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.0	UNITED STATES DISTRICT COURT	
1	FOR THE SOUTHERN D	DISTRICT OF CALIFORNIA
12	BRAIN LIFE, LLC, a Delaware limited	) Case No.: 10cv1539 CAB (BGS)
13	liability company,	)
15	Plaintiff,	THIRD AMENDED COMPLAINT  TO SHEED IN COMPLAINT
6	VS.	) FOR INFRINGEMENT ) OF UNITED STATES PATENT NO. 5,398,684
7	BRAINLAB, INC., a Delaware corporation,	)
8	Defendant.	)
19		) <b>JURY TRIAL DEMANDED</b> )
20		_)
21		
23	On January 24, 2013, this Court entered an Order granting Plaintiff leave to amend the	
24	Second Amended Complaint on or before February 11, 2013 to "sufficiently plead contributor	
25	infringement and remove allegations against dismissed parties." (Docket No. 118)	
	On or about January 13, 2012, this Court severed Eleka, Inc. from this litigation an	
26	ordered Brain Life, LLC to bring a separate action against Elekta, Inc., now Civil Case No.	
27	3:12-cv-0030-CAB-BGS. (Docket No. 69)	This Third Amended Complaint in this action
28	deletes Paragraphs 7, 13, 24 and 29-34 from	om the Second Amended Complaint, omitting

THIRD AMENDED COMPLAINT

allegations as to Elekta to properly reflect the correct parties. Moreover, the actions against Defendants, Varian Medical Systems, Inc. and Medtronic, Inc. having been dismissed on October 1, 2012 (Docket No. 103) and on November 8, 2012 (Docket No. 108), respectively, this Third Amended Complaint deletes all reference in the Second Amended Complaint to those two parties. This Complaint re-alleges the claim in the Second Amended Complaint found deficient in the above-identified Order of January 24, 2013 (Docket No. 118) for indirect contributory infringement under 35 U.S.C. § 271(c).

# THE PARTIES

- 1. Brain Life is a limited liability company formed and existing under the laws of Delaware with a principal place of business located at 500 Newport Center Drive, 7<sup>th</sup> Floor, Newport Beach, California 92660.
- 2. Upon information and belief, BrainLab, Inc. ("BrainLab") is a corporation formed and existing under the laws of the State of Delaware, with a principal place of business at 3 Westbrook Corporate Center, Suite 400, Westchester, IL 60154.

# **JURISDICTION AND VENUE**

- 3. This is a civil action for patent infringement seeking damages arising under the Patent Laws of the United States, 35 U.S.C. §§ 1, et seq. Jurisdiction is conferred upon this Court pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 4. BrainLab does business in this judicial district as set forth in detail below, including but not limited to the sale of goods and services to medical centers and other entities at which medical professionals practice various forms of surgery and oncology treatment and planning using the methods of a patent owned by Brain Life. BrainLab is subject to the personal jurisdiction of this Court and is amenable to service of process pursuant to the California long-arm statute, Cal.Civ.Proc.Code, § 413.10 and Fed.R.Civ.P. 4(c).

# **GENERAL ALLEGATIONS**

5. Brain Life is the exclusive licensee of MIDCO (Medical Instrumentation and Diagnostics Corporation) by assignment in and to United States Patent No. 5,398,684 (the "684 Patent" or "patent in suit") entitled Method and Apparatus for Video Presentation from Scanner

Imaging Sources issued on March 21, 1995. A true and correct copy of the '684 Patent is attached hereto as Exhibit 1. The '684 Patent is valid and expired on March 31, 2009; therefore, Brain Life seeks only damages and not an injunction in this suit. All maintenance fees for the '684 Patent were paid during the patent life. The predecessor of Brain Life, MIDCO, during the period in which it sold a treatment planning system known as CASS (Computer Assisted Stereotactic Surgery) marked the system with proper patent notice; Brain Life has not manufactured or sold any treatment planning system covered by any claims of the '684 Patent.

- 6. The '684 Patent relates to the acquisition, conversion, storage, manipulation, comparison, measurement and display of images for use in computer-assisted stereotactic surgical procedures.
- 7. BrainLab has developed, manufactured, and distributed hardware and software systems and has practiced and/or induced purchasers of such systems to practice one or more method claims of the '684 Patent. The systems are generally marketed under the trademarks or model designations including but not limited to, Novalis TX, BrainSUITE, Kolibri, VectorVision, ExacTrac and Digital Lightbox that integrate software modules marketed under the name iPlan or some derivative thereof (as described in greater detail below). BrainLab also provides in the United States various services, publications and training to users of the hardware and software systems that it sells.

# HISTORICAL BACKGROUND

- 8. On December 17, 1997, MIDCO, the predecessor-in-interest of the exclusive rights under the patent in suit, brought an action against Elekta AB, Elekta Instruments, AB, Elekta Instruments, Inc. and Elekta Oncology ("Earlier Defendants") in this Court, Civil Action No. 97cv2271 for infringement of the patent in suit and also United States Patent Nos. 5,099,846, 5,354,314, 5,176,689 and 5,143,076. The effective complaint included claims for trade secret misappropriation and breach of a nondisclosure agreement (hereinafter "Prior Litigation"). The accused products in the Prior Litigation were the GammaKnife/GammaPlan 4, SurgiPlan, SurgiScope, ViewScope and Viewing Wand.
  - 9. In the course of the Prior Litigation, MIDCO asserted, and the Court construed,

certain apparatus claims of the patent in suit, including Claim 1. Earlier Defendants brought a motion in limine to dismiss with prejudice all claims other than the apparatus claims specifically asserted. On January 14, 2002 this Court dismissed all of the non-asserted claims, including all of the method claims, without prejudice. Prior to the dismissal, MIDCO brought a motion for summary judgment that the apparatus claims were not invalid; on November 6, 2001 this Court granted the motion that the apparatus claims asserted were not invalid.

- 10. The Prior Litigation went to trial beginning January 23, 2002 and a jury found that the claims of the '684 and '846 patents were infringed and since validity had been established, a damage award was made by the jury in the amount of \$16,595,000.
- 11. On September 23, 2002, Earlier Defendants timely filed a Notice of Appeal and the case was briefed and heard before the United States Federal Circuit Court of Appeals ("Federal Circuit") (Appellate Docket No. 03-1032). The judgment of infringement and the damage award were reversed on the grounds that the apparatus claims asserted had not been properly construed. (*Medical Instrumentation and Diagnostics Corp. v. Elekta*, 344 F.3d 1205 (Fed. Cir. 2003). When construed in the manner determined by the Federal Circuit, all of the apparatus claims were not infringed by the Earlier Defendants. The Federal Circuit also reversed the lower court's judgment that the '684 Patent claims asserted were not invalid on the grounds that a genuine issue of material fact for the jury existed. The case was then remanded to the lower court for further proceedings.
- 12. On February 12, 2004, MIDCO brought a motion to amend the complaint in the Prior Litigation to assert the method claims in the '684 Patent. That motion was denied by this Court. MIDCO then timely filed a Notice of Appeal to the Federal Circuit and the case was briefed, argued and this Court was affirmed. The date on which the Federal Circuit affirmed this Court's judgment dismissing the MIDCO complaint was June 2, 2005.
- 13. As a result of the infringement by the Earlier Defendants, MIDCO could not compete with other companies developing, manufacturing and selling treatment planning systems for stereotactic surgery and MIDCO struggled to survive. MIDCO attempted to raise funds necessary to underwrite the cost of a suit against the Earlier Defendants, including Elekta,

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based on the method claims that had been dismissed without prejudice in the Prior Litigation. Despite a showing of interest by a number of financial and legal entities, MIDCO was unable to find any investor who would defray the cost of pursuing a second patent infringement case against the Earlier Defendants (including Elekta) as well as a suit for patent infringement against Medtronic, Varian and BrainLab.

14. On or about September 21, 2009, MIDCO entered into a business arrangement with the present Plaintiff, Brain Life, granted an exclusive license to a company who then assigned the license to Brain Life and agreed to cooperate in the negotiation of any patent license and prosecution of a patent infringement suit.

# THE PATENTED TECHNOLOGY

15. The '684 Patent discloses and claims a method for presenting a plurality of scanned images in a video presentation. Scanned images are radiological images taken by devices and techniques such as Computed Tomography (CT), Nuclear Magnetic Resonance or Image (NMR or MRI), Digital Subtraction Angiography (DSA), Positron Emission Tomography (PET) and other types of diagnostic radiological images. The '684 method produces what is commonly referred to as a treatment plan, performed on computer hardware and software in accordance with the present invention. The treatment plan is used in performing stereotactic surgery and involves the steps of acquiring of the images, converting of the images to a common format, storing of the images, manipulating and comparing of the images, measuring lines, areas and volume, and selectively recalling and simultaneously displaying at least two of the scanned images so as to appear in combination on a single display device. At least one of the scanned images is stereotactic to provide a three-dimensional reference system to enable localization of a structure-of-interest such as a tumor or implements used in invasive surgery or treatment. In one embodiment of the invention, graphic brain map atlas images may be imported into the treatment planning hardware and software system; the graphic images may be fitted to the scanned images of the patient's brain. In addition to presenting the images in two dimensions, simulated three-dimensional images including both scanned and graphic images can be displayed.

16. The value of the method described and claimed in the '684 Patent is enhanced visualization of the patient's brain, it being understood that the brain is encased in the patient's skull and is not visually accessible to the surgical team, who without the benefit of the images, would be forced to estimate the particular location of, for example, a tumor in the patient's brain. In particular, one advantage of the present invention is that images from different scanning sources, for example, a CT-scanned image and an MR-scanned image, can be combined for synchronous viewing on the screen of the hardware and software treatment planning system thus offering the benefits that each individual type of scan affords. The combination of images is often referred to as "fusion" images and may be rendered in various ways, such as a transparency, an overlay, a technique such as flicker frame, and various other types of image data-set combinations. Through the use of these fused images, and particularly when used with the brain map images, a high level of precision and accuracy as to the location and size of, for example, a tumor, may be achieved.

- 17. Once a structure-of-interest is localized in stereotactic space and characterized, a decision may be made regarding whether to employ invasive or non-invasive neurosurgery. In the case of invasive neurosurgery, the procedure involves maintaining the patient's head in a stereotactic frame or other immobilizing device so that the precise location of the structure-of-interest can be identified, an appropriate opening in the patient's skull may be made, and the surgeon's probe or a radioactive isotope may be directed to the specific location of the structure-of-interest.
- 18. Alternatively, non-invasive surgery may be selected using a radiosurgery apparatus, such as the GammaKnife or a radiotherapy apparatus equipped for stereotactic surgery.

# INFRINGING ACTS OF BRAINLAB

19. During the period commencing with the date that is six years prior to the date of filing of this Complaint, BrainLab has manufactured and/or sold certain systems comprising computer hardware and/or software. BrainLab also sells various software programs (identified below) independently of system sales to customers who implement the software on non-

BrainLab hardware. There are a variety of system families ("BrainLab Systems") each comprised of individual hardware and software products that are used for both invasive and non-invasive surgery. The BrainLab Systems include: (1) navigation systems used intra-operatively for invasive surgery, such as Kolibri and VectorVision (that may be integrated with BrainSUITE that permits MRI or CT radiologic images to be taken during surgery); (2) ExacTrac IGRT used in radiation therapy treatment (non-invasive procedures) that provide frameless stereotaxy for single fraction radiosurgery; and (3) the Novalis Tx radiosurgery platform using a Varian Medical Systems Linac. The software components of these BrainLab Systems comprise a number of families, one of which is styled iPlan and includes at least seven separate software products bearing the family name: iPlan RT Image, iPlan RT Dose, iPlan Stereotaxy, iPlan ENT, iPlan Cranial, iPlan Flow and iPlan Spine. Other software components of the BrainLab Systems include PatXfer (acquisition and conversion of images), BrainSCAN (stereotactic treatment planning system for radiation therapy), and Cranial/ENT Essential (intraoperative image guided localization).

20. Kolibri is a mobile platform system that includes a computer planning and navigation workstation that displays images and includes localization hardware and software used for navigation during invasive surgery. VectorVision is also a mobile platform system with a computer planning and navigation workstation used during invasive surgery, or may be a stationary ceiling-mounted system for frameless stereotaxy localization and navigation, called VectorVision Sky. VectorVision may be used for frameless stereotaxy localization and navigation based on treatment plans performed on the VectorVision workstation, or other BrainLab workstations. BrainSUITE systems combine intra-operative MR or CT imaging with stereotactic planning and navigation based on VectorVision hardware and may be used in conjunction with the above-mentioned software. Digital Lightbox is a computer monitor that is wall mounted for use by surgeons in or out of the operating room. ExacTrac is an automated IGRT system including a patient couch (platform) and floor-mounted and ceiling-mounted components of an optical infrared tracking (navigation) system for correct patient positioning throughout surgery including tumor motion management. ExacTrac may be used in conjunction

with iPlan RT software images that are updated during the intraoperative procedure. The Kolibri and VectorVision BrainLab Systems are stereotactic systems accused of infringing when used with iPlan treatment planning software.

- 21. The BrainLab systems may also include graphic scanned brain images, called Brain Maps, used in treatment planning and/or intra-operative navigation as additional features of the System.
- 22. Brain Life accuses the BrainLab Systems of literally infringing each of the limitations in each of the Asserted Claims (including the preamble if construed as a positive limitation). Should the Court construe any limitation such that it is not literally infringed, Brain Life contends that the limitation is infringed under the doctrine of equivalents on the grounds that the differences between the limitation and the corresponding element of the BrainLab Systems are insubstantial and/or the element performs substantially same function in substantially the same way to obtain substantially the same result.
- 23. Direct infringement of the '684 patent occurs when a user, such as one, or any combination of, a surgeon, oncologist, physicist or other treatment planning professional acting in concert, uses the BrainLab System in the course of practicing at least one of the methods claimed in the Asserted Claims. In addition to direct infringement by its customers, BrainLab has also directly infringed the claims by practicing the method through on-call services in which a BrainLab technician (agent) accompanies the BrainLab System for temporary use and participates in the procedure being performed, or in the course of testing and/or demonstrating BrainLab Systems.
- 24. BrainLab also infringes by active inducement of its customers for BrainLab Systems and BrainLab software, to use BrainLab Systems so as to infringe the Asserted Claims. BrainLab has actively and knowingly promoted and/or aided and abetted a user's direct infringement of the '684 patent by, for example, advertising the use of the BrainLab Systems and/or providing instructions on how to use the BrainLab Systems in a way that would infringe the Asserted Claims. BrainLab's design, manufacture, and sale of BrainLab Systems used for direct infringement of the Asserted Claims is further evidence of its intent to induce

infringement by another.

- 25. BrainLab's infringement by inducement is based, *inter alia*, on BrainLab's awareness of the '684 patent, at a minimum no later than February, 2002, the date the jury returned its verdict in Case No. 97-cv-2271-RHW, *Medical Instrumentation and Diagnostics Corp. v. Elekta*, *AB*. In addition, BrainLab's knowledge of the '684 patent is evidenced by the suit for patent infringement, brought by Medtronic, Inc. against BrainLab, on May 12, 1998 (Civil Action No. 98-cv-01072) based on Bucholtz U.S. Patent No. 5,383,454 that cites MIDCO U.S. Patent No. 5,099,846 (the parent patent of the '684 patent in this suit) as prior art. On information and belief, BrainLab in preparing its defense against the patent infringement suit by Medtronic, would require competent counsel to study each of the prior art patents cited on the cover page of the Bucholtz patent to assess whether the Bucholtz patent was valid. BrainLab's knowledge of the '684 patent is further reflected by the fact that BrainLab and its subsidiaries have obtained at least one European patent in which the MIDCO U.S. Patent No. 5,099,846 (the parent patent of the '684 patent in this suit) was cited as prior art in October 2008.
- 26. Brain Life also accuses BrainLab of contributory infringement by the sale of the family of treatment planning software products identified above, that are separable components from the hardware products of BrainLab Systems or other hardware manufacturers. Specifically, the treatment planning products that are separable components of the BrainLab Systems, include but are not limited to, iPlan RT Image, iPlan RT Dose, iPlan Stereotaxy, iPlan Cranial, iPlan Flow, BrainSCAN, Cranial ENT Essential and PatXfer (Contributory Infringement Accused Products ("CIAP")). Each of these software components enables stereotactic treatment planning when integrated with hardware components such as, but not limited to, ExacTrac, VectorVision and Kolibri to perform navigation and/or frameless stereotaxy. Brain Maps are additional components of the BrainLab Systems and software. BrainLab knows that the above-identified treatment planning software components, when executed on BrainLab hardware, as part of a BrainLab System or non-BrainLab hardware, constitutes a material part of the invention of the Asserted Claims of the '684 patent, are especially made for use in an infringement of the Asserted Claims of the '684 patent, and are

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27 28 not staple articles or commodities of commerce. The CIAP cannot be used for purposes other than infringement of Claim 53 of the '684 patent except possible uses that may be unusual, impractical, occasional or experimental. The CIAP is not suitable for substantial non-infringing use other than to perform the steps of method Claim 53 and claims dependent thereon.

- 27. By way of example of the CIAP, the iPlan Stereotaxy software is represented in BrainLab customer instruction materials for use in preparing and presenting patient image data based on CT, MR, and X-Ray (Fluoro) scans. The instructions provide that the iPlan Stereotaxy component is used for image preparation, image fusion, and image segmentation that are steps in the performance of the method of Claim 53. This iPlan software component provides a treatment plan for use in stereotactic surgery. The iPlan Stereotaxy component instructions direct the user to perform four of the most critical steps of method Claim 53 including acquisition of images using the software component PatXfer and then conversion to a BrainLab format, storing the images, performing stereotactic localization utilizing the images, and fusing the images all as part of the use of accused BrainLab Systems. As another example of the CIAP, BrainLab provides its customers with a software component that permits the customer to perform critical steps of the Claim 53 method and also instruct the customer in the use of the component for localization utilizing the Brain Map component to create registration points used in determining stereotactic coordinates for the images in the operating room. Another function of the iPlan software component, iPlan Stereotaxy, provides measuring and/or calculating distances, volumes, and areas as well as locations in Cartesian coordinates based on the image data provided by the software component. The iPlan Stereotaxy software component instructions inform the user to compare images by adjusting grayscale values or by pseudocoloring. The software component can also be used in a manipulating step performed by shifting or adjusting one image set to a reference image set.
- 28. Use of the exemplary iPlan Stereotaxy software component is authorized in instructional materials provided to customers specifying the correct use of the software component, warnings of misuse, and requiring that the software component is to be used only with BrainLab specified equipment. Similarly, the instructional materials of the iPlan

Stereotaxy software component specify that BrainLab's software may be installed and used in a BrainLab System or with a customer's non-BrainLab equipment.

29. Another example of the provision by BrainLab of software components that have no non-infringing uses includes the Novalis system radiation therapy delivery device that utilizes the RT image and/or RT dose CIAP. These two software components are separable and distinct from hardware and other software components of the Novalis system. The CIAP iPlan cannot be used for purposes other than as a treatment planning system in conjunction with radiotherapy delivery devices of the Novalis system. BrainLab knew that the iPlan RT and iPlan RT Dose CIAP were especially made for use in an infringement of method Claim 53 of the '684 patent. Neither iPlan RT nor iPlan RT Dose are staple articles or commodities of commerce nor are they good for any purpose other than treatment planning. Any use other than as a treatment planning system, would be unusual, impractical, occasional or experimental. In short, iPlan RT Image and iPlan RT Dose are not usable for substantial non-infringing purposes.

# **COUNT I**

# DIRECT PATENT INFRINGEMENT BY BRAINLAB

- 30. Brain Life realleges and incorporates by reference Paragraphs 1-29 set forth above.
- 31. BrainLab has directly infringed the Asserted Claims by selling or offering to sell BrainLab Systems in the United States during the period commencing six years prior to the filing date of the original Complaint in this action. Such direct infringement has been practiced by its own employees or agents through on-call services, by testing the BrainLab system prior to or at the time of delivery to customers in the United States, and by demonstrating BrainLab Systems in the United States to potential customers.
- 32. BrainLab is willfully infringing the Asserted Claims of the '684 patent by conduct and acts that demonstrate at least an objective recklessness in performing such acts.
- 33. As a result of the above-described acts of direct infringement, Brain Life has suffered damages.

# **COUNT II**

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#### INDUCEMENT PATENT INFRINGEMENT BY BRAINLAB

- 34. Brain Life realleges and incorporates by reference Paragraphs 1 33 set forth above.
- 35. BrainLab has indirectly infringed the Asserted Claims of the '684 patent by inducing users of the BrainLab Systems to practice the methods of the Asserted Claims of the '684 patent in the United States ("Acts of Inducement"). The Acts of Inducement are set forth in greater detail in Paragraphs 24 and 25.
- 36. Upon information and belief, BrainLab is willfully infringing the Asserted Claims of the '684 patent through its Acts of Inducement performed in the United States during the period commencing six years prior to the Complaint in this action.
- 37. BrainLab is willfully infringing the Asserted Claims of the '684 patent through its Acts of Inducement that demonstrate at least an objective recklessness in performing such acts.
- 38. As a result of the above-described acts of indirect infringement by Acts of Inducement, Brain Life has suffered damages.

# **COUNT III**

# CONTRIBUTORY INFRINGEMENT BY BRAINLAB

- 39. Brain Life realleges and incorporates by reference Paragraphs 1-38 set forth above.
- 40. BrainLab has offered to sell and has sold in the United States, or imported into the United States, a software component of the BrainLab Systems for use in practicing a method that directly infringes the Asserted Claims of the '684 patent and that constitutes a material part of the invention, knowing the same to be especially made or adapted for use in an infringement of the Asserted Claims and not a staple article or commodity of commerce suitable for substantial non-infringing use ("Acts of Contributory Infringement").
- 41. BrainLab is willfully infringing the Asserted Claims of the '684 patent through its Acts of Contributory Infringement that demonstrate at least an objective recklessness in performing such acts.

1	42. As a result of the above-described acts of indirect infringement by Acts of		
2	Contributory Infringement, Brain Life has suffered damages.		
3	REQUEST FOR RELIEF		
4	WHEREFORE, Brain Life respectfully requests that the Court:		
5	A. Award Plaintiff Brain Life, LLC past damages together with prejudgment and		
6	postjudgment interest to compensate Brain Life, LLC for the infringement by BrainLab of th		
7	Asserted Claims of the '684 Patent in accordance with 35 U.S.C. § 284, and to increase such		
8	award by up to three (3) times the amount found or assessed in accordance with 35 U.S.C		
9	§ 284;		
0	B. Declare this case exceptional and award reasonable attorneys fees to Brain Life		
1	LLC pursuant to 35 U.S.C. § 285; and		
2	C. Permit Brain Life, LLC to recover its costs, disbursements, attorneys' fees and		
3	such further and additional relief as is deemed appropriate by this Court.		
4	JURY TRIAL DEMANDED		
5	Brain Life, LLC requests a trial by jury for all claims that permit a jury trial in thi		
6	action.		
7			
8	Dated: February 9, 2013 THE ADAMS LAW FIRM, LLC		
9			
20	By: /S/ Paul Adams		
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28	Attorneys for Brain Life, LLC		
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**CERTIFICATE OF SERVICE** 

The undersigned hereby certifies that I have taken steps to cause this document to be transmitted electronically to the Electronic Case Filing ("ECF") system of the United States District Court for the Southern District of California, constituting service of the final document to all registered participants, all of whom have consented to electronic service.

Dated this 9<sup>th</sup> day of February, 2013.

/S/ Paul Adams Paul Adams