

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VARIAN MEDICAL SYSTEMS, INC.,)
)
Plaintiff,)
)
v.) C.A. No _____
)
ELEKTA AB, ELEKTA HOLDINGS U.S., INC.,) **JURY TRIAL DEMANDED**
ELEKTA INSTRUMENT AB, and ELEKTA)
INC.,)
)
Defendants.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff VARIAN MEDICAL SYSTEMS, INC. (“Plaintiff” or “Varian”) hereby asserts the following claim for patent infringement against Defendants ELEKTA AB, ELEKTA HOLDINGS U.S., INC., ELEKTA INSTRUMENT AB and ELEKTA, INC. (collectively “Defendants” or “Elekta”), and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*
2. Elekta has infringed and continues to infringe, has contributed to and continues to contribute to the infringement of and/or has actively and knowingly induced and continues to actively and knowingly induce the infringement of one or more claims of Varian’s U.S. Patent No. 6,888,919 (the “919 Patent” or “Asserted Patent”). Varian is the legal owner by assignment of the Asserted Patent, which was duly and legally issued by the United States Patent and Trademark Office. Varian seeks injunctive relief and monetary damages.

THE PARTIES

3. Varian is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 3100 Hansen Way, Palo Alto, California.

4. Varian is a world leader in the design and manufacture of medical devices and software for treating cancer and other medical conditions with radiotherapy, radiosurgery, proton therapy and brachytherapy. Varian is also a premier supplier of X-ray imaging components for medical, scientific and industrial applications. Varian provides a fully integrated line of products for treating cancer with radiation, including linear accelerators, treatment simulation and verification products, information management and treatment planning software and sophisticated ancillary devices.

5. Upon information and belief, Defendant Elekta AB (“EAB”) is a corporation organized and existing under the laws of Sweden, having a principal place of business at Kungstengatan 18, SE-103 93 Stockholm, Sweden.

6. Upon information and belief, Defendant Elekta Holdings U.S., Inc. (“EHUS”) 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, and EHUS is a wholly-owned subsidiary of Defendant EAB.

7. Upon information and belief, Defendant Elekta Instrument AB (“EIAB”) is a corporation organized and existing under the laws of Sweden, having a principal place of business at Kungstengatan 18, SE-103 93 Stockholm, Sweden, and EIAB is a wholly-owned subsidiary of Defendant EAB.

8. Upon information and belief, Defendant Elekta, Inc. (“EI”) 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, and EI is a wholly-owned subsidiary of Defendant EHUS.

9. All of the Defendants operate under and identify with the trade name, “Elekta.” Upon information and belief, each of the Defendants directly or indirectly imports, develops, designs, manufactures, distributes, markets, offers to sell and/or sells products and services in the United States, including in the District of Delaware, and otherwise purposefully directs activities to the same. Upon information and belief, the Defendants have been and are acting in concert and are otherwise liable jointly, severally or in the alternative for a right to relief with respect to or arising out of the same transaction, occurrence or series of transactions or occurrences related to the making, using, importing into the United states, offering for sale or selling of at least one infringing product or process.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

11. Upon information and belief, this Court has personal jurisdiction over EAB because it has committed acts of patent infringement and/or contributed to or induced acts of patent infringement by others in the District of Delaware. As such, EAB has established sufficient minimum contacts with this District such that it should reasonably and fairly anticipate being called into court in this District, and has purposefully directed activities at residents of the state and this District.

12. This Court has personal jurisdiction over EHUS because EHUS is a corporation organized and existing under the laws of the State of Delaware.

13. Upon information and belief, this Court has personal jurisdiction over EIAB because it has committed acts of patent infringement and/or contributed to or induced acts of patent infringement by others in the District of Delaware. As such, EIAB has established sufficient minimum contacts with this District such that it should reasonably and fairly anticipate

being called into court in this District, and has purposefully directed activities at residents of the state and this District.

14. Upon information and belief, this Court has personal jurisdiction over EI because it has committed acts of patent infringement and/or contributed to or induced acts of patent infringement by others in the District of Delaware. As such, EI has established sufficient minimum contacts with this District such that it should reasonably and fairly anticipate being called into court in this District, and has purposefully directed activities at residents of the state and this District.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400 at least because EHUS is incorporated in this District, acts amounting to or in furtherance of patent infringement have been committed in this District and/or the Defendants are subject to personal jurisdiction in this District.

BACKGROUND TO THE ACTION

16. Varian is a world leader in medical technology. Varian's research and development teams and partnerships have produced a wide array of products, including hardware, software and services that help doctors and hospitals identify and treat various medical conditions.

17. Varian's greatest contribution to medical innovation has taken shape through its relentless battle against cancer, which has produced a range of treatment technologies, including radiotherapy, radiosurgery, proton therapy and brachytherapy solutions. Varian's foremost mission is to save lives by making cancer treatment safer and more effective.

18. In 1956, Varian built the first medical-grade linear accelerator in the western hemisphere, which was used by doctors at Stanford-Lane Hospital in San Francisco. Linear accelerators are cancer-fighting treatment devices that accelerate charged subatomic particles or

ions along a fixed path in order to destroy cancerous tissue. In the decades since, Varian has continued to be at the forefront of linear accelerator technology used to battle cancer.

19. In 1960, Varian introduced the Clinac 6 medical linear accelerator—the first commercial, fully rotational radiotherapy linear accelerator built in the United States—which featured a 360° rotational gantry and helped prove that linear accelerators were superior to older cobalt radiation systems.

20. In 1972, Varian’s Clinac 18 featured a “gridded electron gun” that gave unprecedented control over the radiation dosage.

21. In the 1990s, Varian continued to improve on linear accelerator hardware and further developed complementary imaging and treatment planning systems. These innovations included:

- 1991’s Dynamic Wedge technology allowed doctors to shape linear accelerator beams, which helped prevent unnecessary damage to healthy tissue and allowed doctors to more accurately focus treatment on malignant tumors;
- 1993’s PortalVision™ portal imaging technology, which allowed doctors to verify exact beam placement in relation to a patient’s anatomy;
- 1996’s CadPlan® treatment planning software, which used diagnostic images of a tumor and surrounding tissues to generate computerized instructions for targeting the tumor with high-intensity X-ray beams; and
- 1999’s Real-Time Position Management™ (RPM) Respiratory Gating system, which ensured accuracy when imaging and treating tumors that

move when the patient breathes by turning on the radiation beam only when a targeted tumor is within a prescribed area.

22. In the 2000s, Varian continued to develop industry-leading innovations, developing the Eclipse™ treatment planning software, Dynamic Targeting™ image-guided radiotherapy, ARIA® oncology information system, RapidArc® volumetric modulated arc therapy system and a “Smart Segmentation” tool for the Eclipse™ treatment planning software—technology that won an R&D 100 award.

23. Varian has earned significant industry accolades, and the success of its medical products has made it one of the most important companies in the cancer treatment industry. Today, Varian appears on both the Fortune 1000 and S&P 500 stock indices. In 2004, Varian was named to the Forbes Platinum 400 list. In 2006, Varian received an R&D 100 award and was named a Forbes Global High Performer. From 2007-2009, Varian was named one of *IndustryWeek*'s “50 Best Manufacturing Companies” in the U.S. three years in a row and was named a top-15 best performing public corporation by *BusinessWeek* in 2007 and 2009. In 2011, Varian's TrueBeam system earned the company yet another R&D 100 award, as well as the prestigious Red Dot Award for Product Design.

VARIAN'S PATENTED TECHNOLOGY

24. Varian's pioneering vision and relentless innovation have also made Varian the assignee of groundbreaking patents in medical technology, as issued by the United States Patent and Trademark Office (“USPTO”) and its equivalents worldwide.

25. One of Varian's important patents in the cancer treatment space is U.S. Patent No. 6,888,919 (the “'919 Patent”), which was granted by the USPTO on May 3, 2005. The '919 Patent is entitled “Radiotherapy Apparatus Equipped with an Articulated Gantry for Positioning an Imaging Unit” and was invented by Ulrich Martin Graf, who was a VP of Engineering at

Varian at the time the patent was filed. Varian is the original and current owner by assignment of the '919 Patent. A true and correct copy of the '919 Patent is attached hereto as **Exhibit A**.

26. Because radiation therapy has the inherent potential to damage healthy tissue, precise and accurate application of radiation is one of the most important measures of successful cancer treatment. Maintaining precision in radiation treatment typically requires use of imaging technology that identifies the size, shape, and position of a tumor relative to surrounding tissue and the position of a patient receiving treatment. Technologies such as cone beam CT can be implemented in imaging devices that rotate around a patient to generate 3D images of their anatomy and any cancerous tissue.

27. The '919 Patent addresses the challenge of positioning a tumor in a radiation treatment field for configurations of treatment devices in which it is advantageous for an imaging device to have freedom of movement. Specifically, Claim 1 of the '919 Patent describes a therapeutic radiation source attached to a first gantry, at least one second radiation source (such as a cone beam CT X-ray source), a rotatable second gantry attached to the first gantry and an imager attached to an articulable end of the second gantry.

28. This patented use of two gantries in the same device—including where one is attached to a treatment radiation component, and the other flexibly deploys an imaging component—allows for greater treatment adaptability and, ultimately, more effective and precise radiation therapy. The '919 Patent reflects just one of the many contributions that Varian has made to improve cancer treatment throughout the United States and across the world.

ACTS GIVING RISE TO THIS ACTION

29. Elekta has been manufacturing, marketing and selling a line of radiation treatment devices under the trademark “Gamma Knife” in the United States since 1987. The Gamma

Knife devices use cobalt-60 to generate and deploy gamma radiation to treat neuropathologies such as brain tumors.

30. On April 25, 2015, Elekta announced the launch of a new version of the Gamma Knife devices called “Gamma Knife Icon.” The Gamma Knife Icon is the first Gamma Knife product to feature a built-in imager and cone beam CT radiation source as part of the Gamma Knife device. The integrated Gamma Knife Icon imager is mounted on an arm that can rotate around a patient to help doctors identify the position, size and shape of a brain tumor.

31. Elekta has touted the benefits of the added imager in marketing and sales materials that are actively directed to the United States. As is evident from Elekta’s own published materials and ongoing marketing efforts, the Gamma Knife Icon infringes at least one claim of the ’919 Patent and exploits the innovations—and attendant benefits—described therein. Elekta has marketed the Gamma Knife Icon with descriptions and depictions of intended use, including through its marketing website, careforthebrain.com, and, upon information and belief, demonstrates and instructs customers and potential customers to use Gamma Knife Icon in an infringing manner at trade shows, consultations, training programs and otherwise, such as in connection with sales activity.

32. Elekta has made extensive use of Varian’s patented technologies, including the ’919 Patent. Varian has no choice but to defend its industry-leading innovations and substantial research and development investments. Varian thus requests that this Court award reasonable compensation for Elekta’s infringement of the ’919 Patent, including treble damages for Elekta’s willful and deliberate infringement of the ’919 Patent, and further requests that this Court grant an injunction against Elekta to prevent ongoing infringement of the ’919 Patent throughout the United States.

CLAIM FOR RELIEF

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,888,919

33. Varian incorporates by reference and realleges all the foregoing paragraphs of this Complaint as if fully set forth herein.

34. The USPTO duly and legally issued the '919 Patent on May 3, 2005. Varian is the legal owner of the '919 Patent by assignment.

35. Elekta has infringed and continues to infringe, has contributed to and continues to contribute to acts of infringement and/or has actively and knowingly induced and continues to actively and knowingly induce the infringement of one or more claims of the '919 Patent, including at least Claim 1, either literally or under the doctrine of equivalents, by advertising, distributing, making, using, selling and/or offering for sale within the United States and/or importing into the United States medical devices, related software, and related services, including but not limited to the Gamma Knife Icon.

36. Elekta has marketed the Gamma Knife Icon by describing and depicting use in an infringing manner, including through its website, www.careforthebrain.com, and upon information and belief, demonstrates and instructs customers and potential customers to use Gamma Knife Icon in an infringing manner at trade shows, consultations, training programs and otherwise, such as in connection with sales activity. Additionally, the Gamma Knife Icon was especially designed, made and/or adapted for use in an infringing manner. The Gamma Knife Icon embodies either the claimed inventions on its own or is a material, non-staple component of end-use products that embody the claimed inventions, which have no substantial noninfringing uses. For at least the aforementioned reasons, Elekta has demonstrated and continues to demonstrate its specific intent to induce direct infringement of at least one claim of the '919 Patent.

37. Elekta's infringement has caused, and is continuing to cause, damage and irreparable injury to Varian, and Varian will continue to suffer damage and irreparable injury unless and until that infringement is enjoined by this Court.

38. Varian is entitled to injunctive relief and damages in accordance with 35 U.S.C. §§ 271, 281, 283, and 284.

39. Upon information and belief, Elekta has had knowledge of the '919 Patent since at least April 5, 2006, as evidenced by the USPTO's Non-Final Rejection of claims of patent application no. 11/220,110 in light of the '919 Patent and Elekta's remarks against anticipation in its September 21, 2006 Amendment in response thereto, or alternatively, since March 20, 2012, as evidenced by citation to the '919 Patent in connection with the USPTO's issuance of a Notice of Allowance for Elekta's U.S. Patent No. 8,218,718.

40. Elekta's infringement of the '919 Patent has been and continues to be willful and deliberate, justifying a trebling of damages under 35 U.S.C. § 284. Upon information and belief, Elekta's accused actions continue despite an objectively high likelihood that they constitute infringement of the '919 Patent. Elekta either knows or should have known about its risk of infringing the '919 Patent. Elekta's conduct despite this knowledge is made with both objective and subjective reckless disregard for the infringing nature of its activities.

41. Elekta's infringement of the '919 Patent is exceptional and entitles Varian to attorneys' fees and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Varian respectfully requests:

1. Judgment be entered that Defendants have infringed the '919 Patent;
2. Judgment be entered that the commercial use, sale, offer for sale, manufacture or importation by Elekta of the Gamma Knife Icon infringes the '919 Patent;

3. That, in accordance with 35 U.S.C. § 283, Elekta, and all affiliates, employees, agents, officers, directors, attorneys, successors, and assigns and all those acting on behalf of or in active concert or participation with any of them, be preliminarily and permanently enjoined from infringing the '919 Patent;

4. A declaration that Elekta must render a full and complete accounting to Varian for Elekta's profits, gains, advantages or the value of business opportunities received from the foregoing acts of infringement;

5. An award of damages sufficient to compensate Varian for Elekta's direct infringement of the '919 Patent, including lost profits suffered by Varian as a result of Elekta's infringement and in an amount not less than a reasonable royalty;

6. An award of damages sufficient to compensate Varian for Elekta's indirect infringement of the '919 Patent, including lost profits suffered by Varian as a result of Elekta's infringement and in an amount not less than a reasonable royalty;

7. An order awarding Varian treble damages under 35 U.S.C. § 284 as a result of Elekta's willful and deliberate infringement of the '919 Patent;

8. That the case be found exceptional under 35 U.S.C. § 285 and that Varian be awarded its attorneys' fees;

9. Costs and expenses in this action;

10. An award of prejudgment and post-judgment interest; and

11. Such other and further relief as the Court may deem just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Varian demands a trial by jury on all issues raised by the Complaint.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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