

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BEST MEDICAL INTERNATIONAL, INC.,)	
)	
<i>Plaintiff,</i>)	Civil Action No.: 1:18-cv-1600-MN
v.)	
)	JURY TRIAL DEMANDED
ELEKTA AB, ELEKTA HOLDINGS U.S.,)	
INC., ELEKTA INC., ELEKTA LTD., AND)	
IMPAC MEDICAL SYSTEMS, INC.,)	
)	
<i>Defendants.</i>)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Best Medical International, Inc. (“Plaintiff” or “Best”), by and through its undersigned counsel, for its first amended complaint against Defendants Elekta AB, Elekta Holdings U.S., Inc. (“Elekta Holdings”), Elekta Inc., Elekta Ltd., and IMPAC Medical Systems, Inc. (“IMPAC”) (together, “Defendants”), hereby alleges and states the following:

PARTIES

1. Plaintiff Best Medical International, Inc. is a corporation organized under the laws of the Commonwealth of Virginia with a principal place of business located at 7643 Fullerton Road, Springfield, Virginia 22153.

2. Best is the owner by assignment of the entire right, title, and interest in and to U.S. Patent No. 6,038,283 (“the ’283 Patent”), titled “Planning Method and Apparatus for Radiation Dosimetry.” A copy of the ’283 Patent is attached hereto as **Exhibit A**.

3. Best is the owner by assignment of the entire right, title, and interest in and to U.S. Patent No. 6,393,096 (“the ’096 Patent”), titled “Planning Method and Apparatus for Radiation Dosimetry.” A copy of the ’096 Patent is attached hereto as **Exhibit B**.

4. Best is the owner by assignment of the entire right, title, and interest in and to U.S. Patent No. 7,266,175 (“the ’175 Patent”), titled “Planning Method for Radiation Therapy.” A copy of the ’175 Patent is attached hereto as **Exhibit C**.

5. Best is the owner by assignment of the entire right, title, and interest in and to U.S. Patent No. 7,015,490 (“the ’490 Patent”), titled “Method and Apparatus for Optimization of Collimator Angles in Intensity Modulated Radiation Therapy Treatment.” A copy of the ’490 Patent is attached hereto as **Exhibit P**.

6. Best, through Best Nomos[®], sells an external beam treatment planning system, Corvus[®], that incorporates embodiments of the patented technologies of the ’283 Patent, ’096 Patent, ’175 Patent, and ’490 Patent (together, the “Patents-In-Suit”).

7. Defendants are competitors of Best in the field of radiotherapy.

8. Upon information and belief, Defendant Elekta AB is a corporation organized and existing under the laws of Sweden, with its principal place of business at Kungstensgatan 18, SE-103 93, Stockholm, Sweden. Upon information and belief, Elekta AB is the parent company of the other Defendants.

9. Upon information and belief, Defendant Elekta AB makes, uses, sells, offers for sale in the United States and/or imports into the United States linear accelerators (“LINACs”), including the Precise Treatment System[™], Versa HD[™], Infinity[™], Synergy[®], and Compact[™] as well as the Monaco[®] treatment planning system.

10. Upon information and belief, Defendant Elekta Holdings is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Perimeter Center Terrace, Suite 50, Atlanta, Georgia 30346.

11. Upon information and belief, Defendant Elekta Holdings makes, uses, sells, offers for sale in the United States and/or imports into the United States LINACs, including the Precise Treatment System™, Versa HD™, Infinity™, Synergy®, and Compact™ as well as the Monaco® treatment planning system.

12. Upon information and belief, Defendant Elekta Inc. is a corporation organized and existing under the laws of the State of Georgia, with its principal place of business at 400 Perimeter Center Terrace, Suite 50, Atlanta, Georgia 30346.

13. Upon information and belief, Defendant Elekta Inc. makes, uses, sells, offers for sale in the United States and/or imports into the United States LINACs, including the Precise Treatment System™, Versa HD™, Infinity™, Synergy®, and Compact™ as well as the Monaco® treatment planning system.

14. Upon information and belief, Defendant Elekta Ltd. is a corporation organized and existing under the laws of the United Kingdom, with its principal place of business at Linac House, Fleming Way, RH10 9RR Crawley, United Kingdom. Upon information and belief, Elekta Ltd. is a subsidiary of Elekta AB.

15. Upon information and belief, Defendant Elekta Ltd. makes, uses, sells, offers for sale in the United States and/or imports into the United States LINACs, including the Precise Treatment System™, Versa HD™, Infinity™, Synergy®, and Compact™ as well as the Monaco® treatment planning system.

16. Upon information and belief, Defendant IMPAC is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Mathilda Place, 5th Floor, Sunnyvale, California 94086.

17. Upon information and belief, Defendant IMPAC makes, uses, sells, and offers for sale in the United States at least the Monaco[®] treatment planning system.

JURISDICTION AND VENUE

18. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, §§ 100 *et seq.*

19. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

20. This Court has personal jurisdiction over Defendants in that each has, directly or through its agents and/or intermediates, committed acts within Delaware giving rise to this action and/or has established minimum contacts with Delaware such that the exercise of jurisdiction would not offend traditional notions of fair play and substantial justice.

21. Defendants Elekta AB, Elekta Holdings, and Elekta Inc. have also purposefully availed themselves of the courts of this venue, having brought counterclaims in, *e.g.*, Civil Action 1:15-cv-00871-LPS, in the federal courts of the District of Delaware. The use of the courts of this jurisdiction is sufficient to give rise to jurisdiction over Defendants Elekta AB, Elekta Holdings, and Elekta Inc.

22. Upon information and belief, each of Defendants regularly conducts business in Delaware and purposefully avails itself of the privileges of conducting business in Delaware. In particular, upon information and belief, each of Defendants directly and/or through its agents and/or intermediates makes, uses, imports, offers for sale, sells, and/or advertises its products and affiliated services in Delaware.

23. Upon information and belief, each of Defendants has committed patent infringement in Delaware that has led to foreseeable harm and injury to Plaintiff. Upon

information and belief, each of Defendants derives substantial revenue from the sale of infringing products distributed within Delaware and/or expect or should reasonably expect its actions to have consequences within Delaware. In addition, upon information and belief, each of Defendants knowingly induced and/or contributed to, and continues to knowingly induce and/or contribute to, infringement of one or more of the Patents-In-Suit within Delaware by offering for sale, selling, and/or contracting with others to market infringing products with the knowledge and intent to facilitate infringing use of the products by others within Delaware and by creating and/or disseminating product information and other materials providing instructions for infringing use.

24. In addition, Defendants Elekta AB and Elekta Ltd. are subject to jurisdiction in the United States, and specifically in Delaware, pursuant to FED. R. CIV. P. 4(k)(2). Elekta AB and Elekta Ltd. each has contacts with the United States that include, but are not limited to, advertising, offering to sell, and/or selling infringing products and software and related products therefor throughout the United States, including in Delaware and this Judicial District.

25. This Court also has personal jurisdiction over Defendants Elekta Holdings and IMPAC by virtue of each being an entity organized and existing under the laws of the State of Delaware, and thus resident within this Judicial District.

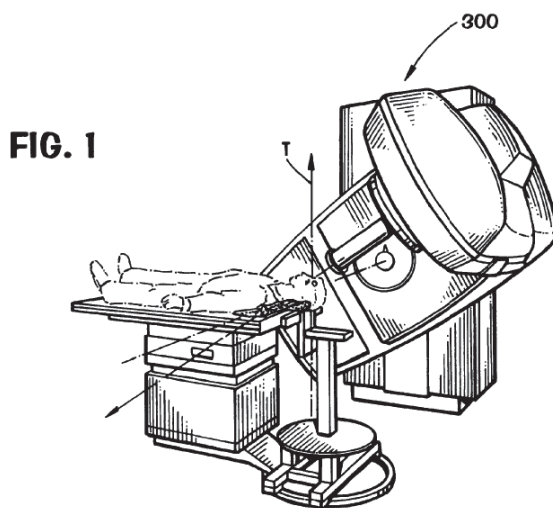
26. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), 1391(c), 1391(d), and/or 1400(b).

BACKGROUND OF THE PATENTS-IN-SUIT

27. The Patents-In-Suit list “Nomos Corporation” as the assignee. Nomos, founded in 1992, was a leading supplier of, *inter alia*, planning and delivery technology for intensity modulated radiation therapy (“IMRT”). As an example, Nomos’ Non-Invasive Scalpel™ IMRT

allowed escalated radiation doses to be delivered to a tumor while limiting exposure and damage to nearby healthy tissue. Nomos changed its name to Best Nomos, Inc. in 2007 as a result of acquisition by Best Medical International, Inc. Best Nomos[®] designs products and solutions that help medical professionals treat a variety of cancers. Those products and solutions accurately plan, target, and deliver radiation treatments to patients all over the world.

28. The Patents-In-Suit relate to radiation therapy for the treatment of tumors. When treating tumors via “conformal radiation therapy,” two major goals include (i) eradicating the tumor and (ii) minimizing damage to healthy tissue and organs located near the tumor. Conformal radiation therapy typically uses a LINAC as the source of the radiation beam used to treat the tumor. The radiation beam source of a LINAC was historically rotated about a patient with the beam directed toward the tumor to be treated.



See Exhibit A, Figure 1, col. 8, ll. 32-34 (depicting a “conventional linear accelerator, including a rotatable couch, collimator and gantry”). Approaches for conformal radiation therapy prior to the Patents-In-Suit included using multi-leaf collimators, which have multiple leaf, or finger, projections that can be moved individually into and out of the path of the radiation beam to form an outline of the tumor shape in an effort to block radiation from transmitting outside a tumor’s

spatial outline. Another approach involved using collimator jaws, which can scan a slit field across a stationary patient at the same time that a separate set of collimator jaws follows the target volume as the gantry of the LINAC rotates. Yet another approach has been the use of narrow pencil beams of high energy photons, whose energy can be varied, and the beams are scanned over the tumor target so as to deliver the best possible radiation dose distribution in each orientation of the gantry upon which the photon beam source is mounted.

29. Yet, all approaches encountered major problems associated with the morphology of tumors and their surroundings. For example, radiation beam intensity needed to be higher for a thick section of a tumor than for a thin section. While attempts were made to combat these problems using, *e.g.*, dedicated scanning beam therapy where beam intensity is modulated by increasing the power of its electron gun generating the beam, such attempts were expensive, time-consuming, and not optimal. Moreover, plans for maximizing eradication of tumor volume while minimizing the amount of radiation delivered to surrounding structures were woefully insufficient.

30. The Patents-In-Suit represent a tremendous advance in radiation therapy by maximizing eradication of a tumor while minimizing damage to healthy tissue and organs located near the tumor.

31. The advances in radiation treatment offered by the Patents-In-Suit swept through the industry, and, upon information and belief, Defendants eventually adopted and copied Best's technologies as claimed in the Patents-in-Suit.

32. The inventions of the Patents-In-Suit are embodied in Best's Corvus[®] treatment planning system.

33. Corvus[®] is a specialized treatment planning system, which includes a computer and software that, in combination with existing LINACs, delivers conformal radiation therapy to tumors while at the same time optimizing the treatment to minimize the harm to other structures.

34. Best, through its predecessor Nomos Corporation, brought Corvus[®] to market and revolutionized conformal radiation therapy. Embodiments of the technology of the Patents-In-Suit included in Corvus[®] enabled radiation oncologists and other clinicians to optimize radiation therapy by balancing competing costs and benefits through a cost-function utilizing partial volume data to determine an optimized beam arrangement that minimizes the dangers of radiation to healthy tissues versus delivering a fully-prescribed dose to the tumor and other targets.

35. Corvus[®] is an inverse treatment planning system that optimizes the delivery of radiation, such as the delivery of a treatment plan of thousands of pencil beams of radiation to meet prescription dose goals and constraints. Corvus[®] provides the ability to manipulate isodose lines after plan determination to improve the plan with immediate, graphical feedback. It also enhances productivity by eliminating the iterative trial and error process of generating the perfect treatment plan thus increasing accuracy and safety while saving patient and clinician time.

36. A further embodiment of the Patents-In-Suit is ActiveRx,[™] which lets treatment providers manipulate isodose lines directly on CT scans, interactively “push” dose out of sensitive structures, and “click and drag” to adjust dose planning volumes. This technology is typically used for complex IMRT treatments using thousands of beams that produce results in seconds. This allows clinicians to quickly understand the subtle interplays of competing goals and move directly to the point of best balance for their patients.

37. At all relevant times, Corvus[®] has been marked with the then-issued Patents-In-Suit.

38. Defendants are a leading provider of equipment and software designed to enhance the delivery of radiation therapy, radiosurgery, and brachytherapy.

39. Defendants develop the accused Monaco[®] treatment planning system in the United States and export the Monaco[®] treatment planning software outside of the United States to be used in Defendants' LINAC systems, including the Precise Treatment System[™], Versa HD[™], Infinity[™], Synergy[®], and Compact[™].

COUNT 1: DIRECT INFRINGEMENT OF THE '283 PATENT

40. Plaintiff incorporates by reference paragraphs 1-39 as if set forth fully herein.

41. This cause of action arises under the patent laws of the United States, including 35 U.S.C. §§ 271 *et seq.*

42. The '283 Patent was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on March 14, 2000, to listed co-inventors Mark P. Carol, Robert C. Campbell, Bruce Curran, Richard W. Huber, and Richard V. Nash. *See Exhibit A, Cover.*

43. Plaintiff is the owner by assignment of all right, title, and interest in and to the '283 Patent. Evidence of the assignment of the '283 Patent from the co-inventors to Nomos Corporation is recorded at the USPTO at Reel 012973, Frame 0723 and from Nomos Corporation to Plaintiff at Reel 020062, Frame 0709.

44. The '283 Patent is titled "Planning Method and Apparatus for Radiation Dosimetry." *See Exhibit A, Cover.*

45. The '283 Patent is directed to, *inter alia*, methods and apparatuses for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while

minimizing radiation of a structure volume in a patient. *See Exhibit A, Abstract.* One of the [1] apparatuses for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient claimed in the '283 Patent comprises [2] a computer, [3] adapted to computationally obtain a proposed radiation beam arrangement, the computer [4] adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights, the computer being [5] further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription and the computer being [6] further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement. *See Exhibit A, Claim 25.*

46. Upon information and belief, at all relevant times Defendants had knowledge of the '283 Patent.

47. Upon information and belief, each of the Defendants has directly infringed, literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), one or more claims of the '283 Patent, including at least Claims 25-28 of the '283 Patent, by making, using, selling, offering for sale, importing, and/or advertising in the United States at least Defendants' LINACs, including the Precise Treatment System™ (*see Exhibit D*), Versa HD™ (*see Exhibit E*), Elekta Infinity™ (*see Exhibit F*), Elekta Synergy® (*see Exhibit G*) and Elekta Compact™ (*see Exhibit H*)

in conjunction with Elekta's Monaco[®] treatment planning system (*see Exhibit I*) (the "Accused Products").

48. Upon information and belief, Defendants' LINACs, including the Precise Treatment System[™], Versa HD[™], Elekta Infinity[™], Elekta Synergy[®], and Elekta Compact[™], in conjunction with Elekta's Monaco[®] treatment planning system, provide and provided apparatuses as set forth in at least Claims 25-28 of the '283 Patent.

49. Upon information and belief, Defendants' Precise Treatment System[™] is an [1] apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient. As noted in the Precise Treatment System[™] brochure, "[i]n radiation dose delivery, it is essential to have constant high speed monitoring and precise control in order to have confidence in the performance of the radiation delivery. . . . [T]he Precise Treatment System provides this confidence. It ensures that the dose rate is prescribed, monitored and managed as it is being delivered through real time communication with additional independent verification at regular intervals against the treatment prescription." *See Exhibit D. p. 4.* The Precise Treatment System[™] has "integrated beam shaping" which allows "[t]he desire to deliver high doses to the target" to be "finely balanced against the growing need to minimize dose to healthy tissue outside of the target volume." *See Exhibit D. p. 7.*

50. Upon information and belief, Defendants state that their Monaco[®] treatment planning system "strives to match optimized plan doses while meeting linac deliverability. In addition, the unique biological modeling capabilities of Monaco apply defined clinical objectives, maximizing confidence in plan assessment and selection." *See Exhibit I, p. 2.* In Defendants' Monaco[®] treatment planning system, "[m]ulti-criterial optimization assures organs

at risk are spared to the highest degree possible while maintaining target coverage. Real time interaction during and after optimization provides the flexibility to precisely tune the plan results as needed.” *See Exhibit I, p. 2.* Accordingly, Defendants’ Precise Treatment System™, when used with Defendants’ Monaco® treatment planning system, is an [1] apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient comprising [2] a computer, [3] adapted to computationally obtain a proposed radiation beam arrangement and [4] changes the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights, the computer being [5] further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription and the computer being [6] further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

51. That Defendants’ Accused Products have infringed the ’283 Patent is further supported by information made public as a result of a proceeding before the International Trade Commission titled “In the Matter of Certain Radiotherapy Systems and Treatment Planning Software, and Components Thereof,” Investigation No. 337-TA-968 (“the ITC Matter”) between complainants Varian Inc. and Varian AG and respondents Elekta AB, Elekta Ltd., Elekta GmbH, Elekta Inc., IMPAC Medical Systems, Inc., Elekta Instrument (Shanghai) Limited, and Elekta

Beijing Medical System Co. Ltd. *See Exhibit J.*

52. Upon information and belief, Defendants' Monaco[®] treatment planning system included and includes software for planning radiation treatment. *See Exhibits I, K.*

53. The Final Initial Determination in the ITC Matter states that "[t]he evidence shows that the combination of Monaco and the Accused Linacs practice a method for planning delivery of radiation dose to a target region within a subject such as a patient or phantom." *See Exhibit J, p. 312.*

54. The Final Initial Determination in the ITC Matter states that Defendants' Monaco[®] treatment planning system uses "(1) fluence map optimization, (2) arc sequencing and (3) direct aperture optimization, to generate a VMAT plan." *See Exhibit J, p. 233.*

55. The Final Initial Determination in the ITC Matter states that "[t]he evidence shows **that Monaco's stage one optimization process**, which as discussed above iteratively optimizes the simulated dose distribution relative to the set of one or more optimization goals over the initial plurality of control points, **uses a set of optimization parameters representative of a beam shape as well as a beam intensity.**" *See Exhibit J, p. 322* (emphasis added).

56. The ITC Matter revealed that a user of Defendants' Monaco[®] software can specify "**one or more optimization goals, including a desired dose distribution . . . for the patient . . . in an attempt to target the tumor while avoiding healthy tissue.**" *See Exhibit J, p. 313* (emphasis added).

57. Accordingly, Defendants' Accused Products include an [1] apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, or equivalent thereof.

58. Defendants' Monaco[®] treatment planning system includes software which

executes on and uses [2] a computer for planning radiation treatment. *See Exhibits I, K.*

59. The User Guide for the Monaco[®] treatment planning system states:

By selecting the Planning activity, you are using highly developed, inverse planning methods to generate a treatment plan based on CT or Transverse MR images. **The Monaco IMRT software lets you identify the clinical goals first and then use the optimization algorithm to find the best configuration of beam intensities. During the first stage of optimization, Monaco divides the beam fields into beamlets (often hundreds or thousands) of varying intensities that, when summed, deliver the prescribed dose.**

Monaco optimizes treatment plans using cost functions that model several different types of tissue and volume specific radiation responses. Monaco uses constrained optimization, in which dose limiting constraints are satisfied while attempting to deliver target dose objectives. The optimization algorithms work within parameters that impose several limits on the decision variables so that the dose delivered to the tumor is the maximum effective dose under the given dose constraints. Monaco allows coplanar and non-coplanar beam arrangements using isocentric, non-SSD beams.

Exhibit O, p. 56 (emphasis added).

60. Accordingly, Defendants' Accused Products include a computer [3] adapted to computationally obtain a proposed radiation beam arrangement, or equivalent thereof and [4] computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights, or equivalents thereof.

61. The User Guide for the Monaco[®] treatment planning system states that in Monaco[®], “[t]he DVH [dose volume histogram] function automatically sums the volumes of component anatomical structures and considers the doses to all component structures when calculating the DVH for an anatomical structure.” *Exhibit N, p. 53.*

62. The User Guide for the Monaco[®] treatment planning system states that “Monaco uses a two-stage process of optimizing dose distributions. Generally, in stage one, the ‘ideal

fluence' distribution of beams is optimized to meet a user-defined prescription for a single set of beams. In stage two, the ideal fluence distribution is translated into a set of segments where the shapes and weights are optimized based on the same prescription." *Exhibit L, p. 8-1.*

63. The Final Initial Determination in the ITC Matter states that "[t]he evidence shows that Monaco's stage one optimization process, which as discussed above iteratively optimizes the simulated dose distribution relative to the set of one or more optimization goals over the initial plurality of control points, uses a set of optimization parameters representative of a beam shape as well as a beam intensity." *Exhibit J, p. 322.*

64. Accordingly, Defendants' Accused Products comprise a computer which is adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights.

65. The Monaco[®] Training Guide identifies various algorithms and their implementation for Monaco's Physical cost functions and Biological cost functions. *See Exhibit L, pp. 18-2-18-6.* These cost functions have control points or control region values used as input variables to a parameterized influence function for each target or structure. *See Exhibit L, pp. 18-2-18-32.* The resultant values from the influence function calculation for each control point or control region value of each target and structure are summed to produce a final cost of the proposed beam weights reflected by a proposed CDVH curve, similar to or equivalent to the influence type cost functions of the '283 Patent. *See Exhibit L, pp. 18-2-18-32.*

Monaco Cost Functions

Biological (dose response-based) Cost Functions

- Poisson (EUD) –Targets
- Serial (EUD)/Parallel – OARs
- Implementation in IMRT treatment planning system is conceptually new

Physical (dose-based) Cost Functions

- Overdose/Underdose Volume Constraints
- Quadratic Overdose/Underdose
- Common to all current IMRT treatment planning systems

See Exhibit M, p. 1-10.

66. The User Guide for the Monaco[®] treatment planning system states that “Monaco provides a dose volume histogram (DVH) of each structure that is contoured on two or more transverse images. The DVH summarizes dose distribution information throughout normal tissue and tumors . . . [d]ose volume histograms are plotted as cumulative, not differential, histograms showing the total volume for every structure defined in the patient. The cumulative DVH shows the volume of a structure that will receive a specific dose or greater. The DVHs are created by summing the number of dose points from high dose to low dose.” *See Exhibit N, p. 51.*

67. Accordingly, Defendants’ Accused Products comprise a computer [5] further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, or equivalent thereof.

68. The Monaco[®] Training Guide states that “Monaco uses a two-stage process of optimizing dose distributions. Generally, in stage one, the ‘ideal fluence’ distribution of beams is optimized to meet a user-defined prescription for a single set of beams. In stage two, the ideal fluence distribution is translated into a set of segments where the shapes and weights are

optimized based on the same prescription.” *Exhibit L, p. 8-1.*

69. The Final Initial Determination in the ITC Matter states that “[t]he evidence shows that the combination of Monaco and the Accused Linacs practice a method for planning delivery of radiation dose to a target region within a subject such as a patient or phantom . . . [t]he evidence shows that Monaco iteratively optimizes [by a processor] a simulated dose distribution relative to a set of optimization goals, including a desired dose distribution entered by a user, over an initial set of control points along a trajectory.” *Exhibit J, pp. 312-313.*

70. The Final Initial Determination in the ITC Matter further states that “the simulated dose distribution is iteratively optimized by Monaco’s stage one optimization process over the initial plurality of control points” and that “Monaco’s stage two optimization process will optimize the simulated dose distribution relative to the one or more optimization goals over the increased plurality of control points, in order to determine a radiation delivery plan.” *Exhibit J, pp. 316-320.*

71. Accordingly, Defendants’ Accused Products comprise a computer [6] further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement, or equivalent thereof.

72. Upon information and belief, Defendants’ past direct infringement of the ’283 Patent has irreparably harmed Best.

73. Upon information and belief, Defendants’ past direct infringement of the ’283 Patent has caused and will cause Best damages.

74. Upon information and belief, Defendants' past direct infringement of the '283 Patent was knowing and willful.

COUNT 2: INDIRECT INFRINGEMENT OF THE '283 PATENT BY INDUCEMENT

75. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-74 above as if fully set forth herein.

76. Upon information and belief, at all relevant times Defendants had knowledge of the '283 Patent.

77. Upon information and belief, Defendants are liable for inducing infringement of the '283 Patent under 35 U.S.C. § 271(b) by having knowledge of the '283 Patent and knowingly causing or intending to cause direct infringement of the '283 Patent, with specific intent, by their customers.

78. Upon information and belief, Defendants have actively induced infringement of the '283 Patent by, *inter alia*, training their customers on the use of the Accused Products and/or promotion, sales, and/or importation of the Accused Products to Defendants' customers.

79. Upon information and belief, Defendants' customers for the Accused Products directly infringed the '283 Patent by, *inter alia*, using the Accused Products.

80. Upon information and belief, Defendants intended to indirectly infringe the '283 Patent by inducement by having sold the Accused Products for use by Defendants' customers.

81. Upon information and belief, Defendants knew or should have known of the '283 Patent and have acted in an egregious and wanton manner by indirectly infringing the '283 Patent.

82. Upon information and belief, despite knowing that their actions constituted induced infringement of the '283 Patent and/or despite knowing that there was a high likelihood that their actions constituted induced infringement of the '283 Patent, Defendants nevertheless

continued their infringing actions, and continued making, using, offering for sale, and selling the Accused Products.

83. Upon information and belief, Defendants' past induced infringement of the '283 Patent has irreparably harmed Best.

84. Upon information and belief, Defendants' past induced infringement of the '283 Patent has and will cause Best damages.

85. Upon information and belief, Defendants' past induced infringement of the '283 Patent was knowing and willful.

COUNT 3: INDIRECT INFRINGEMENT OF THE '283 PATENT BY CONTRIBUTORY INFRINGEMENT

86. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-85 above as if fully set forth herein.

87. Upon information and belief, at all relevant times Defendants had knowledge of the '283 Patent.

88. Upon information and belief, Defendants are liable for contributory infringement of the '283 Patent under 35 U.S.C. § 271(c) by, *inter alia*, having sold or offered to sell the Accused Products within the United States and/or by having imported the Accused Products into the United States because the Accused Products constituted a material part of the invention embodied in the '283 Patent, which, upon information and belief, Defendants knew to be especially made and/or especially adapted for use in infringement of the '283 Patent, and which were not staple articles or commodities of commerce suitable for substantial non-infringing use.

89. Upon information and belief, Defendants are liable for contributory infringement of the '283 Patent by having had knowledge of the '283 Patent and having knowingly caused or having intended to cause direct infringement of the '283 Patent by their customers, including,

e.g., end users of the Accused Products.

90. Upon information and belief, Defendants contributed to infringement of the '283 Patent by, *inter alia*, promotion, sales, and/or importation of the Accused Products to Defendants' customers, including, *e.g.*, end users who used apparatuses claimed in the '283 Patent and perform methods claimed in the '283 Patent. Upon information and belief, Defendants' customers directly infringed the '283 Patent by, *e.g.*, using the Accused Products.

91. Upon information and belief, Defendants' past contributory infringement of the '283 Patent has irreparably harmed Best.

92. Upon information and belief, Defendants' past contributory infringement of the '283 Patent has caused Best damages.

93. Upon information and belief, Defendants' past contributory infringement of the '283 Patent was knowing and willful.

COUNT 4: INDIRECT INFRINGEMENT OF THE '283 PATENT UNDER 271(f)(2)

94. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-93 above as if fully set forth herein.

95. Upon information and belief, Defendants are liable for indirect infringement of the '283 Patent under 35 U.S.C. § 271(f)(2) by, *inter alia*, supplying or causing to be supplied in or from the United States at least one component (*e.g.* the Monaco[®] treatment planning system), uncombined in whole or in part, which was especially made or especially adapted for use in practicing the inventions of one or more claims of the '283 Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use. This supply has been made with Defendants' knowledge that such component is especially made or adapted for use in the inventions of one or more claims of the '283 Patent and with Defendants' intent that such component will be combined outside of the United States, resulting in Defendants' LINAC

systems, including the Precise Treatment System™, Versa HD™, Infinity™, Synergy®, and Compact™, that employ the inventions of one or more of the claims of the '283 Patent.

96. The Final Initial Determination in the ITC Matter states that “IMPAC Medical Systems, Inc. develops and manufactures Elekta treatment planning software within the United States.” *Exhibit J, p. 3.*

97. The Final Initial Determination in the ITC Matter further states that “Elekta’s Monaco treatment planning software . . . was developed in the United States, and is supplied from Elekta’s location in the United States, which employs U.S. employees. Monaco has not been imported.” *Exhibit J, p. 17.*

98. Upon information and belief, Defendants export the Monaco® treatment planning software outside of the United States to be used in LINAC systems, including Defendants’ LINAC systems, including the Precise Treatment System™, Versa HD™, Infinity™, Synergy®, and Compact™.

99. Upon information and belief, Defendants’ past indirect infringement of the '283 Patent under 35 U.S.C. § 271(f)(2) has irreparably harmed Best.

100. Upon information and belief, Defendants’ past indirect infringement of the '283 Patent under 35 U.S.C. § 271(f)(2) has and will cause Best damages.

101. Upon information and belief, Defendants’ past indirect infringement of the '283 Patent under 35 U.S.C. § 271(f)(2) was knowing and willful.

COUNT 5: DIRECT INFRINGEMENT OF THE '096 PATENT

102. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-101 above as if fully set forth herein.

103. This cause of action arises under the patent laws of the United States, including 35 U.S.C. §§ 271 *et seq.*

104. The '096 Patent was duly and lawfully issued by the USPTO on May 21, 2002, to listed co-inventors Mark P. Carol, Robert Hill, Bruce Curran, and Richard V. Nash. *See Exhibit B, Cover.*

105. Plaintiff is the owner by assignment of all right, title, and interest in and to the '096 Patent. Evidence of the assignment of the '096 Patent from co-inventors Carol, Hill, and Nash to Nomos Corporation is recorded at the USPTO at Reel 012973, Frame 0698, from co-inventor Curran to Nomos Corporation at Reel 012973, Frame 0694, and from Nomos Corporation to Plaintiff at Reel 020062, Frame 0709.

106. The '096 Patent is titled "Planning Method and Apparatus for Radiation Dosimetry." *See Exhibit B, Cover.*

107. The '096 Patent is directed to, *inter alia*, methods and apparatuses for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient. *See Exhibit B, Abstract.* One of the [1] apparatuses for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient claimed in the '096 Patent comprises [2] a computer adapted to [3] computationally obtain a proposed radiation beam arrangement, [4] computationally change the proposed radiation beam arrangement iteratively to conform to a target CDVH curve, [5] incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription, [6] reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change

of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement, and [7] exceed the cost function by a set amount if such excess allows better conformation with the target CDHV curve. *See Exhibit B, Claim 31.*

108. Upon information and belief, at all relevant times Defendants had knowledge of the '096 Patent.

109. Upon information and belief, each of the Defendants has been and is now directly infringing, literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), one or more claims of the '096 Patent, including at least Claims 31-33 of the '096 Patent, by making, using, selling, offering for sale, importing, and/or advertising in the United States at least Defendants' LINACs, including the Precise Treatment System[™] (*see Exhibit D*), Versa HD[™] (*see Exhibit E*), Elekta Infinity[™] (*see Exhibit F*), Elekta Synergy[®] (*see Exhibit G*) and Elekta Compact[™] (*see Exhibit H*) in conjunction with Elekta's Monaco[®] treatment planning system (*see Exhibit I*).

110. Upon information and belief, Defendants' LINACs, including the Precise Treatment System[™], Versa HD[™], Elekta Infinity[™], Elekta Synergy[®], and Elekta Compact[™], in conjunction with Elekta's Monaco[®] treatment planning system, provide apparatuses as set forth in at least Claims 31-33 of the '096 Patent.

111. Upon information and belief, Defendants' Precise Treatment System[™] is an [1] apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume. As noted in the Precise Treatment System[™] brochure, "[i]n radiation dose delivery, it is essential to have constant high speed monitoring and precise control in order to have confidence in the performance of the

radiation delivery. . . . [T]he Precise Treatment System provides this confidence. It ensures that the dose rate is prescribed, monitored and managed as it is being delivered through real time communication with additional independent verification at regular intervals against the treatment prescription.” *See Exhibit D, p. 4.* The Precise Treatment System™ has “integrated beam shaping” which allows “[t]he desire to deliver high doses to the target” to be “finely balanced against the growing need to minimize dose to healthy tissue outside of the target volume.” *See Exhibit D, p. 7.*

112. Upon information and belief, Defendants’ Monaco® treatment planning system “strives to match optimized plan doses while meeting linac deliverability. In addition, the unique biological modeling capabilities of Monaco apply defined clinical objectives, maximizing confidence in plan assessment and selection.” *See Exhibit I, p. 2.* In Defendants’ Monaco® treatment planning system, “[m]ulti-criterial optimization assures organs at risk are spared to the highest degree possible while maintaining target coverage. Real time interaction during and after optimization provides the flexibility to precisely tune the plan results as needed.” *See Exhibit I, p. 2.* Accordingly, Defendants’ Precise Treatment System™, when used with Defendants’ Monaco® treatment planning system, is an [1] apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient comprising [2] a computer adapted to [3] computationally obtain a proposed radiation beam arrangement, [4] computationally change the proposed radiation beam arrangement iteratively to conform to a target CDVH curve, [5] incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription, [6] reject the change of the proposed radiation beam arrangement if the change of

the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement, and [7] exceed the cost function by a set amount if such excess allows better conformation with the target CDHV curve.

113. That Defendants' Accused Products have infringed the '096 Patent is further supported by information made public as a result of the ITC Matter. *See Exhibit J.*

114. Upon information and belief, Defendants' Monaco[®] treatment planning system includes software for planning radiation treatment. *See Exhibits I, K.*

115. The Final Initial Determination in the ITC Matter states that "[t]he evidence shows that the combination of Monaco and the Accused Linacs practice a method for planning delivery of radiation dose to a target region within a subject such as a patient or phantom." *See Exhibit J, p. 312.*

116. The Final Initial Determination in the ITC Matter states that Defendants' Monaco[®] treatment planning system uses "(1) fluence map optimization, (2) arc sequencing and (3) direct aperture optimization, to generate a VMAT plan." *See Exhibit J, p. 233.*

117. The Final Initial Determination in the ITC Matter states that "[t]he evidence shows **that Monaco's stage one optimization process**, which as discussed above iteratively optimizes the simulated dose distribution relative to the set of one or more optimization goals over the initial plurality of control points, **uses a set of optimization parameters representative of a beam shape as well as a beam intensity.**" *See Exhibit J, p. 322* (emphasis added).

118. The ITC Matter revealed that a user of Defendants' Monaco[®] software can specify "**one or more optimization goals, including a desired dose distribution . . . for the**

patient . . . in an attempt to target the tumor while avoiding healthy tissue.” *See Exhibit J, p. 313* (emphasis added).

119. Accordingly, Defendants’ Accused Products include an [1] apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, or equivalent thereof.

120. Defendants’ Monaco[®] treatment planning system includes software which executes on and uses [2] a computer for planning radiation treatment. *See Exhibits I, K.*

121. The User Guide for the Monaco[®] treatment planning system states:

By selecting the Planning activity, you are using highly developed, inverse planning methods to generate a treatment plan based on CT or Transverse MR images. **The Monaco IMRT software lets you identify the clinical goals first and then use the optimization algorithm to find the best configuration of beam intensities. During the first stage of optimization, Monaco divides the beam fields into beamlets (often hundreds or thousands) of varying intensities that, when summed, deliver the prescribed dose.**

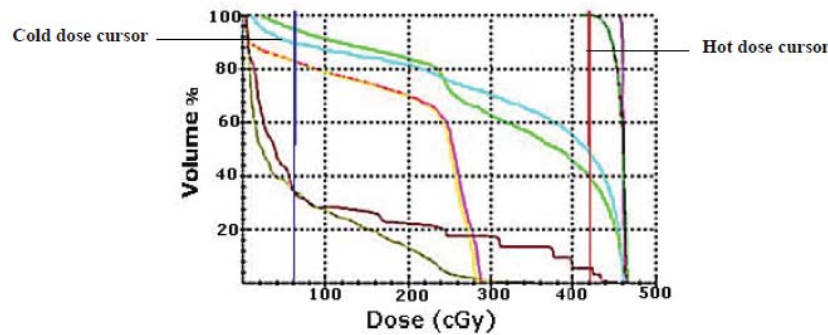
Monaco optimizes treatment plans using cost functions that model several different types of tissue and volume specific radiation responses. Monaco uses constrained optimization, in which dose limiting constraints are satisfied while attempting to deliver target dose objectives. The optimization algorithms work within parameters that impose several limits on the decision variables so that the dose delivered to the tumor is the maximum effective dose under the given dose constraints. Monaco allows coplanar and non-coplanar beam arrangements using isocentric, non-SSD beams.

Exhibit O, p. 56 (emphasis added).

122. Accordingly, Defendants’ Accused Products include a computer adapted to [3] computationally obtain a proposed radiation beam arrangement, or equivalent thereof.

123. The User Guide for the Monaco[®] treatment planning system states that in Monaco[®], “[t]he DVH [dose volume histogram] function automatically sums the volumes of these component structures and considers the doses to all component structures when calculating

the DVH for an anatomical structure.” *Exhibit N, p. 53.*



Dose volume histograms are plotted as cumulative, not differential, histograms showing the total volume for every structure defined in the patient. The cumulative DVH shows the volume of a structure that will receive a specific dose or greater. The DVHs are created by summing the number of dose points from high dose to low dose. This method adds the number of dose points in the highest dose bin to those in the next highest (smaller) dose bin, then adding this total to the dose points in the second to next highest dose bin and so on. Therefore, in the cumulative DVH, volumes for higher doses will always be less than or equal to volumes for lower doses.

See Exhibit N, p. 51.

124. The Final Initial Determination in the ITC Matter states that “[t]he evidence shows that Monaco’s stage one optimization process, which as discussed above iteratively optimizes the simulated dose distribution relative to the set of one or more optimization goals over the initial plurality of control points, uses a set of optimization parameters representative of a beam shape as well as a beam intensity.” *Exhibit J, p. 322.*

125. Accordingly, Defendants’ Accused Products comprise a computer which is adapted to [4] computationally change the proposed radiation beam arrangement iteratively to conform to a target CDVH curve, or equivalent thereof.

126. The Monaco[®] Training Guide identifies various algorithms and their implementation for Monaco’s Physical cost functions and Biological cost functions. *See Exhibit L, pp. 18-2-18-6.* These cost functions have control points or control region values used as an input variable to a parameterized influence function for each target or structure. *See Exhibit L, pp. 18-2-18-32.* The resultant values from the influence function calculation for each control

point or control region value of each target and structure are summed to produce a final cost of the proposed beam weights reflected by a proposed CDVH curve, similar to or equivalent to the influence type cost functions of the '096 Patent. *See Exhibit L, pp. 18-2-18-32.*

Monaco Cost Functions

Biological (dose response-based) Cost Functions

- Poisson (EUD) –Targets
- Serial (EUD)/Parallel – OARs
- Implementation in IMRT treatment planning system is conceptually new

Physical (dose-based) Cost Functions

- Overdose/Underdose Volume Constraints
- Quadratic Overdose/Underdose
- Common to all current IMRT treatment planning systems

See Exhibit M, p. 1-10.

127. The User Guide for the Monaco[®] treatment planning system states that “Monaco provides a dose volume histogram (DVH) of each structure that is contoured on two or more transverse images. The DVH summarizes dose distribution information throughout normal tissue and tumors . . . [d]ose volume histograms are plotted as cumulative, not differential, histograms showing the total volume for every structure defined in the patient. The cumulative DVH shows the volume of a structure that will receive a specific dose or greater. The DVHs are created by summing the number of dose points from high dose to low dose.” *See Exhibit N, p. 51.*

128. Accordingly, Defendants’ Accused Products comprise a computer adapted to [5] incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription, or equivalent thereof.

129. The Monaco[®] Training Guide states that “Monaco uses a two-stage process of optimizing dose distributions. Generally, in stage one, the ‘ideal fluence’ distribution of beams is optimized to meet a user-defined prescription for a single set of beams. In stage two, the ideal fluence distribution is translated into a set of segments where the shapes and weights are optimized based on the same prescription.” *Exhibit L, p. 8-1.*

130. The Final Initial Determination in the ITC Matter states that “[t]he evidence shows that the combination of Monaco and the Accused Linacs practice a method for planning delivery of radiation dose to a target region within a subject such as a patient or phantom . . . [t]he evidence shows that Monaco iteratively optimizes [by a processor] a simulated dose distribution relative to a set of optimization goals, including a desired dose distribution entered by a user, over an initial set of control points along a trajectory.” *Exhibit J, pp. 312-313.*

131. The Final Initial Determination in the ITC Matter further states that “the simulated dose distribution is iteratively optimized by Monaco’s stage one optimization process over the initial plurality of control points” and that “Monaco’s stage two optimization process will optimize the simulated dose distribution relative to the one or more optimization goals over the increased plurality of control points . . . in order to determine a radiation delivery plan.” *Exhibit J, pp. 316-320.*

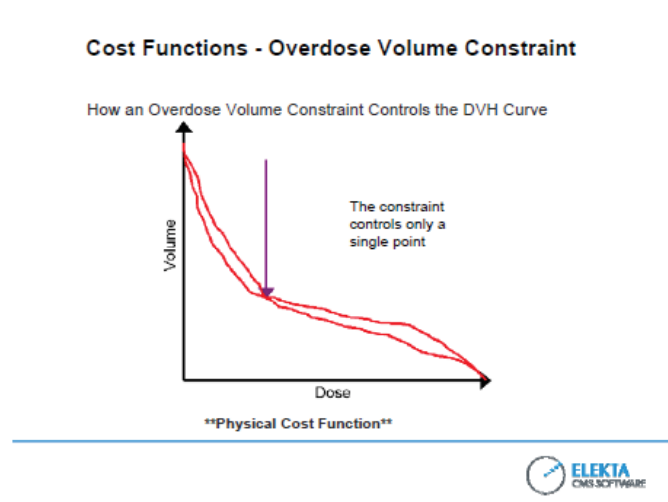
132. Accordingly, Defendants’ Accused Products comprise a computer adapted to [6] reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement, or equivalent thereof.

133. The Monaco[®] Training Guide states that “Monaco provides feedback for each target volume defining which constraint should be relaxed in order to improve target coverage.”

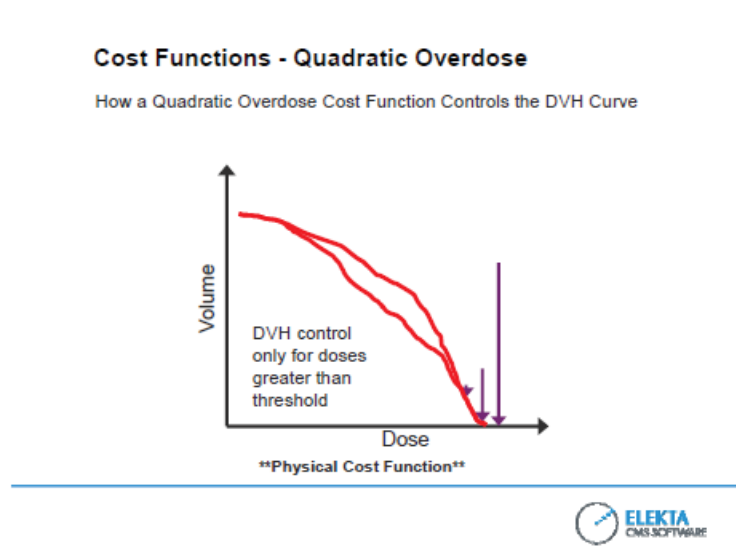
See Exhibit L, p. 8-3.

134. The Monaco[®] Training Guide further states that in Monaco Step and Shoot IMRT Delivery Mode, “[t]he beamlet and segment weights are optimized using constrained optimization **where the Minimum MU/Segment is evaluated and segments are refined.**” *See Exhibit L, p. 8-5 (emphasis added).*

135. The Monaco[®] Training Guide discloses that in Monaco[®], the Overdose Volume Constraint is a physical cost function that controls the DVH curve at a point or points. **The quadratic overdose cost function controls the DVH curve for doses greater than threshold.**



Notice this physical cost function only controls dose to a point (or points, if you applied multiple ones).



This physical cost function only control high doses. This is actually a useful one to employ in addition to some biological cost functions.

See Exhibit M, pp. 1-11, 1-12.

136. The Monaco[®] Training Guide further discloses that in Monaco[®], the Underdose-Volume Constraint (DVH) is a physical cost function that is the equivalent of a DVH constraint for targets. *See Exhibit M, p. 9-25.* This constraint “requires two parameters, the **Threshold Dose** and the isoconstraint **% Volume < Threshold Dose**. Applying this cost function keeps the volume that receives less than the threshold dose above the isoconstraint, which is given as a percentage of the total volume.” *See Exhibit M, p. 10-18* (emphasis original). The Underdose DVH controls a point on the DVH curve. *See Exhibit M, pp. 10-14, 10-15, 10-18* (“For example, use this constraint if you want at least 80% of a structure to receive a dose of at least 50 Gy.”).

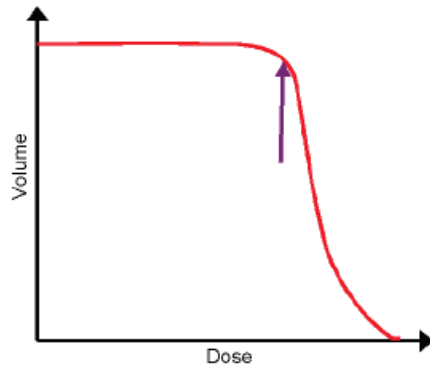


Figure 10-22: How an Underdose DVH Constraint Controls the DVH Curve

See Exhibit M, p. 10-18.

137. Accordingly, Defendants' Accused Products comprise a computer adapted to [7] exceed the cost function by a set amount if such excess allows better conformation with the target CDHV curve, or equivalent thereof.

138. Upon information and belief, Defendants' past and ongoing direct infringement of the '096 Patent has and will continue to irreparably harm Best.

139. Upon information and belief, Defendants' past and ongoing direct infringement of the '096 Patent has and will cause Best damages.

140. Upon information and belief, Defendants' past and ongoing direct infringement of the '096 Patent has been knowing and willful.

141. Upon information and belief, Defendants' actions have caused Best to suffer irreparable harm resulting from the abuse of its patent rights, including the ability to exclude others from the market. Upon information and belief, Defendants will continue these infringing acts unless enjoined by this court.

COUNT 6: INDIRECT INFRINGEMENT OF THE '096 PATENT BY INDUCEMENT

142. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-141 above as if fully set forth herein.

143. Upon information and belief, at all relevant times Defendants had knowledge of the '096 Patent.

144. Upon information and belief, Defendants are liable for inducing infringement of the '096 Patent under 35 U.S.C. § 271(b) by having knowledge of the '096 Patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, direct infringement of the '096 Patent, with specific intent, by their customers.

145. Upon information and belief, Defendants actively induce infringement of the '096 Patent by, *inter alia*, training their customers on the use of the Accused Products and/or promotion, sales, and/or importation of the Accused Products to Defendants' customers.

146. Upon information and belief, Defendants' customers for the Accused Products directly infringe the '096 Patent by, *inter alia*, using the Accused Products.

147. Upon information and belief, Defendants intend to, and continue to intend to, indirectly infringe the '096 Patent by inducement by selling the Accused Products for use by Defendants' customers.

148. Upon information and belief, Defendants knew or should have known of the '096 Patent and have acted, and continue to act, in an egregious and wanton manner by indirectly infringing the '096 Patent.

149. Upon information and belief, despite knowing that their actions constituted induced infringement of the '096 Patent and/or despite knowing that there was a high likelihood that their actions constituted induced infringement of the '096 Patent, Defendants nevertheless continue their infringing actions, and continue to make, use, offer for sale, and sell the Accused Products.

150. Upon information and belief, Defendants' past and ongoing induced infringement

of the '096 Patent have and will continue to irreparably harm Best.

151. Upon information and belief, Defendants' past and ongoing induced infringement of the '096 Patent has and will cause Best damages.

152. Upon information and belief, Defendants' past and ongoing induced infringement of the '096 Patent has been knowing and willful.

153. Upon information and belief, Defendants' actions have caused Best to suffer irreparable harm resulting from the abuse of its lawful patent rights, including the ability to exclude others from the market. Upon information and belief, Defendants will continue these infringing acts unless enjoined by this court.

COUNT 7: INDIRECT INFRINGEMENT OF THE '096 PATENT BY CONTRIBUTORY INFRINGEMENT

154. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-153 above as if fully set forth herein.

155. Upon information and belief, at all relevant times Defendants had knowledge of the '096 Patent.

156. Upon information and belief, Defendants are liable for contributory infringement of the '096 Patent under 35 U.S.C. § 271(c) by, *inter alia*, having sold or offered to sell, and continuing to sell or offer to sell, the Accused Products within the United States and/or by importing the Accused Products into the United States because the Accused Products constitute a material part of the invention embodied in the '096 Patent, which, upon information and belief, Defendants know to be especially made and/or especially adapted for use in infringement of the '096 Patent, and which are not staple articles or commodities of commerce suitable for substantial non-infringing use.

157. Upon information and belief, Defendants are liable for contributory infringement

of the '096 Patent by having knowledge of the '096 Patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, direct infringement of the '096 Patent by their customers, including, *e.g.*, end users of the Accused Products.

158. Upon information and belief, Defendants contribute to infringement of the '096 Patent by, *inter alia*, promotion, sales, and/or importation of the Accused Products to Defendants' customers, including, *e.g.*, end users who use apparatuses claimed in the '096 Patent and perform methods claimed in the '096 Patent. Upon information and belief, Defendants' customers directly infringe the '096 Patent by, *e.g.*, using the Accused Products.

159. Upon information and belief, Defendants' past and ongoing contributory infringement of the '096 Patent has and will continue to irreparably harm Best.

160. Upon information and belief, Defendants' past and ongoing contributory infringement of the '096 Patent has and will cause Best damages.

161. Upon information and belief, Defendants' past and ongoing contributory infringement of the '096 Patent has been knowing and willful.

162. Upon information and belief, Defendants' actions have caused Best to suffer irreparable harm resulting from the abuse of its lawful patent rights, including the ability to exclude others from the market. Upon information and belief, Defendants will continue these infringing acts unless enjoined by this court.

COUNT 8: INDIRECT INFRINGEMENT OF THE '096 PATENT UNDER 271(f)(2)

163. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-162 above as if fully set forth herein.

164. Upon information and belief, Defendants are liable for indirect infringement of the '096 Patent under 35 U.S.C. § 271(f)(2) by, *inter alia*, supplying or causing to be supplied in or from the United States at least one component (*e.g.* the Monaco[®] treatment planning system),

uncombined in whole or in part, which was especially made or especially adapted for use in practicing the inventions of one or more claims of the '096 Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use. This supply has been made with Defendants' knowledge that such component is especially made or adapted for use in the inventions of one or more claims of the '096 Patent and with Defendants' intent that such component will be combined outside of the United States, resulting in Defendants' LINAC systems, including the Precise Treatment System[™], Versa HD[™], Infinity[™], Synergy[®], and Compact[™], that employ the inventions of one or more of the claims of the '096 Patent.

165. The Final Initial Determination in the ITC Matter states that "IMPAC Medical Systems, Inc. develops and manufactures Elekta treatment planning software within the United States." *Exhibit J, p. 3.*

166. The Final Initial Determination in the ITC Matter further states that "Elekta's Monaco treatment planning software . . . was developed in the United States, and is supplied from Elekta's location in the United States, which employs U.S. employees. Monaco has not been imported." *Exhibit J, p. 17.*

167. Upon information and belief, Defendants export the Monaco[®] treatment planning software outside of the United States to be used in LINAC systems, including Defendants' LINAC systems, including the Precise Treatment System[™], Versa HD[™], Infinity[™], Synergy[®], and Compact[™].

168. Upon information and belief, Defendants' indirect infringement of the '096 Patent under 35 U.S.C. § 271(f)(2) has irreparably harmed Best.

169. Upon information and belief, Defendants' indirect infringement of the '096 Patent under 35 U.S.C. § 271(f)(2) has and will cause Best damages.

170. Upon information and belief, Defendants' indirect infringement of the '096 Patent under 35 U.S.C. § 271(f)(2) was knowing and willful.

COUNT 9: DIRECT INFRINGEMENT OF THE '175 PATENT

171. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-170 above as if fully set forth herein.

172. This cause of action arises under the patent laws of the United States, including 35 U.S.C. §§ 271 *et seq.*

173. The '175 Patent was duly and lawfully issued by the USPTO on September 4, 2007, to listed inventor Merle Romesberg. *See Exhibit C, Cover.*

174. Plaintiff is the owner by assignment of all right, title, and interest in and to the '175 Patent. Evidence of the assignment of the '175 Patent from inventor Romesberg to Nomos Corporation is recorded at the USPTO at Reel 016920, Frame 0083 and from Nomos Corporation to Plaintiff at Reel 020062, Frame 0709.

175. The '175 Patent is titled "Planning Method for Radiation Therapy." *See Exhibit C, Cover.*

176. The '175 Patent is directed to, *inter alia*, methods for controlling the correlation between the factors of treatment plan efficiency and dosimetric fitness to optimize the radiation therapy or radiotherapy plan. *See Exhibit C, Abstract.* One of the methods [1] of providing control of a trade-off between treatment plan delivery efficiency and dosimetric fitness to optimize a radiation treatment plan within a continuum between delivery efficiency and dosimetric fitness claimed in the '175 Patent comprises the steps of [2] assigning a delivery cost term within an optimizer to each of a plurality of intensity maps representing a potential radiation beam arrangement, the assignment based on complexity of each respective intensity map; and [3] evaluating an objective cost function for each of the plurality of intensity maps, the

objective function including a dosimetric cost term and the delivery cost term, the dosimetric cost term representing dosimetric fitness of the respective intensity map and the delivery cost term representing delivery efficiency. *See Exhibit C, Claim 13.*

177. Upon information and belief, at all relevant times Defendants had knowledge of the '175 Patent.

178. Upon information and belief, each of the Defendants has been and is now directly infringing, literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), one or more claims of the '175 Patent, including at least Claim 13 of the '175 Patent, by making, using, selling, offering for sale, importing, and/or advertising in the United States at least Defendants' LINACs, including the Precise Treatment System™ (*see Exhibit D*), Versa HD™ (*see Exhibit E*), Elekta Infinity™ (*see Exhibit F*), Elekta Synergy® (*see Exhibit G*) and Elekta Compact™ (*see Exhibit H*) in conjunction with Elekta's Monaco® treatment planning system (*see Exhibit I*).

179. Upon information and belief, Defendants' LINACs, including the Precise Treatment System™, Versa HD™, Elekta Infinity™, Elekta Synergy®, and Elekta Compact™, in conjunction with Elekta's Monaco® treatment planning system, practice methods as set forth in at least Claim 13 of the '175 Patent.

180. For example, Defendants' Monaco® system is a “comprehensive system to support all major modalities of treatment, supporting 3D conformal radiation therapy, IMRT, VMAT, stereotactic MLC and cones. . . . As a vendor neutral IMRT planning platform, Monaco supports all major linear accelerators and connects to any record-and-verify information system.” *Exhibit K, pp. 2, 5.*

181. Defendants' Monaco® system “offers Segment Shape Optimization™, which smoothes and clusters segments and then optimizes beam weights and shapes. In addition, the

unique biological modeling capabilities of Monaco apply defined clinical objectives, maximizing confidence in plan assessment and selection. Multi-criterial optimization assures organs at risk are spared to the highest degree possible while maintaining target coverage. . . . [Monaco provides] [c]omplete control of the DVHs for healthy tissue and tumor volumes.” *Exhibit K, pp. 2, 6.*

182. According to the Monaco[®] Training Guide, “Monaco provides feedback for each target volume defining which constraint should be relaxed in order to improve target coverage.” *Exhibit L, p. 8-3.*

183. That Defendants’ Accused Products have infringed the ’175 Patent is supported by information made public as a result of the ITC Matter. *See Exhibit J.*

184. The Final Initial Determination in the ITC Matter states that “Monaco is tailored to work with and has specific documentation and source code tied to the Accused Linacs, using the parameters specific to the Accused Linacs as inputs . . . for VMAT plans. The Accused Linacs [which include Elekta’s Versa HD[™], Infinity[™], Synergy[®]/Synergy S linac systems] are adapted to work with compatible treatment software such as Monaco because their parameters have been built into the source code itself.” *See Exhibit J, pp. 227, 265.*

185. Accordingly, Defendants’ Accused Products practice a method [1] of providing control of a trade-off between treatment plan delivery efficiency and dosimetric fitness to optimize a radiation treatment plan within a continuum between delivery efficiency and dosimetric fitness, or equivalent thereof.

186. The User Guide for the Monaco[®] treatment planning system states that “Monaco optimizes treatment plans using cost functions that model several different types of tissue and volume specific radiation responses. Monaco uses constrained optimization, in which dose

limiting constraints are satisfied while attempting to deliver target dose objectives. The optimization algorithms work within parameters that impose several limits on the decision variables so that the dose delivered to the tumor is the maximum effective dose under the given dose constraints. Monaco allows coplanar and non-coplanar beam arrangements using isocentric, non-SSD beams.” *Exhibit O, p. 56.*

187. The User Guide for the Monaco[®] treatment planning system further states that “[b]y selecting the Planning activity, you are using highly developed, inverse planning methods to generate a treatment plan based on CT or Transverse MR images. The Monaco IMRT software lets you identify the clinical goals first and then use the optimization algorithm to find the best configuration of beam intensities. During the first stage of optimization, Monaco divides the beam fields into beamlets (often hundreds or thousands) of varying intensities that, when summed, deliver the prescribed dose.” *Exhibit O, p. 56.*

188. The Final Initial Determination in the ITC Matter states that “[t]he evidence shows **that Monaco’s stage one optimization process**, which as discussed above iteratively optimizes the simulated dose distribution relative to the set of one or more optimization goals over the initial plurality of control points, **uses a set of optimization parameters representative of a beam shape as well as a beam intensity.**” *Exhibit J, p. 322* (emphasis added).

189. Moreover, Monaco[®] documentation shows that a user of the Monaco software can specify “**one or more optimization goals, including a desired dose distribution . . . for the patient . . . in an attempt to target the tumor while avoiding healthy tissue.**” *Exhibit J, p. 313* (emphasis added).

190. Accordingly, Defendants’ Accused Products practice a method comprising the step of [2] assigning a delivery cost term within an optimizer to each of a plurality of intensity

maps representing a potential radiation beam arrangement, the assignment based on complexity of each respective intensity map, or equivalent thereof.

191. According to the Monaco[®] Training Guide, “Monaco uses a two-stage process of optimizing dose distributions. Generally, in stage one, the ‘ideal fluence’ distribution of beams is optimized to meet a user-defined prescription for a single set of beams. In stage two, the ideal fluence distribution is translated into a set of segments where the shapes and weights are optimized based on the same prescription.” *Exhibit L, p. 8-1.*

192. The Monaco[®] Training Guide further provides that in Monaco Step and Shoot IMRT Delivery Mode, “[t]he beamlet and segment weights are optimized using constrained optimization **where the Minimum MU/Segment is evaluated and segments are refined.**” *Exhibit L, p. 8-5* (emphasis added).

193. The Final Initial Determination in the ITC Matter states that “[i]n particular, the Monaco documentation, source code and deposition testimony of Elekta witnesses show that **Monaco . . . optimize[s] a desired dose distribution, including a desired dose rate, in order to determine a VMAT treatment plan for delivery on an Accused Linac [Elekta Linacs].**” *Exhibit J, p.242* (emphasis added).

194. Accordingly, Defendants’ Accused Products practice a method comprising the step of evaluating an objective cost function for each of the plurality of intensity maps, the objective function including a dosimetric cost term and the delivery cost term, the dosimetric cost term representing dosimetric fitness of the respective intensity map and the delivery cost term representing delivery efficiency, or equivalent thereof.

195. Upon information and belief, Defendants’ past and ongoing direct infringement of the ’175 Patent has and will continue to irreparably harm Best.

196. Upon information and belief, Defendants' past and ongoing direct infringement of the '175 Patent has and will cause Best damages.

197. Upon information and belief, Defendants' past and ongoing direct infringement of the '175 Patent has been knowing and willful.

198. Upon information and belief, Defendants' actions have caused Best to suffer irreparable harm resulting from the abuse of its patent rights, including the ability to exclude others from the market. Upon information and belief, Defendants will continue these infringing acts unless enjoined by this court.

COUNT 10: INDIRECT INFRINGEMENT OF THE '175 PATENT BY INDUCEMENT

199. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-198 above as if fully set forth herein.

200. Upon information and belief, at all relevant times Defendants had knowledge of the '175 Patent.

201. Upon information and belief, Defendants are liable for inducing infringement of the '175 Patent under 35 U.S.C. § 271(b) by having knowledge of the '175 Patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, direct infringement of the '175 Patent, with specific intent, by their customers.

202. Upon information and belief, Defendants actively induce infringement of the '175 Patent by, *inter alia*, training their customers on the Accused Products that perform methods claimed in the '175 Patent and/or by promotion, sales, and/or importation of the Accused Products to Defendants' customers.

203. Upon information and belief, Defendants' customers for the Accused Products directly infringe the '175 Patent by, *inter alia*, using the Accused Products.

204. Upon information and belief, Defendants intend to, and continue to intend to,

indirectly infringe the '175 Patent by inducement by selling the Accused Products for use by Defendants' customers.

205. Upon information and belief, Defendants knew or should have known of the '175 Patent and have acted, and continue to act, in an egregious and wanton manner by indirectly infringing the '175 Patent.

206. Upon information and belief, despite knowing that their actions constituted induced infringement of the '175 Patent and/or despite knowing that there was a high likelihood that their actions constituted induced infringement of the '175 Patent, Defendants nevertheless continue their infringing actions, and continue to make, use, offer for sale, and sell the Accused Products.

207. Upon information and belief, Defendants' past and ongoing induced infringement of the '175 Patent have and will continue to irreparably harm Best.

208. Upon information and belief, Defendants' past and ongoing induced infringement of the '175 Patent has and will cause Best damages.

209. Upon information and belief, Defendants' past and ongoing induced infringement of the '175 Patent has been knowing and willful.

210. Upon information and belief, Defendants' actions have caused Best to suffer irreparable harm resulting from the abuse of its lawful patent rights, including the ability to exclude others from the market. Upon information and belief, Defendants will continue these infringing acts unless enjoined by this court.

**COUNT 11: INDIRECT INFRINGEMENT OF THE '175 PATENT BY
CONTRIBUTORY INFRINGEMENT**

211. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-210 above as if fully set forth herein.

212. Upon information and belief, at all relevant times Defendants had knowledge of the '175 Patent.

213. Upon information and belief, Defendants are liable for contributory infringement of the '175 Patent under 35 U.S.C. § 271(c) by, *inter alia*, having sold or offered to sell, and continuing to sell or offer to sell, the Accused Products within the United States and/or by importing the Accused Products into the United States because the Accused Products constitute a material part of the invention embodied in the '175 Patent, which, upon information and belief, Defendants know to be especially made and/or especially adapted for use in infringement of the '175 Patent, and which are not staple articles or commodities of commerce suitable for substantial non-infringing use.

214. Upon information and belief, Defendants are liable for contributory infringement of the '175 Patent by having knowledge of the '175 Patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, direct infringement of the '175 Patent by their customers, including, *e.g.*, end users of the Accused Products.

215. Upon information and belief, Defendants contribute to infringement of the '175 Patent by, *inter alia*, promotion, sales, and/or importation of the Accused Products to Defendants' customers, including, *e.g.*, end users who perform methods claimed in the '175 Patent. Upon information and belief, Defendants' customers directly infringe the '175 Patent by, *e.g.*, using the Accused Products.

216. Upon information and belief, Defendants' past and ongoing contributory infringement of the '175 Patent has and will continue to irreparably harm Best.

217. Upon information and belief, Defendants' past and ongoing contributory infringement of the '175 Patent has and will cause Best damages.

218. Upon information and belief, Defendants' past and ongoing contributory infringement of the '175 Patent has been knowing and willful.

219. Upon information and belief, Defendants' actions have caused Best to suffer irreparable harm resulting from the abuse of its lawful patent rights, including the ability to exclude others from the market. Upon information and belief, Defendants will continue these infringing acts unless enjoined by this court.

COUNT 12: DIRECT INFRINGEMENT OF THE '490 PATENT

220. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-219 above as if fully set forth herein.

221. This cause of action arises under the patent laws of the United States, including 35 U.S.C. §§ 271 *et seq.*

222. The '490 Patent was duly and lawfully issued by the USPTO on March 21, 2006, to listed co-inventors Duan Qiang Wang, Robert W. Hill, and Simon Chun-pin Lam. *See Exhibit P, Cover.*

223. Plaintiff is the owner by assignment of all right, title, and interest in and to the '490 Patent. Evidence of the assignment of the '490 Patent from co-inventors Hill and Lam to Nomos Corporation is recorded at the USPTO at Reel 016910, Frame 0448, from co-inventor Wang to Nomos Corporation at Reel 016922, Frame 0363, and from Nomos Corporation to Plaintiff at Reel 020062, Frame 0709.

224. The '490 Patent is titled "Method and Apparatus for Optimization of Collimator Angles in Intensity Modulated Radiation Therapy Treatment." *See Exhibit P, Cover.*

225. The '490 Patent is directed to, *inter alia*, methods and apparatuses for determining an optimum collimator angle of a multi-leaf collimator having an opening and multiple leaf pairs for closing portions of the opening to form a radiation beam arrangement having multiple

radiation beam segments. *See Exhibit P, Abstract.* One of the [1] apparatuses claimed in the '490 Patent for use in conformal radiation therapy of a target tumor comprises [2] a multi-leaf collimator having a plurality of selectable discrete collimator angles, an opening to pass a radiation beam, and a plurality of multi-leaf collimator leaf pairs to close portions of the opening to form a radiation beam arrangement having a plurality of radiation beam segments; and [3] a computer in communication with the multi-leaf collimator to form the radiation beam arrangement incorporating a cost function to determine a collimator angle of the multi-leaf collimator to thereby enhance the radiation beam arrangement, the cost function including both parameters to enhance conformity of the radiation beam arrangement to a shape of the target, and parameters to enhance delivery efficiency by reducing a number of segments and reducing a number of monitor units required for delivery of a desired radiation prescription. *See Exhibit P, Claim 17.*

226. Upon information and belief, at all relevant times Defendants had knowledge of the '490 Patent.

227. Upon information and belief, each of the Defendants has been and is now directly infringing, literally and/or under the doctrine of equivalents, under 35 U.S.C. § 271(a), one or more claims of the '490 Patent, including at least Claim 17 of the '490 Patent, by making, using, selling, offering for sale, importing, and/or advertising in the United States at least Defendants' LINACs, including the Precise Treatment System™ (see *Exhibit D*), Versa HD™ (see *Exhibit E*), Elekta Infinity™ (see *Exhibit F*), Elekta Synergy® (see *Exhibit G*) and Elekta Compact™ (see *Exhibit H*) in conjunction with Elekta's Monaco® treatment planning system (see *Exhibit I*).

228. Upon information and belief, Defendants' LINACs, including the Precise Treatment System™, Versa HD™, Elekta Infinity™, Elekta Synergy®, and Elekta Compact™, in

conjunction with Elekta's Monaco[®] treatment planning system, provide apparatuses as set forth in at least Claim 17 of the '490 Patent.

229. Upon information and belief, Defendants' Precise Treatment System[™] is an [1] apparatus as claimed in the '490 Patent for use in conformal radiation therapy of a target tumor. As noted in the Precise Treatment System[™] brochure, "the Precise Treatment System ensures improved dose conformity to target structures while reducing delivery time" *See Exhibit D, p. 5.*

230. Upon information and belief, Defendants' Precise Treatment System[™] comprises [2] a multi-leaf collimator having a plurality of selectable discrete collimator angles, an opening to pass a radiation beam, and a plurality of multi-leaf collimator leaf pairs to close portions of the opening to form a radiation beam arrangement having a plurality of radiation beam segments. As noted in the Precise Treatment System[™] brochure, "[t]he desire to deliver high doses to the target is finely balanced against the growing need to minimize dose to healthy tissue outside of the target volume. The MLCi2 Multileaf Collimator on the Precise Treatment System helps you achieve this fine balance through its innovative and integrated design." *See Exhibit D, p. 7.*

231. Upon information and belief, Defendants' Precise Treatment System[™] comprises [3] a computer in communication with the multi-leaf collimator to form the radiation beam arrangement incorporating a cost function to determine a collimator angle of the multi-leaf collimator to thereby enhance the radiation beam arrangement, the cost function including both parameters to enhance conformity of the radiation beam arrangement to a shape of the target, and parameters to enhance delivery efficiency by reducing a number of segments and reducing a number of monitor units required for delivery of a desired radiation prescription. As noted in the Precise Treatment System[™] brochure, "Elekta's open systems and vendor-neutral connectivity

ensure cross-platform flexibility to integrate the most advanced and useful tools.” *See Exhibit D, p. 8.*

232. That Defendants’ Accused Products have infringed the ’490 Patent is further supported by information made public as a result of the ITC Matter. *See Exhibit J.*

233. For example, the Final Initial Determination in the ITC Matter states that “the Monaco source code and documentation show, Monaco is tailored to work with and has specific documentation and source code tied to the Accused Linacs, using the parameters specific to the Accused Linacs as inputs . . . for VMAT plans. The Accused Linacs are adapted to work with compatible treatment software such as Monaco because their parameters have been built into the source code itself.” *See Exhibit J, p. 265.*

234. The Monaco[®] Training Guide states that in Monaco “[p]rior to stage one optimization, the system divides a sequence into sectors that are used to simulate the arc during stage one optimization. You determine the number of sectors by dividing the total arc degree by the increment. For example, a 360 deg arc with a 30 deg increment equals 12 ‘static’ sectors to optimize. So, on the console, you would see 12 rays created before optimization (Figure 6-15).” *Exhibit L, p. 6-30.*

235. The Monaco[®] Training Guide further states that in Monaco “the system calculates a number of static sectors that the optimizer uses to create rays based on the Arc and the Increment you selected. . . . The system creates beamlets for each sector. Beamlet width is user-defined and the beamlet length is the length of the individual MLC leaves.” *Exhibit L, p. 8-11.*

236. The Monaco[®] Training Guide provides that in Monaco “[t]he basic paradigm of a sweeping leaf sequencer is that the leaves move from their start position to their end position in a continuous, unidirectional manner. **By varying the leaf gap, the system modulates the**

intensity of the delivered fluence.” *Exhibit L, p. 6-32* (emphasis added).

237. The Monaco[®] Training Guide also discloses that in Monaco “[s]tarting with the optimized fluence profiles from stage 1, the system converts each profile to a series of leaf trajectories (i.e. leaf position as a function of MU). **All trajectories are synchronized to arrive at the same MU count for all leaf pairs.** These leaf trajectory positions are sampled using the beamlet width. *Exhibit L, p. 8-10* (emphasis added).

238. Accordingly, Defendants’ Precise Treatment System[™], when used with Defendants’ Monaco[®] treatment planning system, is an [1] apparatus as claimed in the ’490 Patent for use in conformal radiation therapy of a target tumor comprising [2] a multi-leaf collimator having a plurality of selectable discrete collimator angles, an opening to pass a radiation beam, and a plurality of multi-leaf collimator leaf pairs to close portions of the opening to form a radiation beam arrangement having a plurality of radiation beam segments.

239. Defendants’ Monaco[®] treatment planning system executes on and uses a computer for treatment planning. *See Exhibits I, K.*

240. The User Guide for the Monaco[®] treatment planning system states that “Monaco optimizes treatment plans using cost functions that model several different types of tissue and volume specific radiation responses. Monaco uses constrained optimization, in which dose limiting constraints are satisfied while attempting to deliver target dose objectives. The optimization algorithms work within parameters that impose several limits on the decision variables so that the dose delivered to the tumor is the maximum effective dose under the given dose constraints. Monaco allows coplanar and non-coplanar beam arrangements using isocentric, non-SSD beams.” *Exhibit O, p. 56.*

241. The User Guide for the Monaco[®] treatment planning system further states that

“[t]he Monaco IMRT software lets you identify the clinical goals first and then use the optimization algorithm to find the best configuration of beam intensities. During the first stage of optimization, Monaco divides the beam fields into beamlets (often hundreds or thousands) of varying intensities that, when summed, deliver the prescribed dose.” *Exhibit O, p. 56.*

242. The Monaco[®] Training Guide states that “Monaco uses a two-stage process of optimizing dose distributions. Generally, in stage one, the ‘ideal fluence’ distribution of beams is optimized to meet a user-defined prescription for a single set of beams. In stage two, the ideal fluence distribution is translated into a set of segments where the shapes and weights are optimized based on the same prescription.” *Exhibit L, p. 8-1.*

243. Defendants’ Monaco[®] system “offers Segment Shape Optimization[™], which smoothes and clusters segments and then optimizes beam weights and shapes. In addition, the unique biological modeling capabilities of Monaco apply defined clinical objectives, maximizing confidence in plan assessment and selection. Multi-criterial optimization assures organs at risk are spared to the highest degree possible while maintaining target coverage. . . . [Monaco provides] [c]omplete control of the DVHs for healthy tissue and tumor volumes.” *Exhibit K, pp. 2, 6.*

244. Segment Shape Optimization[™] is a “[p]roprietary approach to smoothing and clustering segments, then optimizing beam weights and shapes enables clinicians to improve dose conformity, plan quality and delivery efficiency. [It] [r]educe[s] the number of segments, shortening treatment times.” *Exhibit K, p. 7.*

245. The Monaco[®] Training Guide also discloses that in Monaco “[u]sing Max. Sweep Efficiency can improve the MU efficiency during sequencing of dMLC beams without negatively affecting plan quality. It works by positioning some leaf pairs further apart at the start

or end of a sweep pattern, thereby minimizing overall leaf travel. By using the Max. Sweep Efficiency option on a typical prostate plan, you can reduce the total number of MU by 100 or more, with only a slight reduction in dose quality.” *Exhibit L, p. 8-20.*

246. The Final Initial Determination in the ITC Matter states that “[t]he evidence shows that the combination of Monaco and the Accused Linacs practice a method for planning delivery of radiation dose to a target region within a subject such as a patient or phantom . . . [t]he evidence shows that Monaco iteratively optimizes [by a processor] a simulated dose distribution relative to a set of optimization goals, including a desired dose distribution entered by a user, over an initial set of control points along a trajectory.” *Exhibit J, pp. 312-313.*

247. The Final Initial Determination in the ITC Matter further states that “[t]he evidence shows **that Monaco’s stage one optimization process**, which as discussed above iteratively optimizes the simulated dose distribution relative to the set of one or more optimization goals over the initial plurality of control points, **uses a set of optimization parameters representative of a beam shape as well as a beam intensity.**” *See Exhibit J, p. 322 (emphasis added).*

248. As such, Defendants’ Accused Products also include [3] a computer in communication with the multi-leaf collimator to form the radiation beam arrangement incorporating a cost function to determine a collimator angle of the multi-leaf collimator to thereby enhance the radiation beam arrangement, the cost function including both parameters to enhance conformity of the radiation beam arrangement to a shape of the target, and parameters to enhance delivery efficiency by reducing a number of segments and reducing a number of monitor units required for delivery of a desired radiation prescription, or an equivalent thereof.

249. Upon information and belief, Defendants’ past and ongoing direct infringement of

the '490 Patent has and will continue to irreparably harm Best.

250. Upon information and belief, Defendants' past and ongoing direct infringement of the '490 Patent has and will cause Best damages.

251. Upon information and belief, Defendants' past and ongoing direct infringement of the '490 Patent has been knowing and willful.

252. Upon information and belief, Defendants' actions have caused Best to suffer irreparable harm resulting from the abuse of its patent rights, including the ability to exclude others from the market. Upon information and belief, Defendants will continue these infringing acts unless enjoined by this court.

COUNT 13: INDIRECT INFRINGEMENT OF THE '490 PATENT BY INDUCEMENT

253. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-252 above as if fully set forth herein.

254. Upon information and belief, at all relevant times Defendants had knowledge of the '490 Patent.

255. Upon information and belief, Defendants are liable for inducing infringement of the '490 Patent under 35 U.S.C. § 271(b) by having knowledge of the '490 Patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, direct infringement of the '490 Patent, with specific intent, by their customers.

256. Upon information and belief, Defendants actively induce infringement of the '490 Patent by, *inter alia*, training their customers on the use of the Accused Products and/or promotion, sales, and/or importation of the Accused Products to Defendants' customers.

257. Upon information and belief, Defendants' customers for the Accused Products directly infringe the '490 Patent by, *inter alia*, using the Accused Products.

258. Upon information and belief, Defendants intend to, and continue to intend to,

indirectly infringe the '490 Patent by inducement by selling the Accused Products for use by Defendants' customers.

259. Upon information and belief, Defendants knew or should have known of the '490 Patent and have acted, and continue to act, in an egregious and wanton manner by infringing the '490 Patent.

260. Upon information and belief, despite knowing that their actions constituted induced infringement of the '490 Patent and/or despite knowing that there was a high likelihood that their actions constituted induced infringement of the '490 Patent, Defendants nevertheless continue their infringing actions, and continue to make, use, offer for sale, and sell the Accused Products.

261. Upon information and belief, Defendants' past and ongoing induced infringement of the '490 Patent have and will continue to irreparably harm Best.

262. Upon information and belief, Defendants' past and ongoing induced infringement of the '490 Patent has and will cause Best damages.

263. Upon information and belief, Defendants' past and ongoing induced infringement of the '490 Patent has been knowing and willful.

264. Upon information and belief, Defendants' actions have caused Best to suffer irreparable harm resulting from the abuse of its lawful patent rights, including the ability to exclude others from the market. Upon information and belief, Defendants will continue these infringing acts unless enjoined by this court.

**COUNT 14: INDIRECT INFRINGEMENT OF THE '490 PATENT BY
CONTRIBUTORY INFRINGEMENT**

265. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-264 above as if fully set forth herein.

266. Upon information and belief, at all relevant times Defendants had knowledge of the '490 Patent.

267. Upon information and belief, Defendants are liable for contributory infringement of the '490 Patent under 35 U.S.C. § 271(c) by, *inter alia*, having sold or offered to sell, and continuing to sell or offer to sell, the Accused Products within the United States and/or by importing the Accused Products into the United States because the Accused Products constitute a material part of the invention embodied in the '490 Patent, which, upon information and belief, Defendants know to be especially made and/or especially adapted for use in infringement of the '490 Patent, and which are not staple articles or commodities of commerce suitable for substantial non-infringing use.

268. Upon information and belief, Defendants are liable for contributory infringement of the '490 Patent by having knowledge of the '490 Patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, direct infringement of the '490 Patent by their customers, including, *e.g.*, end users of the Accused Products.

269. Upon information and belief, Defendants contribute to infringement of the '490 Patent by, *inter alia*, promotion, sales, and/or importation of the Accused Products to Defendants' customers, including, *e.g.*, end users who use apparatuses claimed in the '490 Patent and perform methods claimed in the '490 Patent. Upon information and belief, Defendants' customers directly infringe the '490 Patent by, *e.g.*, using the Accused Products.

270. Upon information and belief, Defendants' past and ongoing contributory infringement of the '490 Patent has and will continue to irreparably harm Best.

271. Upon information and belief, Defendants' past and ongoing contributory infringement of the '490 Patent has and will cause Best damages.

272. Upon information and belief, Defendants' past and ongoing contributory infringement of the '490 Patent has been knowing and willful.

273. Upon information and belief, Defendants' actions have caused Best to suffer irreparable harm resulting from the abuse of its lawful patent rights, including the ability to exclude others from the market. Upon information and belief, Defendants will continue these infringing acts unless enjoined by this court.

COUNT 15: INDIRECT INFRINGEMENT OF THE '490 PATENT UNDER 271(f)(2)

274. Plaintiff repeats and realleges the allegations set forth in paragraphs 1-273 above as if fully set forth herein.

275. Upon information and belief, Defendants are liable for indirect infringement of the '490 Patent under 35 U.S.C. § 271(f)(2) by, *inter alia*, supplying or causing to be supplied in or from the United States at least one component (*e.g.* the Monaco[®] treatment planning system), uncombined in whole or in part, which was especially made or especially adapted for use in practicing the inventions of one or more claims of the '490 Patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use. This supply has been made with Defendants' knowledge that such component is especially made or adapted for use in the inventions of one or more claims of the '490 Patent and with Defendants' intent that such component will be combined outside of the United States, resulting in Defendants' LINAC systems, including the Precise Treatment System[™], Versa HD[™], Infinity[™], Synergy[®], and Compact[™], that employ the inventions of one or more of the claims of the '490 Patent.

276. The Final Initial Determination in the ITC Matter states that "IMPAC Medical Systems, Inc. develops and manufactures Elekta treatment planning software within the United States." *Exhibit J, p. 3.*

277. The Final Initial Determination in the ITC Matter further states that "Elekta's

Monaco treatment planning software . . . was developed in the United States, and is supplied from Elekta's location in the United States, which employs U.S. employees. Monaco has not been imported." *Exhibit J, p. 17.*

278. Upon information and belief, Defendants export the Monaco[®] treatment planning software outside of the United States to be used in LINAC systems, including Defendants' LINAC systems, including the Precise Treatment System[™], Versa HD[™], Infinity[™], Synergy[®], and Compact[™].

279. Upon information and belief, Defendants' indirect infringement of the '490 Patent under 35 U.S.C. § 271(f)(2) has irreparably harmed Best.

280. Upon information and belief, Defendants' indirect infringement of the '490 Patent under 35 U.S.C. § 271(f)(2) has and will cause Best damages.

281. Upon information and belief, Defendants' indirect infringement of the '490 Patent under 35 U.S.C. § 271(f)(2) was knowing and willful.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter:

A. A judgment in favor of Best declaring and adjudging that each of the Defendants has directly infringed, engaged in the contributory infringement of, actively induced others to infringe, and indirectly infringed the '283 Patent under 35 U.S.C. § 271(f)(2), either literally or under the doctrine of equivalents;

B. A judgment in favor of Best declaring and adjudging that each of Defendants' infringement, contributory infringement, active inducement of infringement, and infringement under 35 U.S.C. § 271(f)(2) of the '283 Patent was willful and deliberate;

C. A judgment in favor of Best requiring each of the Defendants to account for and pay over to Best all actual damages suffered by Best by reason of Defendants' infringement of the '283 Patent, including without limitation lost profits and/or reasonable royalty;

D. A judgment in favor of Best declaring and adjudging that each of the Defendants has directly infringed, engaged in the contributory infringement of, actively induced others to infringe, and indirectly infringed the '096 Patent under 35 U.S.C. § 271(f)(2) either literally or under the doctrine of equivalents;

E. A judgment in favor of Best declaring and adjudging that each of Defendants' infringement, contributory infringement, and active inducement of infringement, and infringement under 35 U.S.C. § 271(f)(2) of the '096 Patent was willful and deliberate;

F. An order of this Court permanently enjoining each of the Defendants and its officers, directors, agents, affiliates, employees, divisions, branches, subsidiaries, parents, and all others in concert therewith from infringing, including inducing the infringement of and contributing to the infringement of, the '096 Patent;

G. A judgment in favor of Best requiring each of the Defendants to account for and pay over to Best all actual damages suffered by Best by reason of Defendants' infringement of the '096 Patent, including without limitation lost profits and/or reasonable royalty;

H. A judgment in favor of Best declaring and adjudging that each of the Defendants has directly infringed, engaged in the contributory infringement of, actively induced others to infringe the '175 Patent, either literally or under the doctrine of equivalents;

I. A judgment in favor of Best declaring and adjudging that each of Defendants' infringement, contributory infringement, and active inducement of infringement of the '175 Patent was willful and deliberate;

J. An order of this Court permanently enjoining each of the Defendants and its officers, directors, agents, affiliates, employees, divisions, branches, subsidiaries, parents, and all others in concert therewith from infringing, including inducing the infringement of and contributing to the infringement of, the '175 Patent;

K. A judgment in favor of Best requiring each of the Defendants to account for and pay over to Best all actual damages suffered by Best by reason of Defendants' infringement of the '175 Patent, including without limitation lost profits and/or reasonable royalty;

L. A judgment in favor of Best declaring and adjudging that each of the Defendants has directly infringed, engaged in the contributory infringement of, and actively induced others to infringe, and indirectly infringe the '490 Patent under 35 U.S.C. § 271(f)(2), either literally or under the doctrine of equivalents;

M. A judgment in favor of Best declaring and adjudging that each of Defendants' infringement, contributory infringement, active inducement of infringement, and indirect infringement under 35 U.S.C. § 271(f)(2) of the '490 Patent was willful and deliberate;

N. An order of this Court permanently enjoining each of the Defendants and its officers, directors, agents, affiliates, employees, divisions, branches, subsidiaries, parents, and all others in concert therewith from infringing, including inducing the infringement of and contributing to the infringement of, the '490 Patent;

O. A judgment in favor of Best requiring each of the Defendants to account for and pay over to Best all actual damages suffered by Best by reason of Defendants' infringement of the '490 Patent, including without limitation lost profits and/or reasonable royalty;

P. A judgment and order requiring each of the Defendants to pay Best its damages, costs, expenses, pre-judgment interest, and post-judgment interest for each of Defendants' infringement of any of the '283 Patent, '096 Patent, '175 Patent and '490 Patent, as provided under 35 U.S.C. § 284.

Q. A judgment in favor of Best trebling damages pursuant to 35 U.S.C. § 284 due to the willful and deliberate nature of each of the Defendants aforesaid infringing acts;

R. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, and award to Best its reasonable attorneys' fees; and

S. An Order for any and all other relief to which Best may show itself to be entitled and/or as the Court may deem just and proper.

Dated: November 5, 2018

/s/ Geoffrey G. Grivner

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