UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VARIAN MEDICAL SYSTEMS, INC.
Petitioner

v.

ELEKTA LIMITED
Patent Owner

Case IPR2017-00884
Patent No. 7,961,843

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

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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").

This Petition provides (1) **ground 1:** claims 7-14 are obvious under §103 in view of the Dynamic Beam Delivery (DBD) Toolbox User's Manual (Ex. 1005, hereinafter "DBDToolbox") and the DMLC Implementation Guide (Ex. 1006, hereinafter "DMLCIG"); and (2) **ground 2:** claims 7-14 are obvious under §103 in view of DBDToolbox and Earl (Ex. 1009.).

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].)

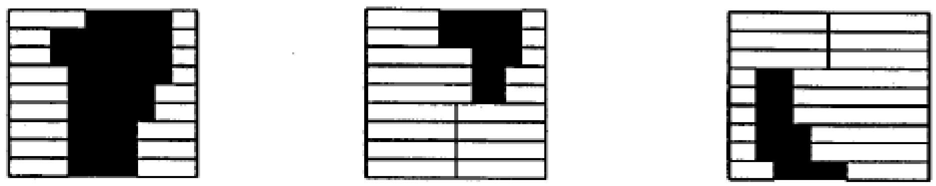

Figure 2

(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.)

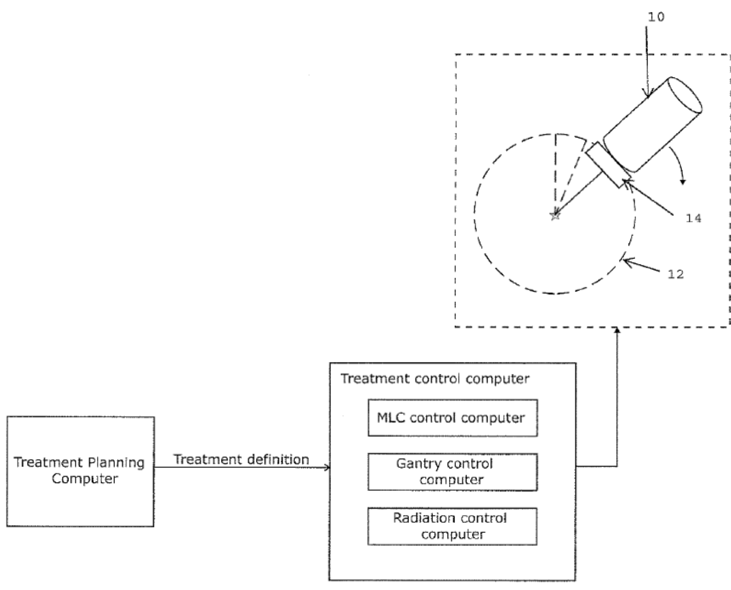

Fig 6

(*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 PTAB 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 when the claim language does not use "means." *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 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 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.

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

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.

DBDToolbox (Ex. 1005) is a user's manual for the Dynamic Beam Delivery Toolbox component of Petitioner Varian's Clinac linear accelerator radiation therapy apparatus. (DBDToolbox, 1, 4.) DBDToolbox was published by Varian and publicly available at least as early as April 5, 2000. (Ex. 1011, Castellino, ¶¶19-20.)

It was Varian's standard practice to deliver DBDToolbox (i.e., User's Manual) when the product was delivered with, or later installed on, a customer's Clinac equipment. (*Id.*, ¶¶6-7, 17.) Between April 5, 2000 and March 29, 2006, the DBD Toolbox software was installed on 18 customer Clinacs. And copies of DBDToolbox would have been delivered with those installations. (*Id.*, ¶¶19-20.) Thus, for at least this reason, DBDToolbox was published and publicly available as early as April 5, 2000.

As an example of this, at least one copy of DBDToolbox was delivered to Memorial Sloan-Kettering Cancer Center ("MSKCC") during the 2001/2002 timeframe for use with a Varian linac. (Ex. 1012, Mageras, ¶8.) The research performed at MSKCC, using the DBD Toolbox software, is described in "Developments in megavoltage cone beam CT with an amorphous silicon EPID: Reduction of exposure and synchronization with respiratory gating" by Chang *et al.*, (Ex. 2024, "Chang") published March 2, 2005 by the American Association of Physicists in Medicine in *Medical Physics*. (Mageras, ¶¶3-8.)

Furthermore, a POSA would have been aware that Varian manuals were available, upon request from Varian. (Gall Declaration, ¶64.) While Chang does not specifically cite DBDToolbox, a POSA would have known to contact Varian to obtain additional information about the DBD Toolbox software, including DBDToolbox. (*Id*.) Thus, a person skilled in the relevant art, exercising reasonable diligence, could have obtained a copy of DBDToolbox prior to April 27, 2005. (*Id*.) Based on the foregoing, DBDToolbox is prior art under 35 U.S.C. §102(b).

DMLCIG (Exhibit 1006), is an implementation guide for the Dynamic Multileaf Collimator accessory of Petitioner Varian's Clinac linear accelerator radiation therapy apparatus. (DMLCIG, 1-1.) It was Varian's standard practice to ship DMLCIG to customers with Varian's Clinacs. (Castellino, ¶¶6-7, 11.) Between 2002-2005, DMLCIG was issued out of stock to 1,575 customer orders.

(*Id.*, ¶11.) Thus, for at least this reason, DMLCIG was published and publicly available prior to April 27, 2005.

For example, at least one copy of DMLCIG was delivered to St. Joseph's Hospital in Tampa, Florida on October 31, 2002 (Ex.1013, Wedding, ¶4) and at least one copy of DMLCIG was delivered to Florida Hospital in Orlando, Florida on April 1, 2005. (Ex. 1014, Harrell, ¶¶3-4.)

A POSA would have been aware that Varian manuals were available upon request (Gall Declaration, ¶70.) Thus, a POSA, exercising reasonable diligence, could have obtained a copy of DMLCIG prior to April 27, 2005. (*Id.*)

Indeed, prior to the earliest priority date for the '843 Patent, DMLCIG was cited in the literature of the relevant art. For example, DMLCIG was cited in "Communication and sampling rate limitations in IMRT delivery with a dynamic multileaf collimator system" by Xia, et al., (Ex. 1020, Xia) published by the American Association of Physicists in Medicine in Medical Physics on February 21, 2002; in "Dosimetric effect of respiration-gated beam on IMRT delivery" by Duan et al, (Ex. 1021, Duan) published by American Association of Physicists in Medicine in Medical Physics on July 25, 2003; and "QA of intensity-modulated beams using dynamic MLC log files" by Kumar et al, (Ex. 1022, Kumar) published by the Journal of Medical Physics in January-March 2006.

Thus, DMLCIG is prior art under §102(b).

Earl (Exhibit 1004), 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).

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.*, 383 U.S. 1, 17-18 (1966).[4] 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

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[4] 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. 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).

of it, either in the same field or a different one. If a person of 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.

VI. Ground 1: DBDToolbox in view of DMLCIG renders obvious claims 7-14.

The combination of DBDToolbox and DMLCIG teaches or suggests all of the elements of claims 7-14. (Gall Declaration, ¶116.) As explained below, Petitioner Varian developed the systems described in DBDToolbox and DMLCIG to work together, and a POSA would have found it obvious and logical combine the teachings of DBDToolbox and DMLCIG. (*Id*.)

A. DBDToolbox in view of DMLCIG renders claim 7 obvious

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

DBDToolbox teaches that a Conformal Program ("CP") file is created "by software outside the Clinac" such as "a treatment planning system." (DBDToolbox, 5.) Thus, DBDToolbox teaches or suggests this limitation. (Gall Declaration, ¶119.)

2. The combination of DBDToolbox and DMLCIG 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. (*Id.*, ¶120.)

a) DBDToolbox

DBDToolbox is a Varian Clinac option. (DBDToolbox, 4.) A POSA would have understood that Varian Clinacs comprise a rotatable gantry having a source for emitting a radiation beam as the source rotates around the patient. (Gall Declaration, ¶122.)

DBDToolbox can be used to "set up experimental beams where dose is being delivered [to a target] in tight coordination with motion of one or more Clinac axes." (DBDToolbox, 4.) Thus, DBDToolbox teaches or suggests this limitation. (Gall Declaration, ¶123.)

To the extent Patent Owner argues that DBDToolbox does not teach or suggest this limitation, it is taught or suggested by DMLCIG.

b) DMLCIG

DMLCIG provides that "[w]ith the continuous beam and motion technique, it is possible… for the beam to remain on while the MLC moves from one user-defined shape to the next." (DMLCIG 1-3.) DMLCIG further illustrates this concept in Figure 1-1, reproduced and annotated below to show the beam axis.

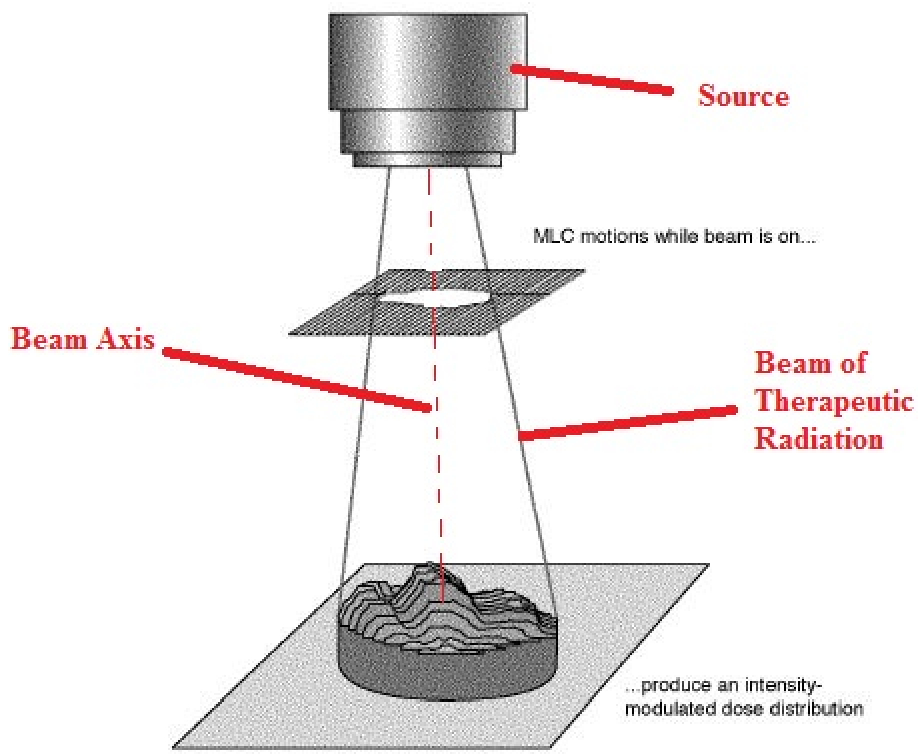

Figure 1-1 Creation of an Intensity-Modulated Profile with the DMLC

(*Id.,* FIG. 1-1.) As shown by the annotated figure, DMLCIG provides a source that emits a beam of therapeutic radiation along a beam axis. (Gall Declaration, ¶126.)

Thus, the combination of DBDToolbox and DMLCIG teaches or suggests this limitation. (*Id*.)

3. DBDToolbox teaches or suggests limitation [7.1.B]: a source able to "rotate about a rotation axis that intersects[5] with the beam axis thereby to describe an arc around the rotation axis"

"DBD Toolbox can be used… where dose is being delivered in tight coordination with motion of one or more Clinac axes. The number of Clinac axes that can be moved and how many simultaneous motions are allowed depends on the specific Clinac configuration." (DBDToolbox, 4.) The axes contemplated by DBDToolbox include ***gantry rotation***. (*Id.*, 11.) DBDToolbox's gantry rotation teaches or suggests a rotation axis as recited in the '843 Patent. (Gall Declaration, ¶128.)

DBDToolbox explains that "while this segment is delivered, as the ***gantry linearly rotates*** from 180.00 to 200.00 degrees… [the] beam is uniformly delivered over the range of motion." (DBDToolbox, 9.) A POSA would have understood that DBDToolbox's rotation axis intersects with the beam axis, as described above, and thereby describes an arc around the rotation axis. (Gall Declaration, ¶128.) Thus, DBDToolbox teaches or suggests this limitation. (*Id*.)

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

4. The combination of DBDToolbox and DMLCIG teaches or suggests limitation [7.2]: "a multi-leaf collimator arranged to collimate the beam to a desired shape"

a) DBDToolbox

DBDToolbox may be used by Clinacs having an MLC. For example, DBDToolbox states that "[f]or Clinacs equipped with a Dynamic Multileaf Collimator (DMLC) the Multileaf Collimator can also be incorporated into the dynamic experiments as an independent axis." (DBDToolbox, 4.) The DBDToolbox explicitly teaches an MLC. A POSA would have understood that DBDToolbox's MLC would collimate the beam to a desired shape when delivering therapeutic radiation, because that is the purpose of the MLC in a linac. (Gall Declaration, ¶129.)

To the extent that the Patent Owner alleges that DBDToolbox does not teach or suggest this limitation, it is taught or suggested by DMLCIG.

b) DMLCIG

DMLCIG is a Clinac option that delivers treatments in which the "***MLC moves through a sequence of shapes*** throughout the treatment." (DMLCIG 1-3.) As illustrated in Figure 1-1, reproduced below, as the MLC moves through a sequence of shapes the beam is collimated to a desired shape. (Gall Declaration, ¶132.)

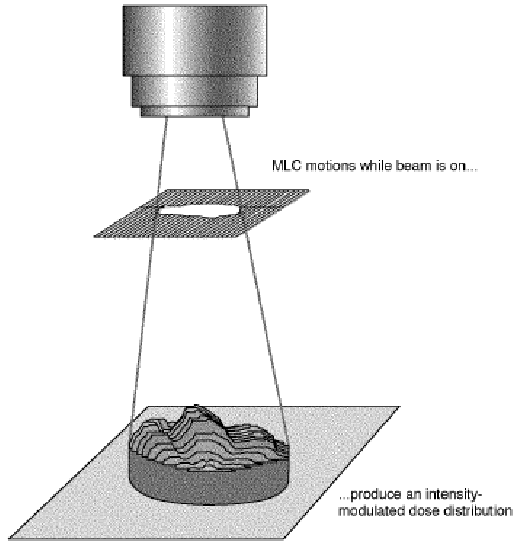

Figure 1-1 Creation of an Intensity-Modulated Profile with the DMLC

(DMLCIG, FIG. 1-1.) DMLCIG explicitly teaches an MLC that collimates the beam to a desired shape. (Gall Declaration, ¶133.) Thus, the combination of DBDToolbox and DMLCIG teaches or suggests this limitation. (*Id.*, ¶134.)

5. The combination of DBDToolbox and DMLCIG 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) DBDToolbox

DBDToolbox teaches or suggests control of various machine "axes" which correspond to the factors in the '843 Patent. (*Id.*, ¶135.) For example, DBDToolbox teaches or suggests a control means able to control dose rate of the source, rotation of the source (*i.e.*, gantry rotation), and a position of the MLC (*i.e.*, MLC incorporated as an independent axis). (*Id.*) When DBDToolbox's segmented treatment table file ("STT file") is loaded on the Clinac, the control system:

> [I]mmediately calculates the ***dose rate and axis speed*** to be used in every segment… [T]he control system sets and actively fine tunes the ***axis speeds, positions and dose delivery*** in real time within the segment to ensure that the above linearity and overall conformance to the prescribed dose vs. position relationships is maintained.

(DBDToolbox, 10.)

The axes (*i.e.*, factors) contemplated by DBDToolbox include ***MLC***, collimator rotation axis, ***gantry rotation*** axis, and couch rotation axis. (*Id.*, 4, 11.)

Thus, DBDToolbox teaches or suggests the function of controlling the dose rate, the rotation of the gantry, and the position of the MLC. (Gall Declaration, ¶138.) And DBDToolbox teaches or suggests that a "control system" performs these functions:

> Two successive instances where the dose changes and the position of one or more mechanical axes also changes, defines a segment with simultaneous dose delivery and motion. For a simultaneous beam and motion segment, the ***control system*** ensures that the segment dose is uniformly distributed through the range of motion specified in the segment.

(DBDToolbox, 8.)

A POSA would have understood that a Clinac control system is "a computer to control treatment" based on a Conformal Program (CP) file created by a user. (Gall Declaration, ¶140.) It would have been obvious to a POSA that the Clinac control system would include an actuator (*i.e.*, "a machine component that causes a radiotherapeutic device to operate") to put into action commands for the digitally controlled linear accelerator to achieve treatment of a patient. (*Id*.)

As discussed 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. To the extent that the Board finds that the '843 Patent implies some algorithm, a POSA would have understood that DBDToolbox's CP and STT files would also have included some algorithm to perform the recited functions. (Gall Declaration, ¶140.) Thus, a POSA would have understood that DBDToolbox teaches or suggests this limitation. (*Id*.)

To the extent Patent Owner argues that DBDToolbox does not teach or suggest a control means able to control the MLC, it is taught or suggested by DMLCIG.

b) DMLCIG

DMLCIG provides that "[t]he sequence of shapes is user-defined or generated automatically using a treatment planning system that supports the DMLC. The ***MLC motions and dose delivery (dose rate) are always under computer control*** to ensure that the dose delivery and MLC motions adhere to the plan." (DMLCIG, 1-3.) DMLCIG's computer performs the function of controlling the dose rate and MLC position. (Gall Declaration, ¶143.)

A POSA would have understood that DMLCIG's control computer is "a computer to control treatment." (*Id.*, ¶144.) To the extent that the Board finds that the '843 Patent implies some algorithm, a POSA would have understood that DMLCIG's treatment plan also would have included some algorithm to perform the recited functions. (*Id*.) Thus, a POSA would have understood that the combination of DBDToolbox and DMLCIG teaches or suggests this limitation. (*Id*.)

6. DBDToolbox 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. DBDToolbox discloses treatment instances which act as arc-segments, as recited in the claim. (*Id.*, ¶146.) The "treatment instances in [the] CP file … define points in the multi-dimensional space defined by ***cumulative dose*** and the ***axis position for each moving axis***." (DBDToolbox, 7.) DBDToolbox provides that, "[i]f you prefer to think in terms of segments two successive instances define a segment." (*Id.*) DBDToolbox further provides:

> Two successive instances where the dose changes and the position of one or more mechanical axes also changes, defines a segment with

> simultaneous dose delivery and motion. For a simultaneous beam and motion segment, the control system ensures that the segment dose is uniformly distributed through the range of motion specified in the segment. There must be at least one position or dose change between two successive instances. In other words, two successive instances cannot be identical.

(*Id.*, 8.) It would have been obvious to a POSA that a treatment plan would have included more than two instances, thereby teaching or suggesting more than one segment. (Gall Declaration, ¶146.)

DBDToolbox further provides that to "perform a conformal therapy experiment," a Conformal Program (CP) file must be created "which describes the experiment." (DBDToolbox, 5.) The CP file created "by a treatment planning system" is a treatment plan. (Gall Declaration, ¶147.)

A POSA would have understood that DBDToolbox's "treatment planning system" performs the recited functions. To the extent that that Board finds that the '843 Patent implies some algorithm, a POSA would have understood that DBDToolbox would also have included some algorithm for dividing the arc into a plurality of arc-segments and preparing a treatment plan, because DBDToolbox teaches or suggests the creation of a CP file (i.e., treatment plan) having multiple arc-segments. (*Id.*, ¶148.) Thus, DBDToolbox teaches or suggests this limitation. (*Id.*)

7. The combination of DBDToolbox and DMLCIG 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) DBDToolbox

This claim element recites additional functionality performed by the treatment planning apparatus. DBDToolbox can be used "where ***dose is being delivered in tight coordination with motion of one or more Clinac axes***. The number of Clinac axes that can be moved and how many simultaneous motions are allowed depends on the specific Clinac configuration." (DBDToolbox, 4.) Among the axes contemplated by DBDToolbox are ***multi-leaf collimator as an independent axis***, collimator rotation, ***gantry rotation***, and couch rotation. (DBDToolbox, 4 and 11; Gall Declaration, ¶150.) Thus, a POSA would have understood that a treatment plan would include simultaneous motions of the MLC and gantry while the dose is being delivered. (*Id*.)

DBDToolbox further explains that "***while*** this segment is delivered, as the ***gantry linearly rotates*** from 180.00 to 200.00 degrees… [the] beam is uniformly delivered ***over the range of motion***." (DBDToolbox, 9.) These citations describe how DBDToolbox's beam is uniformly delivered to a target while the gantry rotates, thereby teaching or suggesting 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 speed. (Gall Declaration, ¶151.)

DBDToolbox further provides that "the dose rate and/or motion velocities ***change between different segments***. These changes are necessary to adhere to the dose vs position relationship that you specified in [the] original CP file." (DBDToolbox, 15-16.) As provided above, among the axes contemplated by DBDToolbox is ***multi-leaf collimator as an independent axis***. (*Id.*, 4.) Thus, DBDToolbox teaches a multi-leaf collimator that has a motion velocity that changes between segments. (Gall Declaration, ¶152.)

As described in Section VI.A.6, a POSA would have understood that DBDToolbox'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 understood that DBDToolbox plan would also have included some algorithm to perform 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 DBDToolbox describes a treatment having the recited capabilities. (Gall Declaration, ¶153.) Thus, a POSA would have understood that DBDToolbox teaches or suggests this limitation. (*Id*.)

To the extent Patent Owner argues that DBDToolbox does not teach or suggest a multi-leaf collimator that changes shape at a first specified rate per degree, it is taught or suggested by DMLCIG.

b) DMLCIG

DMLCIG provides that the "sequence of shapes is user-defined or generated automatically using a treatment planning system that supports the DMLC. The ***MLC motions and dose delivery (dose rate) are always under computer control*** to ensure that the dose delivery and MLC motions adhere to the plan." (DMLCIG, 1-3.) Indeed, the DMLC further provides that the "DMLC field files contain the ***series of dose fractions vs. leaf positions*** only." (*Id.,* 2-2.) Each field specifies a dose rate and the prescribed leaf positions, or shapes. (Gall Declaration, ¶156.)

Thus, DMLCIG teaches or suggests a planning system capable of performing the recited functions. To the extent that the Board finds that the '843 Patent implies some algorithm, a POSA would have understood that DMLCIG would also have included some algorithm to perform preparing a treatment plan in which the multi-leaf collimator changes shape at a first specified rate per degree, because DMLCIG describes computer MLC motions that perform the recited capabilities. (*Id.*, ¶157.)

Thus, the combination of DBDToolbox and DMLCIG teaches or suggests this limitation.

8. The combination of DBDToolbox and DMLCIG 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) DBDToolbox

This claim element recites additional functionality performed by the treatment planning apparatus. As described in Section VI.A.7.a, DBDToolbox teaches multiple arc-segments adapted to deliver a specified dose within that arc-segment, while maintaining a relationship between dose and mechanical positions. (DBDToolbox, 6; Gall Declaration, ¶¶160-161.) Thus, DBDToolbox teaches or suggests both a first arc-segment and a second-arc segment. (*Id*.)

Additionally, as described in Section VI.A.7.a, DBDToolbox teaches a gantry rotating a specified angle.

Further, as described in Section VI.A.7.a, the axes (i.e., factors) contemplated by DBDToolbox include the ***multi-leaf collimator as an independent axis***, collimator rotation axis, ***gantry rotation*** axis, and couch rotation axis. (DBDToolbox, 4, 11.) Further, when the STT file is loaded on the Clinac, the control system "immediately calculates the ***dose rate and axis speed*** to be used in every segment…" (*Id*., 10.) DBDToolbox further specifies that its "dose rate and/or ***motion velocities change between different segments***." (*Id*., 15-16.) Based on the foregoing, a POSA would have understood that DBDToolbox teaches or suggests at least the first and second specified rates per degree differ as between the first and second arc-segments. (Gall Declaration, ¶162.)

At least for the reasons described in Sections VI.A.7.a, a POSA would have understood that DBDToolbox teaches or suggests the structure and would have included some algorithm for performing the recited functions. Thus, DBDToolbox teaches or suggests this limitation. (*Id.*, ¶163.)

To the extent Patent Owner argues that DBDToolbox does not teach or suggest that 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, it is taught or suggested by DMLCIG.

b) DMLCIG

As described in Section VI.A.7.b, DMLCIG teaches a multi-leaf collimator that changes shape at varying speeds based on the prescribed shape. (*Id.*, ¶166.) Further, DMLCIG provides that the "sequence of shapes is user-defined or generated automatically using a treatment planning system that supports the DMLC. The ***MLC motions*** and dose delivery (dose rate) ***are always under computer control*** to ensure that dose delivery and MLC motions adhere to the plan." (DMLCIG, 1-3.) Indeed, the DMLC further provides that the "DMLC field files contain the ***series of**… **leaf positions***…" (*Id.*, 2-2.) Each field specifies the prescribed leaf positions, or shapes. (Gall Declaration, ¶166.)

DMLCIG further provides that the dose rate and leaf speed varies for each segment. For example, "during a DMLC treatment, the MLC application uses ***a different***…***MLC leaf speed*** for every segment." (DMLCIG, 2-22.)

At least for the reasons described in Section VI.A.7.b, a POSA would have understood that DMLCIG teaches or suggests the structure and would have included some algorithm for performing the recited functions. (Gall Declaration, ¶168.)

Thus, a POSA would have understood that the combination of DBDToolbox and DMLCIG teaches or suggests this limitation. (*Id*., ¶169.)

B. The combination of DBDToolbox and DMLCIG teaches or suggests claim 8: "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. DBDToolbox

DBDToolbox provides that for "a simultaneous beam and motion segment, the control system ensures that the segment ***dose is uniformly distributed through the range of motion specified in the segment***. " (DBDToolbox, 8.) DBDToolbox further teaches that "the dose will be **uniformly** delivered over the axis travel" for the segment. (*Id.*, 9, emphasis in original.) DBDToolbox further provides that both the dose rate and axis speed, including gantry rotation, to be used on each segment are calculated. (*Id.*, 9-10.) Because DBDToolbox provides a start and end gantry angle for each arc segment and a total dose to be uniformly distributed over that arc segment, it would have been obvious to a POSA that a uniformly distributed dose could be accomplished by maintaining a constant rotation speed and dose rate during an arc-segment. (Gall Declaration, ¶173.)

Based on the foregoing excerpts, a POSA would have understood that the DBDToolbox's uniformly distributed dose over the axis travel teaches or suggests a treatment plan in which the rotation speed and the dose rate are both constant during an arc-segment. (*Id*., 174)

To the extent Patent Owner argues that DBDToolbox does not teach or suggest that "at least one thereof is different as between the first arc-segment and the second arc-segment," it is taught or suggested by DMLCIG.

2. DMLCIG

DMLCIG provides that "[i]n general, during DMLC treatment, the MLC application uses a different dose rate and MLC leaf speed for every segment… dose rate and individual leaf speed during treatment vary as the control system moves from one segment to the next." (DMLCIG 2-22.) A POSA would have understood that the described DMLC treatment is implemented using a different dose rate for every segment and that the dose rate varies as the control system moves from one segment to the next (not during the segment). (Gall Declaration, ¶176.).

Given the context of the cited portion, it would have been obvious that the dose rate used for every segment is constant. (*Id.*, ¶177.) DMLCIG's discussion regarding a change in dose rate refers to the dose rate modulation that occurs "as the control system moves from one segment to the next." (DMLCIG 2-22; Gall Declaration, ¶177.) Thus, the combination of DBDToolbox and DMLCIG teaches or suggests this dependent claim. (*Id.*)

C. The combination of DBDToolbox and DMLCIG teaches or suggests claim 9: "the first arc-segment and the second arc-segment are consecutive"

1. DBDToolbox

DBDToolbox provides that "two successive instances define a segment. Therefore, N treatment instances define N-1 segments." (DBDToolbox, 7.) It would have been obvious to a POSA that the most straightforward and efficient way to treat a patient would be to provide a treatment plan in which segments are consecutive. (Gall Declaration, ¶179.) To do otherwise would require repositioning the gantry between segments, during which time no radiation would be delivered to a patient. Such movement would introduce unnecessary time and complexity into a radiation treatment. (*Id.*) Thus, DBDToolbox teaches or suggests this claim. (*Id.*)

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

2. DMLCIG

DMLCIG teaches:

> An important feature of DMLC is that increasing the number of segments has little or no impact on the time required to deliver a field. This is due to the fact that ***there is no segment transition overhead; transition from one segment to the next is instantaneous***.

(DMLCIG 2-11.) Thus, the DMLC system can move from one segment to the next instantaneously. (Gall Declaration, ¶181.) A POSA would have understood that for the transition to occur instantaneously, the segments would be "consecutive," as claimed. (*Id*.) Thus, the combination of DBDToolbox and DMLCIG teaches or suggests this dependent claim. (*Id*.)

D. The combination of DBDToolbox and DMLCIG teaches or suggests claim 10: "an output means for transmitting the treatment plan to the radiotherapeutic apparatus"

1. DMLCIG

DMLCIG provides a method for loading each DMLC field file from the treatment planning system into the control system. (DMLCIG, 2-3; Gall Declaration, ¶184.) For example, as shown in Figure 2-1, reproduced below, the DMLC illustrates how the treatment planning system outputs the treatment field files to the Clinac-MLC control system via a network connection and/or a diskette. (DMCLIG, FIG. 2-1; Gall Declaration, ¶184.)

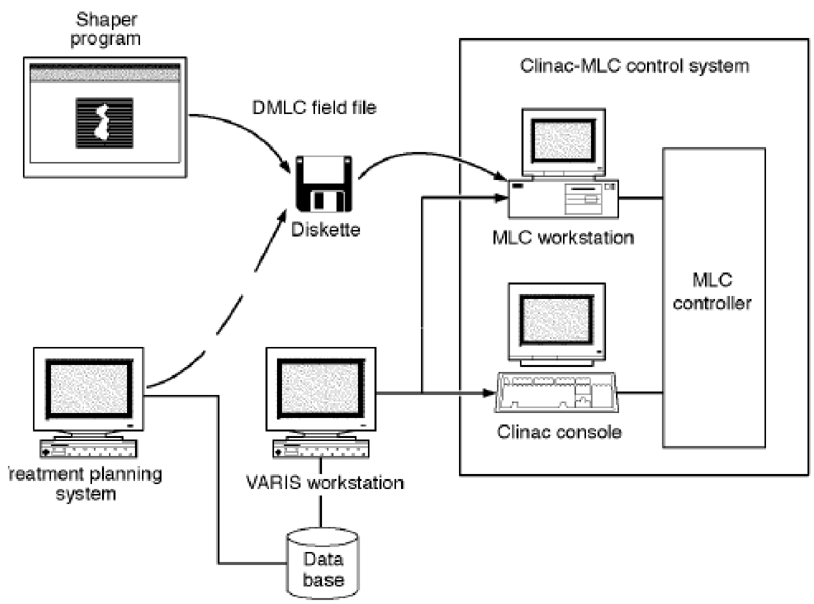

Figure 2-1 Creating and Downloading DMLC Field Files

(DMLCIG, FIG. 2-1.)

Thus, DMLCIG teaches or suggests the function of transmitting the treatment plan to the radiotherapeutic apparatus. (Gall Declaration, ¶184.) And DMLCIG teaches transferring the treatment plan onto a Clinac-MLC control system via a network connection and/or a diskette computer. (*Id*.)

As described in Section III.C.c, 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 DMLCIG's treatment planning system and network connection or diskette teaches or suggests the structure for performing the transmitting function. (*Id*., 185)

Thus, the combination of DBDToolbox and DMLCIG teaches or suggests this dependent claim. (*Id.*, ¶186.)

E. The combination of DBDToolbox and DMLCIG renders obvious claim 11: "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. DBDToolbox

This claim element recites additional functionality performed by the treatment planning apparatus. DBDToolbox's control system, "immediately ***calculates the dose rate and axis speed*** to be used in every segment" (DBDToolbox, 10.) It would have been obvious to a POSA that calculating the dose rate and axis speeds for a segment would include calculating an irradiation time. (Gall Declaration, ¶189.)

As described above, among the axes contemplated by DBDToolbox are collimator rotation, ***gantry rotation***, and couch rotation. (DBDToolbox, 11.) These teachings describe how DBDToolbox's control system controls rotation of the source. (Gall Declaration, ¶190.) A POSA would have understood that inferring a rotation speed from the irradiation time would have been an obvious step in calculating and fine tuning the axis speeds to ensure conformance to the prescribed dose, 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. (DBDToolbox, 10; Gall Declaration, ¶190.) Thus, DBDToolbox renders this claim obvious. (*Id*.)

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

2. DMLCIG

DMLCIG provides a "Clinac gantry" that can be "rotated from outside the treatment room, [to] deliver an entire multi-field DMLC compensated treatment without entering the treatment room between fields." (DMLCIG 1-6.) DMLCIG further provides that:

> Dose rate and MLC leaf speeds are optimized for each segment so that, for any segment, ***either the dose rate is maximized (to the operator-selected dose rate ceiling), or one or more MLC leaves are driven at maximum velocity***. This action minimizes the time required to deliver the segment, ***thereby minimizing the overall treatment time***. This optimization actually results in the shortest achievable time for any particular field.

(DMLCIG 2-23.) DMLCIG's optimization steps are performed in order to minimize the overall treatment time. (Gall Declaration, ¶194.) The parameters that are optimized include a maximum dose rate and a maximum leaf velocity. (DMLCIG 2-23.) In view of the foregoing, it would have been obvious to a POSA that the gantry rotation speed would also be optimized with the dose rate and leaf velocity. (Gall Declaration, ¶194.)

In view of DMLCIG's teaching that "either the dose rate is maximized … or one or more MLC leaves are driven at maximum velocity," it would have been obvious to a POSA that either the dose rate or the MLC velocity is a limiting factor. (DMLCIG 2-23; Declaration, ¶195.) Either the maximum dose rate or the maximum leaf velocity must be reduced in order to accommodate the limiting factor. (*Id*.) Calculating the total irradiation time for each arc-segment would have been an obvious step in determining whether to limit the dose rate or the leaf velocity. (*Id*.) It would also have been obvious to a POSA that rotation speed could be inferred from the irradiation time, 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*.)

DMLCIG provides that "[t]he sequence of shapes is user-defined or generated automatically using a treatment planning system that supports the DMLC. The ***MLC motions and dose delivery (dose rate) are always under computer control*** to ensure that dose delivery and MLC motions adhere to the plan. (DMLCIG, 1-3.) DMLCIG's computer acts as a control means for controlling the dose rate. (Gall Declaration, ¶196.) Thus, it would have been obvious to a POSA for DMLCIG computer to control the speed of the gantry as well. (*Id*.)

Therefore, the combination of DBDToolbox and DMLCIG renders this claim obvious. (*Id*.)

F. DBDToolbox teaches or suggests claim 12: "prescribe a treatment plan that includes motion of a patient positioning system during the treatment in a manner correlated with motion of the source"

This claim element recites additional functionality performed by the treatment planning apparatus. DBDToolbox provides a table "specifying the relationship between dose delivered and the positions of the moving mechanical axes. This defines the dose-position relationship" that the Clinac should adhere to. (DBDToolbox, 6; Gall Declaration, ¶199.)

DBDToolbox further explains with respect to the moving mechanical axes that "translational axes are: … COUCH VRT, COUCH LAT, and COUCH LNG. The rotational axes are:… COUCH RTN." (DBDToolbox, 11.) A couch, as disclosed in DBDToolbox, is a patient positioning system. (Gall Declaration, ¶200.) A POSA would have understood that COUCH VRT refers to the vertical position of the couch relative to the ground, COUCH LAT refers to the latitudinal, or side-to-side, position of the couch, COUCH LNG refers to the longitudinal positions of the couch, and COUCH RTN refers to the couches rotational position, each of which are motions that would be correlated to motion of the source (*Id*.)

DBDToolbox explains "the dose rate and axis speed to be used in every segment" is calculated (DBDToolbox, 10.) DBDToolbox further provides:

> For each segment the Clinac calculates dose rate and axis speed for each moving axis so that the dose rate will never be required to exceed the dose rate that you selected and ***axis speeds are proportionately calculated so that mechanical axes will never have to exceed their maximum speeds***.

(*Id.,* 16.) The Clinac's control system calculates the dose rate and the necessary axis speeds (including gantry speed and couch movements) to deliver the prescribed dose for each segment. (DBDToolbox, 10; Declaration, ¶201.)

When the "dose is actually being delivered, the control system sets and actively fine tunes the ***axis speeds, positions and dose delivery***." (DBDToolbox, 10.) Even though this step is performed at the Clinac, a POSA would have understood that these same calculations and determinations could be made at the treatment planning system and that doing so would have yielded nothing more than predictable results. (Gall Declaration, ¶202.)

Because DBDToolbox teaches calculating the dose rate and axis speeds, fine tuning axis speeds and positions, a POSA would have understood that these calculations would not be limited to one axis. (*Id.*, ¶203.) More specifically, the calculating and fine-tuning steps can apply simultaneously to both the gantry rotation (i.e., motion of the source) and the couch movements (i.e., motion of the patient positioning system) during the treatment. (*Id*.) To the extent that the Board finds that the '843 Patent implies some algorithm, a POSA would have understood that DBDToolbox would also have included some algorithm to perform preparing a treatment plan that includes motion of a patient positioning system, because DBDToolbox teaches or suggests a treatment plan that accounts for couch movements. (*Id*.) Thus, DBDToolbox teaches or suggests this claim. (*Id*.)

G. DBDToolbox teaches or suggests claim 13: "prescribe a treatment plan that includes motion of a patient positioning system during the treatment in a manner correlated with delivery of the dose"

This claim element recites additional functionality performed by the treatment planning apparatus. As described in Section VI.F, DBDToolbox teaches or suggests a treatment plan that includes motion of a patient positioning system during the treatment.

As explained, when the "dose is actually being delivered, the control system sets and actively fine tunes the ***axis speeds, positions and dose delivery***." (DBDToolbox, 10.) DBDToolbox includes axes such as COUCH VRT, COUCH LAT, and COUCH LNG which describe couch movements. (DBDToolbox, 10; Gall Declaration, ¶206.) Taken together, DBDToolbox describes setting the couch position in a manner correlated with delivery of the dose. (*Id*.)

Further, even though this step is performed at the Clinac, a POSA would have understood that these same calculations and determinations could be made at the treatment planning system and that doing so would have yielded nothing more than predictable results. (*Id*., ¶207.) To the extent that the Board finds that the '843

Patent implies some algorithm, a POSA would have understood that DBDToolbox would also have included some algorithm to perform preparing a treatment plan that includes motion of a patient positioning system, because DBDToolbox teaches or suggests a treatment plan that accounts for couch movements. (*Id*.) Thus, DBDToolbox teaches or suggests this claim. (*Id*.)

H. DBDToolbox teaches or suggests claim 14: "the beam axis and the axis of rotation of the source are substantially orthogonal"

The "DBD Toolbox can be used … where dose is being delivered in tight coordination with motion of one or more Clinac axes. The number of Clinac axes that can be moved and how many simultaneous motions are allowed depends on the specific Clinac configuration." (DBDToolbox, 4.) The axes contemplated by DBDToolbox include, collimator rotation, ***gantry rotation***, and couch rotation. (*Id.*, 11.)

In an embodiment, DBDToolbox explains that "while this segment is delivered, as the ***gantry linearly rotates*** from 180.00 to 200.00 degrees… [the] beam is uniformly delivered over the range of motion." (*Id.*, 9.) DBDToolbox beam is uniformly delivered to a target while the gantry rotates, thereby describing an arc around a rotation axis. (Gall Declaration, ¶210.) A POSA would have understood that DBDToolbox's rotation axis intersects with the beam axis at a right (or 90°) angle. (*Id*.) Therefore, DBDToolbox's rotation axis is orthogonal to and intersects with its beam axis. (*Id*.) Thus, DBDToolbox teaches or suggests this claim. (*Id*.)

I. KSR Rationale and Motivation to Combine

DBDToolbox and DMLCIG would have been obvious to combine, and would continue to work as intended after combined. (*Id.*, ¶211.) Indeed, Petitioner Varian developed the systems described in DBDToolbox and DMLCIG to work together. (DBDToolbox, 4; Gall Declaration, ¶211.) DBDToolbox was specifically developed for Varian's "Clinacs equipped with a Dynamic Multileaf Collimator (DMLC)," which is described in DMLCIG. (DBDToolbox, 4; Gall Declaration, ¶211) DBDToolbox and DMLCIG describe components that are used and sold together to enhance Varian's treatment planning and Clinac system capabilities. (*Id*.) A POSA would have read the references together and found that they were obviously a natural and logical combination. (*Id*.) More specifically, when reading one of Varian's references, a POSA would have looked to other Varian references for additional information about features and capabilities of Varian system components and solutions. (*Id*.)

Enhancing DBDToolbox's treatment planning capabilities and Clinac system with DMLCIG's treatment planning and optimization methods, 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, ¶212.)

VII. Ground 2: DBDToolbox in view of Earl renders obvious claims 7-14.

As explained in greater detail below, the combination of DBDToolbox and Earl teaches or suggests claims 7-14 directed toward a treatment planning apparatus. (Gall Declaration, ¶213.) As described in greater detail below, DBDToolbox and Earl would have been obvious to combine, would continue to work as intended after combined, and the combination renders claims 7-14 obvious. (*Id*.)

A. DBDToolbox in view of Earl renders claim 7 obvious

1. The combination of DBDToolbox and Earl teaches or suggests limitation [7.P]

a) DBDToolbox

DBDToolbox teaches or suggests limitation [7.P], at least for the reasons described above in Section VI.A.1. However, to the extent Patent Owner argues that DBDToolbox does not teach or suggest this limitation, it is taught or suggested by Earl.

b) Earl

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, the combination of DBDToolbox and Earl teaches or suggests this limitation. (Gall Declaration, ¶216.)

2. The combination of DBDToolbox and Earl teaches or suggests limitation [7.1.A]

a) DBDToolbox

DBDToolbox teaches or suggests limitation [7.1.A], at least for the reasons described above in Section VI.A.2.a. However, to the extent Patent Owner argues that DBDToolbox does not teach or suggest this limitation, it is taught or suggested by Earl.

b) Earl

Referring to FIG. 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, ¶219.) Thus, the combination of DBDToolbox and Earl teaches or suggests this limitation. (*Id*.)

3. Limitation [7.1.B]

DBDToolbox teaches or suggests limitation [7.1.B], at least for the reasons described above in Section VI.A.3.

4. The combination of DBDToolbox and Earl teaches or suggests limitation [7.2]

a) DBDToolbox

DBDToolbox teaches or suggests limitation [7.2], at least for the reasons described above in Section VI.A.4.a. However, to the extent Patent Owner argues that DBDToolbox does not teach or suggest this limitation, it is taught or suggested by Earl.

b) Earl

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 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, the combination of DBDToolbox and Earl teaches or suggests this limitation. (Gall Declaration, ¶¶222-223.)

5. The combination of DBDToolbox and Earl teaches or suggests [7.3]

a) DBDToolbox

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

b) Earl

Earl discloses a Linac Control System (LCS) that controls the linear accelerator. (*Id.*, ¶225.) 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 id.*, [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***." (*Id.*, [0042].)

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, ¶227.) 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. (*Id.*, ¶228.) Thus, the combination of DBDToolbox and Earl teaches or suggests this limitation. (*Id*.)

6. Limitation [7.4]

DBDToolbox teaches or suggests limitation [7.4], at least for the reasons described above in Section VI.A.6.

7. The combination of DBDToolbox and Earl teaches or suggests [7.4.A]

a) DBDToolbox

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

b) Earl

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. 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, ¶233.)

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, ¶234.)

Further, Earl's MLC has a start and end position. (*Id.*, ¶235.) "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, ¶235.)

A POSA would have understood that Earl's treatment planning system performs the recited functions. (*Id.*, ¶236.) To the extent that the Board finds that the '843 Patent implies some algorithm, a POSA would also have understood that Earl's optimization process would have 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*.)

Thus, the combination of DBDToolbox and Earl teaches or suggests this limitation. (*Id.*, ¶237.)

8. The combination of DBDToolbox and Earl teaches or suggests limitation [7.4.B]

a) DBDToolbox

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

b) Earl

This claim element recites additional functionality performed by the treatment planning apparatus. As described in Section VII.A.7.b, 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. (*Id.*, ¶240.)

Additionally, as described in Section VII.A.7.b, Earl teaches a gantry rotating a specified angle. Earl discloses multiple gantry angles over a prescribed treatment. (Earl, [0040]; Gall Declaration, ¶241.) Thus, Earl teaches or suggests both a first specified rotation angle and a second specified rotation angle. (*Id*.)

Yet further, as described in Section VII.A.7.b, Earl teaches or suggests a multi-leaf collimator that changes shape at varying speeds based on the prescribed shape. (*Id*., ¶242.) 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. 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, ¶243.)

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, ¶244.) 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*.) 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*.)

Thus, 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 an obvious in view of Earl. (*Id*.)

At least for the reasons described in Section VII.A.7.b, a POSA would have understood that Earl teaches or suggests the structure and would have included some algorithm for performing the recited functions. Thus, the combination of DBDToolbox and Earl teaches or suggests this limitation. (*Id.*, ¶246.)

B. Claim 8

DBDToolbox teaches or suggests dependent claim 8, at least for the reasons described above in Section VI.B.1.

C. The combination of DBDToolbox and Earl renders claim 9 obvious

1. DBDToolbox

DBDToolbox teaches or suggests claim 9, at least for the reasons described above in Section VI.C.1. However, to the extent Patent Owner argues that DBDToolbox does not teach or suggest this claim, it is taught or suggested by Earl.

2. Earl

Earl teaches or suggests adjacent (*i.e.*, consecutive) arc-segments. 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, ¶250.) Thus, the combination of DBDToolbox and Earl teaches or suggests this dependent claim. (*Id*.)

D. The combination of DBDToolbox and Earl renders claim 10 obvious

1. DBDToolbox

DBDToolbox teaches or suggests claim 10, at least for the reasons described above in Section VI.D.1. However, to the extent Patent Owner argues that DBDToolbox does not teach or suggest this claim, it is taught or suggested by Earl.

2. Earl

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, ¶254.)

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.*, ¶255.)

Thus, the combination of DBDToolbox and Earl teaches or suggests this dependent claim. (*Id*.)

E. The combination of DBDToolbox and Earl renders claim 11 obvious

1. DBDToolbox

DBDToolbox teaches or suggests claim 11, at least for the reasons described above in Section VI.E.1. However, to the extent Patent Owner argues that DBDToolbox does not teach or suggest this claim, it is taught or suggested by Earl.

2. Earl

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, ¶260.) 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, ¶¶261-262.) A POSA would have understood that Earl's optimized delivery plan could only occur as fast as its slowest parameter. (*Id.*, ¶262.) 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*.) Thus, the combination of DBDToolbox and Earl renders this claim obvious. (*Id*.)

F. DBDToolbox renders claims 12-13 obvious

DBDToolbox teaches or suggests each of dependent claims 12-13 for at least the reasons described in Sections VI.F-G.

G. The combination of DBDToolbox and Earl renders claim 14 obvious

1. DBDToolbox

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

2. Earl

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, ¶267.) Thus, the combination of DBDToolbox and Earl teaches or suggests this claim. (*Id*.)

H. KSR Rationale and Motivation to Combine DBDToolbox with Earl.

As of April 2006, combining the teachings of the DBDToolbox with Earl's teaching of changing the shape of the MLC at a second specified rate per degree, 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, ¶268.)

To provide more robust radiation treatment planning, a POSA would have looked to Earl's treatment planning solutions to enhance the teachings of DBDToolbox. (Gall Declaration, ¶269.) More specifically, a POSA would have enhanced DBDToolbox teachings with Earl's treatment planning system arranged to prepare a treatment plan for delivering a specified dose while the source rotates and the MLC changes shape at a specified rate per degree. (*Id*.) DBDToolbox and Earl are directed to a common field of endeavor, systems designed to provide optimized radiation dose distributions to a patient using an IMAT treatment planning and delivery technique. (*Id*.) Specifically, both DBDToolbox and Earl are directed to control systems that create a treatment plan using a radiotherapeutic apparatus's dose rate, gantry rotation speed, and MLC leaf movement as constraints. (*Id*.) It would have been obvious to enhance DBDToolbox's treatment planning system with the treatment planning methods of Earl. (*Id*.)

Further, a POSA could have enhanced the respective teachings of DBDToolbox and Earl with no change to their respective features or functions, and the combination would have yielded nothing more than predictable results. (*Id.*, ¶270.) The predictable results would be a radiotherapeutic plan prescribing different MLC rates per degree as between the first and second arc-segments. (*Id*.)

VIII. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *Inter Partes Review* of claims 7-14 of the ’843 Patent on Grounds 1 and 2.

IX. 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).

X. 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 OF U.S. PATENT NO. 7,961,843** has 13,889 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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