment plan to the radiotherapeutic apparatus"

Earl teaches that its treatment planning system is "distinct from the LCS…" (Earl, [0034].) Earl further provides that a treatment plan is transferred from Earl's "treatment planning system… to the LCS in the form of a Prescription file. The optimal treatment plan is loaded onto the LCS via a diskette, a computer network link, or any other means known in the art field capable of transferring data between two distinct computers." (*Id.*, [0050].) As such, Earl's diskette and network link provide the structure of an output means capable of providing the function of transmitting the treatment plan to the LCS via a diskette or network link. (Gall Declaration, ¶310.)

As described in Section III.C.1.c, the ’843 Patent is silent as to any structure to perform the recited function, however, for purposes of this Petition, this claim limitation should be construed as any structure that performs the function of transmitting the treatment plan to the radiotherapeutic apparatus. Accordingly, a POSA would have understood that Earl’s treatment planning system and computer network link, diskette, or other means, teach or suggest the structure for performing the transmitting function. (*Id.*) Thus, Earl teaches or suggests this dependent claim. (*Id*.)

### D. Earl renders claim 11 obvious: “arranged to calculate an irradiation time for each arc-segment apt to deliver a required dose and to infer a rotation speed from the irradiation time”

This claim element recites additional functionality performed by the treatment planning apparatus. Earl teaches that time is an important aspect for creating and optimizing a radiation plan. For example, Earl explains that “[a] longer radiation exposure time for a specific location in the treatment portal corresponds to a higher radiation intensity… A modulated intensity radiation field occurs when the MLC opening changes such that different locations of the treatment portal are exposed for different durations.” (Earl, [0031].) As a result, Earl’s geometric constraints should be evaluated in terms of time. (Gall

Declaration, ¶315.) More specifically, a POSA would have understood that calculating an irradiation time would have been an obvious step in determining gantry speed and MLC leaf travel speed because "speed" is generally evaluated in terms of time. (*Id*.) Given this context, Earl provides:

> [T]he treatment planning system determines… if one or more geometric constraints is violated by [a] modification. Examples of geometric constraints include, but are not limited to, the ***MLC leaf positions*** for the particular linear accelerator, the ***linac gantry speed***, the ***dose rate***, and ***MLC leaf travel speed***. If the proposed modified aperture shape or intensity violates any of geometric constraints, the treatment planning system rejects the modified aperture shape…

(Earl, [0042].)

A POSA would have understood that a geometric constraint is violated when an action or intensity exceeds a maximum value. (Gall Declaration, ¶316.) A POSA would have understood that Earl's optimized delivery plan could only occur as fast as its slowest parameter. (*Id*.) Calculating an irradiation time for each arc-segment apt to deliver a required dose and to infer a rotation speed from the irradiation time would have been an obvious step in determining which of Earl's parameters would be limiting, because the relationship between speed, time and distance (e.g., measured in degrees of rotation) is governed by a simple equation (e.g., distance equals speed multiplied by time) that would have been apparent to a POSA. (*Id.*, ¶317.) Thus, Earl teaches or suggests this claim. (*Id*.)

### E. Earl renders claim 14 obvious: "the beam axis and the axis of rotation of the source are substantially orthogonal"

Earl describes a linear accelerator with a gantry that can "rotate about a horizontal axis H of rotation around the patient who is lying on the bed." (Earl, [0025].) Earl's horizontal axis H of rotation is a rotation axis that is substantially orthogonal to and intersects with the beam axis. (Gall Declaration, ¶320.) Thus, Earl teaches or suggests this claim. (*Id*.)

## VII. Ground 2: Earl in view of Bjärngard renders obvious claims 12-13.

As explained in greater detail below, the combination of Earl and Bjärngard renders obvious claims 12-13 directed toward a treatment planning apparatus. (Gall Declaration, ¶322.) As described in greater detail below, Earl and Bjärngard would have been nothing more than combining prior art elements according to known methods, with no change in their respective functions, to yield predictable results, and the combination teaches or suggests claims 12-13. (*Id*., ¶¶322 and 330.)

### A. The combination of Earl and Bjärngard renders claim 12 obvious: "prescribe a treatment plan that includes motion of a patient positioning system during the treatment in a manner correlated with motion of the source"

#### 1. Earl

To the extent Patent Owner argues that Earl does not teach or suggest this claim, it is taught or suggested by Bjärngard.

### 2. Bjärngard

Bjärngard describes a computer control technology designed to operate complex clinical therapy machinery such as linear accelerators. (Bjärngard, 86.) Bjärngard explains that the linear accelerators are modified to "allow control of twelve parameters by a computer [that] has been installed." (*Id*.) Before treatment begins, Bjärngard teaches that the "motions of all parameters must be prescribed and properly synchronized." (Bjärngard, 90.) The treatment prescription further specifies "the position and velocity for each moving parameter as functions of time." (*Id.*)

As illustrated in Table I, reproduced below, the synchronized parameters are listed "with the ranges of their values and the corresponding time derivatives, i.e. velocities and dose rate." (Bjärngard, 87.)

| FUNCTION | POSITION RANGE | MAXIMUM SPEED |
|---|---|---|
| Gantry | -190 to 190° | 6 deg/s |
| Outer jaw (#1) | - 11 to 18 cm | 1.5 cm/sec |
| Outer jaw (#2) | - 11 to 18 cm | 1.5 cm/sec |
| Inner jaw (#3) | 0 to 18 cm | 1.5 cm/sec |
| Inner jaw (#4) | 0 to 18 cm | 1.5 cm/sec |
| Collimator rotation | - 90 to 90° | 6 deg/s |
| Couch vertical | 78 to 133 cm | 1.5 cm/sec |
| Couch lateral | - 24 to 24 cm | 1.5 cm/sec |
| Couch longitudinal | 0 to 80 cm | 1.5 cm/sec |
| Couch isocentric | -120 to 120° | 6 deg/s |
| Dose | 0 to 999 rad | 5 rad/sec |

(Bjärngard, Table I, 88.) As shown, the couch (*i.e.*, patient positioning system) movements, gantry position/speed (*i.e.*, motion of the source), and dose rate are among the controlled and synchronized parameters. (Gall Declaration, ¶325.) In view of the foregoing, a POSA would have understood that the prescribed movements are correlated and are performed while the treatment is delivered. (*Id*.)

Thus, Bjärngard teaches or suggests the function of prescribing a treatment plan. (Gall Declaration, ¶326.) And Bjärngard teaches or suggests a computer for performing these functions. Thus, the combination of Earl and Bjärngard teaches or suggests this claim. (*Id*.)

### B. The combination of Earl and Bjärngard renders claim 13 obvious: "prescribe a treatment plan that includes motion of a patient positioning system during the treatment in a manner correlated with delivery of the dose"

#### 1. Earl

To the extent Patent Owner argues that Earl does not teach or suggest this claim, it is taught or suggested by Bjärngard.

#### 2. Bjärngard

This claim element recites additional functionality performed by the treatment planning apparatus. As described immediately above, Bjärngard explains that the linear accelerators are modified to "allow control of twelve parameters by a computer [that] has been installed." (Bjärngard, 86.) Before treatment begins, Bjärngard teaches that the "motions of all parameters must be prescribed and properly synchronized." (Bjärngard, 90.) The treatment prescription further specifies "the position and velocity for each moving parameter as functions of time." (*Id*.)

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| Inner jaw (#3) | 0 to 18 cm | 1.5 cm/sec |
| Inner jaw (#4) | 0 to 18 cm | 1.5 cm/sec |
| Collimator rotation | - 90 to 90° | 6 deg/s |
| Couch vertical | 78 to 133 cm | 1.5 cm/sec |
| Couch lateral | - 24 to 24 cm | 1.5 cm/sec |
| Couch longitudinal | 0 to 80 cm | 1.5 cm/sec |
| Couch isocentric | -120 to 120° | 6 deg/s |
| Dose | 0 to 999 rad | 5 rad/sec |

(Bjärngard, Table I, 88.) As shown, the couch (*i.e.*, patient positioning system) movements and delivery of the dose rate are among the synchronized parameters. (Gall Declaration, ¶330.) In view of the foregoing, a POSA would have understood that the prescribed movements are correlated with the dose rate while the treatment is delivered. (*Id*.) Thus, the combination of Earl and Bjärngard teaches or suggests this claim. (*Id*.)

### C. *KSR* Rationale and Motivation to Combine Earl and Bjärngard.

Enhancing Earl's radiotherapeutic planning system with Bjärngard's method for synchronizing and controlling the movements of the patient positioning assembly, gantry, and dose rate would have been obvious to a POSA because it would have been nothing more than combining prior art elements according to known methods, with no change in their respective functions, to yield predictable results. (*See KSR*, 550 U.S. at 416; Gall Declaration, ¶331.)

Earl does not disclose a patient positioning assembly. However, by April 27, 2006, planning systems capable of preparing a treatment plan comprising movements of a patient positioning assembly had been developed. To provide a more robust radiation planning system by incorporating a patient positioning assembly into a treatment plan, a POSA would have looked to Bjärngard. As I described above, Bjärngard provides movements of a patient positioning assembly during treatment that are synchronized with gantry position/speed (*i.e.*, source position) and dose rate. Earl and Bjärngard are directed to a common field of endeavor—planning and providing optimized radiation dose distributions to a target mass while reducing damage to surrounding tissue. Specifically, both Earl and Bjärngard are directed to radiotherapeutic planning and control systems that control the dose rate and other parameters to ensure the efficacy of a radiation treatment.

A POSA would have understood that motion of the source, dose rate, and motion of the patient positioning system would have needed to be correlated. (Gall Declaration, ¶333.) Further, a POSA could have enhanced the respective teachings of Earl and Bjärngard with no change to their respective features or functions, and the combination would have yielded nothing more than predictable results. (*Id*.)

The predictable results being radiotherapeutic apparatus having a patient positioning system capable of monitoring and correcting the patient's position relative to the radiation source. (*Id*.)

# VIII. Ground 3: Earl in view of Yu renders obvious claims 7, 9-11 and 14.

As explained in greater detail below, combining Earl and Yu would have been obvious to a POSA because the combination would have merely involved combining known methods, to produce predictable results having a reasonable expectation of success. (Gall Declaration, ¶334.)

## A. Earl in view of Yu renders claim 7 obvious

### 1. Earl teaches or suggests limitation [7.P]: "a treatment planning apparatus, for a radiotherapeutic apparatus of the type comprising

Earl teaches or suggests limitation [7.P], at least for the reasons described in Section VI.A.1 above.

### 2. Earl teaches or suggests limitations [7.1.A], [7.1.B], and [7.2]

Earl teaches or suggests limitations [7.1.A], [7.1.B], and [7.2], at least for the reasons described in Sections VI.A.2-4, respectively.

### 3. The combination of Earl and Yu teaches or suggests limitation [7.3]: "a control means able to control dose rate of the source, rotation of the source, and the multi-leaf collimator"

#### a) Earl

Earl teaches or suggests limitation [7.3], at least for the reasons described in Section VI.A.5 above. However, to the extent Patent Owner argues that Earl does not teach or suggest this limitation, it is taught or suggested by Yu.

#### b) Yu

Yu describes, "[t]he IMAT delivery is implemented on an MLC system equipped on a digitally controlled linear accelerator." (Yu, 455.) Yu further describes that dose rate, the gantry rotation, and the MLC movement can be used as constraints in the treatment planning process::

> Because of the ways the field shapes at each beam angle were determined, the field shapes at neighboring angles typically did not differ significantly. As a result, MLC leaves were not required to ***travel large distances*** from one angle to the next. For most cases, ***gantry rotation speed***, rather than leaf traveling speed, was the ***factor limiting the dose rate***. The MLC prescriptions generated by the leaf sequencer were then sent to the MLC controller for ***dynamic delivery*** through a local network link.

(*Id.*) As described, a POSA would have understood that Yu teaches a linear accelerator having an MLC controller (*i.e.*, control means) capable of controlling the dose rate emitted, the gantry rotational speed, and the positions of the MLC. (Gall Declaration, ¶341.)

The ’843 Patent does not provide a structure or algorithm for the function of controlling the dose rate of the source, rotation of the source, and the multi-leaf collimator. (Gall Declaration, ¶342.) For purposes of this Petition, this claim language covers any structure/algorithm that performs the recited functions, as described in Section III.C.1.b. Accordingly, a POSA would have understood that a digitally controlled linear accelerator includes “a computer to control treatment” for performing the function of controlling the dose rate of the source, rotation of the source, and the multi-leaf collimator. (*Id*.) Further, to the extent that the Board finds that the ’843 Patent implies some algorithm, a POSA would have understood that Yu’s IMAT treatment program would have also included some algorithm to perform the recited functions, because Yu provides a treatment having the recited features. (*Id*.; Yu, 455 (“The IMAT delivery is implemented on an MLC system equipped on a digitally controlled linear accelerator…”).) Thus, the combination of Earl and Yu teaches or suggests this limitation. (Gall Declaration, ¶342.)

#### 4. The combination of Earl and Yu teaches or suggests limitation [7.4]: “the treatment planning apparatus being arranged to divide the arc into a plurality of arc-segments and to prepare a treatment plan which includes”

##### a) Earl

Earl teaches or suggests limitation [7.4], at least for the reasons described in Section VI.A.6 above. However, to the extent Patent Owner argues that Earl does not teach or suggest this limitation, it is taught or suggested by Yu.

**b) Yu**

Yu discloses a treatment planning apparatus for developing intensity-modulated treatment plans in which the arc is divided into a plurality of arc-segments, each segment having a start and an end MLC position. (Gall Declaration, ¶344.) For example, Yu explains that "[a]rcs are approximated as multiple shaped fields spaced every 5–10° around the patient." (Yu, 454.) Yu continues by explaining that "the field shapes are only defined at a set of beam angles spaced 10° apart." (*Id.*, 455.) In another example, Yu describes an IMAT procedure where "[s]haped fields ranging from 4 cm X 4 cm to 30 cm X 30 cm spaced 5–20° were used for approximating an arc [and] was delivered to a cubical phantom both individually as calculations ***were carried out in the plan and in arc fashion***." (*Id.*)

A POSA would have understood that Yu's treatment planning system performs the recited functions. (Gall Declaration, ¶344.) A POSA would have further understood that, for approximating fields spaced around the patient, Yu's system would have included an algorithm for dividing the arc into a plurality of arc-segments and preparing a treatment plan. (Gall Declaration, ¶346.) Thus, Yu teaches or suggests the function of dividing the arc into a plurality of arc-segments and preparing a treatment plan. (*Id*.) Thus, the combination of Earl and Yu teaches or suggests this limitation.

#### 5. The combination of Earl and Yu teaches or suggests limitation [7.4.A]: "a first arc-segment adapted to deliver a first specified dose during which the source rotates a first specified angle and the multi-leaf collimator changes shape at a first specified rate per degree"

##### a) Earl

Earl teaches or suggests limitation [7.4.A], at least for the reasons described in Section VI.A.7 above. However, to the extent Patent Owner argues that Earl does not teach or suggest this limitation, it is taught or suggested by Yu.

##### b) Yu

Yu provides a plan specifying a total dose amount, a gantry rotation, and MLC movement for each arc-segment. (Gall Declaration, ¶348.) For example, "[d]uring delivery, the field shape, which is formed by a multileaf collimator (MLC), changes continuously as determined by the treatment plan….The weight of the arcs, ***or total MUs delivered in different arcs***, are typically different." (Yu, 454.) Thus, Yu teaches or suggests multiple arc-segments adapted to deliver a specified dose within that arc-segment. (Gall Declaration, ¶348.)

While delivering the dose, Yu's gantry rotates a specified angle. (Gall Declaration, ¶349.) Yu provides several embodiments, each having specified gantry angles, including a technique that used "***six fields at gantry angles*** of 0°, 50°, 135°, 180°, 225°, and 310°" [and an] inverse plan [that] used "***seven evenly spaced***…***intensity-modulated fields*** with the first beam at gantry angle 0°." (Yu, 461.) Thus, Yu teaches or suggests rotating the gantry a first specified angle. (Gall Declaration, ¶349.)

Yu teaches or suggests the importance of MLC leaf travel speed. (Gall Declaration, ¶350.) To maintain continuous leaf travel within and between arc-segments, as described above, the leaf travel speed (*i.e.*, rate per degree) is dictated by the prescribed field shape. (*Id*.) For example, where "large leaf travel was required," the leaves may be required to move at a fast speed, while alternatively, field shapes may vary "slowly between angles" and a slower leaf speed is used. (Yu, 456; Gall Declaration, ¶350.) A POSA would have understood that Yu's MLC leaf travel speed is dictated by the prescribed field shape. (Yu, 455-456; Gall Declaration, ¶350.)

A POSA would have understood that Yu's treatment planning system performs the recited functions. To the extent that the Board finds that the '843 Patent implies some algorithm, a POSA would have further understood that Yu's treatment planning system would have also included some algorithm to perform the function of preparing a treatment plan in which a first arc-segment adapted to deliver a first specified dose during which the source rotates a first specified angle and the multi-leaf collimator changes shape at a first specified rate per degree, because Yu provides a treatment having the recited functions. (Gall Declaration,

¶352.) Thus, the combination of Earl and Yu teaches or suggests this limitation. (*Id*.)

**6. The combination of Earl and Yu teaches or suggests limitation [7.4.B]: "a second arc segment adapted to deliver a second specified dose during which the source rotates a second specified angle and the multi-leaf collimator changes shape at a second specified rate per degree, such that at least the first and second specified rates per degree differ as between the first and second arc-segments"**

**a) Earl**

Earl teaches or suggests limitation [7.4.B], at least for the reasons described in Section VI.A.8 above. However, to the extent Patent Owner argues that Earl does not teach or suggest this limitation, it is taught or suggested by Yu.

**b) Yu**

Yu teaches or suggests a second arc-segment adapted to deliver a second specified dose during which the source rotates a second specified gantry angle and the multi-leaf collimator changes shape at a second MLC leaf travel speed per distance per gantry angle, such that at least the first and second specified rates per degree differ as between the first and second arc-segments. (Gall Declaration, ¶354.)

Yu teaches or suggests multiple arc-segments adapted to deliver a specified dose within that arc-segment, as described in Section VIII.A.4.b. (Yu, 454; Gall Declaration, ¶355.) Thus, teaches or suggests both a first arc-segment and a second arc-segment. (*Id*.)

Yu additionally teaches or suggests multiple specified gantry angles, as described in Section VIII.A.5.b. (Yu, 461; Gall Declaration, ¶356.) Thus, Yu teaches or suggests both a first specified rotation angle and a second specified rotation angle. (*Id*.)

Further, Yu describes an MLC that changes shape at a specified rate per degree based on the prescribed leaf travel, as described in Section VIII.A.5.b. (Yu, 455-456; Gall Declaration, ¶357.) Thus, Yu teaches or suggests both a first specified rate per degree and a second specified rate per degree. (*Id*.)

Yu explains that the leaf position may not change in the case where two successive segments are the same. (Yu, 455.) However, in the context of Yu, a POSA would have understood that a case where leaf position does not change would be an anomaly. (Yu, 455; Gall Declaration, ¶358.) More specifically, a POSA would have understood that targets are irregular and changing leaf positions is an obvious method for accommodating changes in target shape. (Gall Declaration, ¶358.) In view of the foregoing, a POSA would have also understood that it is likely that the first and second specified rates per degree differ as between the first and second arc-segments. (*Id*., ¶359.)

At least for the reasons described in Section VIII.A.5.b, a POSA would have understood that Yu teaches or suggests the structure and would have included some algorithm for performing the recited functions. Thus, the combination of Earl and Yu teaches or suggests this limitation. (*Id*., ¶¶360-361.)

### B. The combination of Earl and Yu renders claim 9 obvious: "the first arc-segment and the second arc-segment are consecutive"

#### 1. Earl

Earl teaches or suggests claim 9, at least for the reasons described in Section VI.B above. However, to the extent Patent Owner argues that Earl does not teach or suggest this limitation, it is taught or suggested by Yu.

#### 2. Yu

Yu teaches or suggests a first arc-segment and the second arc-segment are successive segments. (Gall Declaration, ¶364.) For example, Yu provides that:

> It is important to understand that the field shapes are only defined at a set of beam angles spaced 10° apart. In between two successive beam angles, the MLC controller linearly interpolates the leaf positions. Therefore, the leaves are moving continuously throughout the delivery, unless the leaf positions of ***two successive segments*** are the same.

(Yu, 455.) A POSA would have understood that "successive segments" as described in Yu, teaches or suggests consecutive segments, as claimed. (Gall Declaration, ¶365.) Further, in the context of Yu, where the radiation is delivered over a continuous arc delivery, a POSA would have understood that the successive segments may be performed consecutively. (*Id*.) Thus, the combination of Earl and Yu teaches or suggests this claim. (*Id*.)

### C. Earl renders claim 10 obvious: "an output means for transmitting the treatment plan to the radiotherapeutic apparatus"

Earl teaches or suggests claim 10, at least for the reasons described in Section IV.C above.

### D. The combination of Earl and Yu renders claim 11 obvious: "arranged to calculate an irradiation time for each arc-segment apt to deliver a required dose and to infer a rotation speed from the irradiation time"

#### 1. Earl

Earl teaches or suggests claim 11, at least for the reasons described in Section IV.D above. However, to the extent Patent Owner argues that Earl does not teach or suggest this claim, it is taught or suggested by Yu.

#### 2. Yu

This claim element recites additional functionality performed by the treatment planning apparatus. Yu discloses an optimization technique that involves two main parameters gantry rotation speed and MLC leaf speed. (Gall Declaration, ¶370.) Yu states that "[f]or most cases, gantry rotation speed, rather than leaf traveling speed, was the factor limiting the dose rate. The MLC prescriptions generated by the leaf sequencer were then sent to the MLC controller for dynamic delivery through a local network link." (Yu, 455.) A POSA would have understood that Yu's delivery time would depend on the gantry rotation speed and the leaf travel speed/distance. (Gall Declaration, ¶370.)

Yu additionally teaches calculating an irradiation time for each arc segment when it states:

> Because the speed of leaf travel is limited, it is important that the field shapes of adjacent beam angles not differ too much. For most clinical cases, the field shapes varied slowly between angles. Treatments could be delivered with the highest machine dose rate determined by the linac based on the maximum speed of gantry rotation, resulting in ***very short delivery time***. There were cases where large leaf travel was required, and the leaf motion lagged radiation delivery.

(Yu, 456.) A POSA would have understood that gantry rotation speed can dictate the dose rate and the resulting delivery time. (Gall Declaration, ¶371.) To optimize and coordinate the speed of leaf travel and gantry rotation speed, as described by Yu, a POSA would have found that calculating the total irradiation time an obvious part of Yu's method because the relationship between speed, time and distance (e.g., measured in degrees of rotation) is governed by a simple equation (e.g., distance equals speed multiplied by time) that would have been apparent to a POSA. (*Id*.) Further, in view of Yu's teaching that the machine dose rate is determined based on the speed of gantry rotation, inferring a rotation speed from the calculated irradiation time would have been an obvious step because the relationship between speed, time and distance (e.g., measured in degrees of rotation) is governed by a simple equation (e.g., distance equals speed multiplied by time) that would have been apparent to a POSA. (*Id*.) Thus, the combination of Earl and Yu teaches or suggests this claim. (Gall Declaration, ¶372.)

### E. The combination of Earl and Yu renders claim 14 obvious: "the beam axis and the axis of rotation of the source are substantially orthogonal"

#### 1. Earl

Earl teaches or suggests claim 14, at least for the reasons described in Section IV.E above. However, to the extent Patent Owner argues that Earl does not teach or suggest this claim, it is taught or suggested by Yu.

#### 2. Yu

Yu provides that "IMAT treatment delivery was accomplished by programming the linear accelerator (linac) to deliver an arc and the MLC to step through a sequence of fields." (Yu, 453.) Yu further explains that its arcs are, "multiple shaped fields spaced every 5–10° around the patient." (Yu, 454; Gall Declaration, ¶¶376-377.) Further, Yu explains that "[w]e have implemented a new technique, intensity-modulated arc therapy, or IMAT, to deliver highly conformal dose distributions by combining ***gantry rotation*** and dynamic multileaf collimation." (Yu, 454.) A POSA would have understood that Yu's arc around a rotation axis intersects and forms a substantially right angle with its beam axis. (Gall Declaration, ¶¶377-378.) Thus, the combination of Earl and Yu teaches or suggests this claim. (*Id*., ¶379.)

### F. KSR Rationale and Motivation to Combine Earl and Yu.

As of April 2006, enhancing Earl's radiotherapeutic treatment planning system with Yu's treatment delivery method, would have been obvious to a POSA, because it would have been nothing more than combining prior art elements according to known methods, with no change in their respective functions, to yield predictable results. (*See* KSR, 550 U.S. at 416; Gall Declaration, ¶380.)

A POSA would have been directed to Yu upon reading Earl. More specifically, within the body of its specification, Earl expressly cites Yu as a reference—along with other works by Yu. (*See* Earl, [0063].) Moreover, two of the named inventors of Earl, Xinsheng Yu (who also goes by Cedric Xinsheng Yu and Cedric Yu) and David Sheppard, are co-authors of Yu. For at least these reasons, a POSA would have been motivated to combine the teachings of Earl and Yu (Gall Declaration, ¶381.)

Further, Earl and Yu are directed to a common field of endeavor—providing optimized radiation dose distributions to a patient using IMAT treatment planning and delivery techniques. (*Id*., ¶382.) Specifically, both Earl and Yu are directed to control systems that plan control of a radiotherapeutic apparatus's dose rate, gantry rotation speed, and MLC leaves, as described above. (*Id*.) Yu further describes a programmable linac that is programmed to deliver arc treatments and communicate with an MLC controller to dynamically step through a sequence of field shapes in accordance with an optimized radiotherapeutic plan, thereby using two controllers to deliver a prescribed dose. (Yu, 455; Gall Declaration, ¶382.) It would have been obvious to enhance Earl's treatment planning system with Yu's differing radiation delivery, gantry speed, and MLC movement speed between first and second arc-segments, because Earl already describes using those constraints during its DAO process. (Earl, [0035] ("Examples of geometric constraints for the MLC and linac include, but are not limited to, the dose rate, gantry speed, and minimal amount of radiation that can be delivered with acceptable accuracy.")). (Gall Declaration, ¶382.)

A POSA could have enhanced the respective teachings of Earl and Yu with no change to their respective features or functions, and the combination would have yielded nothing more than predictable results. (Gall Declaration, ¶383.) The predictable results being a radiotherapeutic plan prescribing different rates per degree as between the first and second arc-segments. (*Id*.)

## IX. Ground 4: The combination of Earl, Yu, and Otto renders obvious claim 8.

As explained in greater detail below, the combination of Earl, Yu, and Otto renders obvious claim 8 directed toward a treatment planning apparatus. (Gall Declaration, ¶384.) As described in greater detail below, Earl, Yu, and Otto would have been obvious to combine, would continue to work as intended after combined, and the combination teaches or suggests claim 8. (*Id*.)

## A. The combination of Earl, Yu, and Otto renders claim 8 obvious: "the rotation speed and the dose rate are both constant during an arc-segment, and at least one thereof is different as between the first arc-segment and the second arc-segment"

### 1. Yu

Yu's "[t]reatments could be delivered with the highest machine dose rate determined by the linac based on the maximum speed of gantry rotation, resulting in very short delivery time." (Yu, 456.) Yu further describes an example and motivation for keeping the gantry speed constant during an arc segment, including:

> [T]wo to five arcs spanning an angular range 40–180° are used. For dose calculation, each arc is approximated with fixed beams equally spaced at 10° intervals….To keep the ***gantry speed constant*** for smooth delivery, the weights of the beams, *i.e.*, the relative contributions of different beams to the ***dose prescription point***, are determined ***for each arc*** such that each beam angle delivers the same number of MUs.

(Yu, 454.) Further, to achieve the prescribed dose for arc-segments that were spaced at 10° intervals, the dose rate (*i.e.*, highest machine dose rate (Yu, 456) would have remained constant. (Gall Declaration, ¶386.) Thus, Yu teaches or suggests a rotation speed and dose rate that are both constant during an arc-segment. (*Id*.)

To the extent Patent Owner argues that Yu does not teach or suggest at least one of rotation speed and dose rate is different as between the first arc-segment and the second arc-segment, it is taught or suggested by Otto.

### 2. Otto

Otto teaches a 360° arc divided into arc-segments by a plurality of control points along the arc, as the terms "arc" and "arc-segment" are used by the '843 Patent. (Ex. 1026, Otto, 8:24-29; *see also* Ex. 1027, Otto Provisional, 8, 9, and 14.) Otto further provides that for "each of a number of control points along a trajectory, a radiation delivery plan may comprise: a set of motion axes parameters, a set of beam shape parameters and a beam intensity." (Otto, 6:4-7; *see also*, Otto Provisional, 8, 9, and 14.) A POSA would have understood that Otto's optimization process results in a final deliverable treatment plan. (Gall Declaration, ¶387.) Each control point in Otto's final deliverable treatment plan provides the motion axes parameters, beam shape parameters, and beam intensity for the associated arc-segment. (*Id*.)

Otto further provides that one of its objectives is to:

> [E]stablish a radiation treatment plan that will deliver a desired radiation dose distribution to a target volume in a subject S… while minimizing the dose of radiation delivered to tissues surrounding the target volume or at least keeping the dose delivered to surrounding tissues below an acceptable threshold. This objective may be achieved by ***varying:… an intensity of the radiation beam***, while moving radiation source 12 and/or beam 14 along a trajectory 30 relative to subject S… [and] these objectives are achieved while radiation source 12 and/or beam 14 are caused to move continuously along trajectory 30.

(Otto, 10:2-15; *see also* Otto Provisional, 1, 4, 25, and Figure 15.)

A POSA would have understood that in the field of radiation therapy, the phrase "***varying:… an intensity of the radiation beam***" refers to the amount of radiation emitted per unit of time, also referred to as the "dose rate" of the radiation source. (Gall Declaration, ¶389.) Thus, a POSA would have understood that Otto teaches or suggests varying the dose rate (*i.e.*, intensity) between the first arc-segment and the second arc-segment, as claimed. (*Id*.) Therefore, the combination of Earl, Yu, and Otto teach or suggest this claim. (*Id*.)

### B. Motivation to Combine Earl, Yu, and Otto

Enhancing Earl/Yu's radiotherapeutic treatment planning system with Otto's method for varying dose rate, would have been obvious to a POSA, because a POSA as of April 2006 would have been aware of teachings or suggestions that would have motivated a POSA to modify Earl/Yu with Otto, and would thereby arrive at the claimed invention. (Gall Declaration, ¶390.)

As explained above, the combination of Earl and Yu renders claim 7 obvious. However, Earl and Yu are silent with respect to a planning apparatus capable of preparing a plan in which "at least one [of the rotation speed and the dose rate] is different as between the first arc-segment and the second arc-segment", as recited in claim 8. (Gall Declaration, ¶391.) In seeking additional techniques for improving the radiation treatment planning of Earl/Yu, as of April

2006, a POSA would have applied Otto's teachings, since, for example, Earl includes dose rate as a constraint in the treatment planning process. (Earl, [0042] and claim 7; Gall Declaration, ¶391.)

Otto provides that it is "preferable that source 12 and/or beam 14 not have to move back and for the along the same path;" that continuous movement is preferable because "stopping and starting motion axes can cause wear on the components of the radiation delivery apparatus;" and that methods are needed to "deliver desired dose distributions relatively quickly." (Otto, 2:48-50, 8:30-32, 8:57-61.) Otto additionally provides a single-pass trajectory having "an ending point in which case the beam position and orientation at the starting and ending points are the same." (Otto, 7:16-20.) Further, Otto provides that "minimizing the dose of radiation delivered to tissues surrounding the target volume or at least keeping the dose delivered to surrounding tissues below an acceptable threshold" could be accomplished by varying "an intensity of the radiation beam, while moving radiation source 12 and/or beam 14 along a trajectory 30 relative to subject S." (Otto, 10:5-12.) In view of Otto's disclosure, a POSA would have understood that varying beam intensity (i.e., dose rate) would aid in providing a continuous single-pass trajectory that could be performed in a relatively quick manner while causing less wear on the equipment and while delivering an increased dose to the target volume and a decreased dose to surrounding tissue. (Gall Declaration, ¶392.)

Thus, a POSA would have been motivated to apply Otto's teachings of how to plan for and accomplish varying beam intensity (i.e., dose rate) to Earl and Yu. (*Id*., ¶393.)

Under the guidance of Otto, it would have been obvious to enhance Earl/Yu's treatment planning system with Otto's method for varying the dose rate, because doing so would provide a more robust treatment plan that delivers an increased dose to the target volume, a decreased dose to the surrounding tissue, and provides the additional advantages described above. (*Id*., 394)

As of April 2006, it would have been obvious to combine the teachings of Earl, Yu, and Otto, and the combination would have yielded the predictable result of a radiotherapeutic plan prescribing dose rates capable of changing from one arc-segment to the next. (*Id*., 395)

## X. Ground 5: Earl in view of Yu and Bjärngard renders obvious claims 12-13.

### A. Claims 12-13

Bjärngard teaches or suggests each of claims 12 and 13 at least for the reasons described in Sections VII.A.2 and VII.B.2. Thus, the combination of Earl, Yu, and Bjärngard renders claims 12 and 13 obvious. (Gall Declaration, ¶396.)

### B. *KSR* Rationale and Motivation to Combine Earl, Yu, and Bjärngard.

Enhancing Earl/Yu's radiotherapeutic planning system with Bjärngard's method for synchronizing and controlling the movements of the patient positioning assembly, gantry, and dose rate would have been obvious to a POSA because it would have been nothing more than combining prior art elements according to known methods, with no change in their respective functions, to yield predictable results. (*See KSR*, 550 U.S. at 416; Gall Declaration, ¶397.)

Earl/Yu does not disclose a patient positioning assembly. However, as explained above, by April 27, 2006, planning systems capable of preparing a treatment plan comprising movements of a patient positioning assembly had been developed. (Gall Declaration, ¶398.) To provide a more robust radiation planning system by incorporating a patient positioning assembly into a treatment plan, a POSA would have looked to Bjärngard. As I described above, Bjärngard provides movements of a patient positioning assembly during treatment that are synchronized with gantry position/speed (*i.e.*, source position) and dose rate. (*Id*.) Earl, Yu and Bjärngard are directed to a common field of endeavor—planning and providing optimized radiation dose distributions to a target mass while reducing damage to surrounding tissue. (*Id*.) Specifically, Earl, Yu, and Bjärngard are directed to radiotherapeutic planning and control systems that control the dose rate and other parameters to ensure the efficacy of a radiation treatment. (*Id*.)

A POSA would have understood that motion of the source, dose rate, and motion of the patient positioning system would have needed to be correlated. (Gall Declaration, ¶399.) Further, a POSA could have enhanced the respective teachings of Earl, Yu, and Bjärngard with no change to their respective features or functions, and the combination would have yielded nothing more than predictable results. (*Id*.) The predictable results being radiotherapeutic apparatus having a patient positioning system capable of monitoring and correcting the patient's position relative to the radiation source. (*Id*.)

## XI. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *Inter Partes Review* of claims 7-14 of the '843 Patent on Grounds 1-5.

## XII. STANDING (37 C.F.R. §42.104(a))

Petitioner certifies that (1) the '843 patent is available for *inter partes* review and (2) Petitioner, Varian Medical Systems, Inc. is not barred or estopped from requesting *inter partes* review on the grounds identified in this petition. This petition is filed in accordance with 37 C.F.R. §42.106(a). Concurrently filed herewith are Powers of Attorney and an Exhibit List per §42.10(b) and §42.63(e), respectively. The required fee is paid via Deposit Acct. No. 19-0036. The Office is authorized to charge fee deficiencies and credit overpayments to Deposit Acct. No. 19-0036 (Customer ID No. 45324).

## XIII. MANDATORY NOTICES (37 C.F.R. §42.8(a)(1))

Pursuant to 37 C.F.R. §42.8, Petitioner provides the following mandatory disclosures.

### A. Real Parties-In-Interest (37 C.F.R. §42.8(b)(1))

The real party-in-interest in this proceeding is Varian Medical Systems, Inc., including its subsidiaries Varian Medical Systems International Holdings, Inc., Varian Medical Systems Netherlands Holdings, Inc., Varian Medical Systems Nederland BV, Varian Medical Systems UK Holdings Limited, Varian Medical Systems UK Limited, Varian Medical Systems International AG, Varian Medical Systems Deutschland Holdings GmbH, and Varian Medical Systems Deutschland GmbH.

### B. Related Matters (37 C.F.R. §42.8(b)(2))

Patent Owner has asserted the ’843 Patent in Elekta Ltd. v. Varian Medical Systems, Inc., D. Del., 1:16-cv-00082, filed on February 12, 2016. Petitioner is not aware of any pending prosecution of the ’843 Patent. Petitioner requested IPR of claims 1-6 of the ’843 Patent on January 25, 2017, in IPR2017-00763 and IPR2017-00764, and is requesting IPR of claims 7-14 in this petition and in another petition filed concurrently herewith based on different grounds.

### C. Designation of Lead and Back-Up Counsel (37 C.F.R. §42.8(b)(3))

Petitioner appoints **Michael B. Ray (Reg. No. 33,997)** as its lead counsel and **Nirav N. Desai (Reg. No. 69,105)** and **Trent W. Merrell (Reg. No. 73,771)** as its back-up counsel, each at the following address: STERNE, KESSLER, GOLDSTEIN & FOX, 1100 New York Avenue, N.W., Washington, D.C., 20005, phone number (202) 371-2600 and facsimile (202) 371-2540.

**D. Service Information (37 C.F.R. §42.8(b)(4))**

Petitioner consents to electronic service by email at:

| | |
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Respectfully submitted,

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## CERTIFICATION OF WORD COUNT

The undersigned hereby certifies that the portions of the above-captioned **PETITION FOR *INTER PARTES* REVIEW** specified in 37 C.F.R. §42.24 have 13,388 words, in compliance with the 14,000 word limit set forth in 37 C.F.R. §42.24(a)(1)(i). This word count was prepared using Microsoft Word 2010.

Respectfully submitted,

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## CERTIFICATION OF SERVICE

The undersigned hereby certifies that the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,961,843**, Petitioner's Power of Attorney, and all associated exhibits were served on February 10, 2017 on the following address via FedEx Express:

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