IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
PALM BEACH DIVISION

CASE NO.

OBSIDIAN MEDICAL TECHNOLOGIES, LLC,
Plaintiff,

v.

SPERLING RADIOLOGY PC PA,
d/b/a SPERLING PROSTATE CENTER

Defendant.
_____/

OBSIDIAN MEDICAL TECHNOLOGIES, LLC'S ORIGINAL COMPLAINTFOR PATENT INFRINGEMENT

Plaintiff Obsidian Medical Technologies, LLC, files this Original Complaint against Defendant Sperling Radiology PC PA ("Sperling Radiology or Defendant") for infringement of U.S. Patent No. 8,548,562.

THE PARTIES

1. Plaintiff Obsidian Medical Technologies, LLC is a Texas limited liability company with its headquarters and principal place of business at 555 Republic Drive, 2nd Floor, Plano, Texas 75074.

2. Sperling Radiology operates at locations in Florida and California, having a main office located at 4205 West Atlantic Avenue, Building D, Delray

Beach, Florida 33445.

Sperling Radiology advertises and markets through a website titled Sperling Prostate Center. According to its website, the "Sperling Prostate Center in New York City and Florida is a technologically advanced patient-oriented practice dedicated to providing the most effective techniques in prostate cancer diagnosis and treatment."

3. Upon information and belief, Sperling Prostate Center (SPC) is a medical practice that is part of Sperling Radiology, a company organized under the laws of New York, is registered to do business in Florida, and may be served through its registered agent, Sperling Radiology PC PA located at 4205 West Atlantic Ave, Building D, Delray Beach FL 33445.

4. SPC provides urologic care including diagnosis, assessment, and treatment for prostate diseases.

5. Services provided by SPC include MRI-Guided Prostate Ablation and MRI-Guided Prostate Biopsy procedures.

6. The MRI-Guided Prostate Ablation and the MRI-Guided Prostate Biopsy procedures performed by SPC practices one or more claims of Obsidian's '562 Patent.

JURISDICTION AND VENUE

7. Obsidian Medical brings this action for patent infringement under the

patent laws of the United States, namely 35 U.S.C. §§ 271, 21, and 284-285, among others. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1367.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b). Defendant has a regular and established place of business in this judicial district, does business in this judicial district, has provided MRI guided biopsy and focal laser ablation procedures to patients in this district, committed acts of infringement in this judicial district, and has purposefully transacted business in this judicial district involving the subject matter claimed in the ’562 Patent.

9. Defendant maintains established places of business in Delray Beach, Florida.

OBSIDIAN MEDICAL’S ’562 PATENT

10. Defendant has infringed and continues to infringe U.S. Patent No. 8,548,562.

11. The ’562 Patent relates to imaging and diagnostic systems and methods for planning and executing guided treatment, diagnoses, and assessment of prostate tissue.

12. The ’562 Patent describes imaging techniques to help differentiate between suspicious cells and healthy prostate tissue to focus therapeutic treatment such as biopsy resection and ablation for preservation of healthy tissue to minimize

destructive effects of tissue removal.

13. The lead inventor of the ’562 Patent, Dr. John Trachtenberg, led a groundbreaking research group that pioneered the use of multi-parametric magnetic resonance imaging (MRI) to diagnose prostate cancer and guide focal treatment therapies.

14. Dr. Trachtenberg and his co-inventors, Drs. Haider and Wilson, filed a provisional U.S. patent application on April 4, 2006, and were awarded a patent for their inventions seven years later on October 1, 2013.

15. Broadly speaking, Obsidian Medical accuses Defendant of infringing the ’562 Patent by performing MRI-Guided Laser Ablation and Biopsy procedures that practice each step of the claimed systems and methods of imaging and removing or ablating tissue from a prostate.

16. For example, claim 10 of the ’562 patent recites:

a. taking real-time, non-invasive MRI imaging data;

b. executing a software program on the received generated MR image data to provide an indication of differentiation between malignant and non-malignant tissues of prostate by steps comprising:

i. inputting variable “a” to represent the presence of malignant tissue and variable “b” to represent the absence of malignant tissue in accordance with T2 weighted, diffusion weighted and dynamic contrast enhanced images further acquired by the MRI device spanning the prostate tissue; and

ii. using a T1 weighted pulse sequence to obtain at least one

additional dynamic contrast enhanced image;

c. generating an apparent diffusion coefficient map (ADC) on the MRI device;

d. administering an intravenous contrast agent;

e. generating a permeability map sing a modified Brix pharmacokinetic model; and

f. automatically generating a value, by weighting pre-determined regions of the permeability map, to determine the size, location and orientation of the malignant and non-malignant tissue of the prostate represented on an image display;

g. providing a laser ablative energy source through or from an interstitially positioned ablation device to interstitially deliver focal ablation energy to the malignant tissue of the prostate in accordance with the determined size, location and orientation of the malignant tissue;

h. operating in real-time a monitoring system quantifying an amount of energy deposited by the laser ablation device; and

i. interstitially delivering tissue coagulating or tissue ablating focal therapeutic laser coagulating or laser ablating treatment to the malignant tissue of the prostate, in an amount responsive in real-time to the output data of the monitoring system to deliver laser coagulating or laser ablating energy to only remaining malignant tissue.

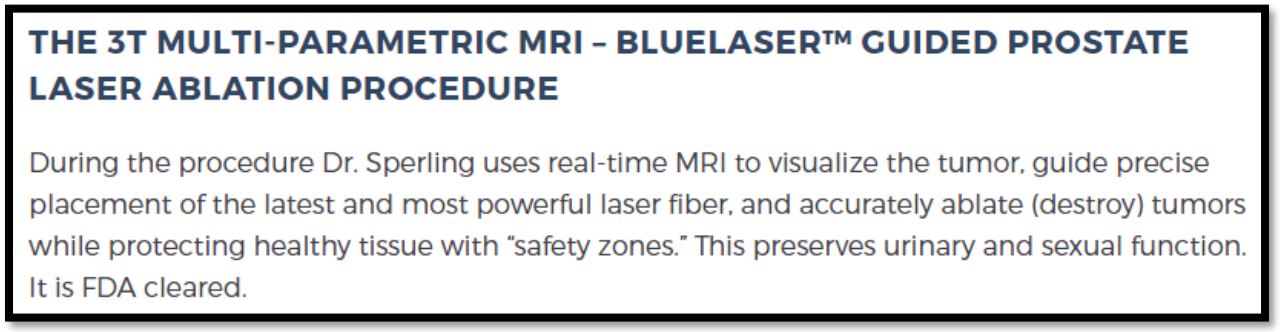
17. SPC developed and performs an MRI-Guided Focal Laser Ablation Procedure that infringes at least claim 10 of the ’562 Patent to perform removal of cancerous tumors of the prostate.

3T Multi-Parametric MRI – BlueLaser™ Guided Focal Laser Ablation

The Sperling Prostate Center in Florida offers our proprietary **3T Multi-Parametric MRI – BlueLaser™** Protocol Guided Focal Laser Ablation using the most powerful laser available for FLA of the prostate.

Our advanced, minimally invasive procedure is designed to target and destroy the prostate tumor while sparing the remaining healthy tissue. Our goal is to control the disease while avoiding collateral damage to sensitive structures. This means a rapid return to baseline urinary and sexual function. In short, our Focal Laser Ablation done by internationally recognized expert Dr. Dan Sperling offers minimal-to-no side effects in order to maintain high quality of life after treatment.

18. Defendant uses a Siemens MRI imaging system to generate a series of MR images through the prostate in real-time.



THE 3T MULTI-PARAMETRIC MRI – BLUELASER™ GUIDED PROSTATE LASER ABLATION PROCEDURE

During the procedure Dr. Sperling uses real-time MRI to visualize the tumor, guide precise placement of the latest and most powerful laser fiber, and accurately ablate (destroy) tumors while protecting healthy tissue with "safety zones." This preserves urinary and sexual function. It is FDA cleared.

19. SPC uses software together with its MRI equipment (e.g., Siemens Skyra MRI imaging system) to differentiate between malignant and non-malignant tissue. SPC's technique can distinguish normal from diseased tissue by precising locating suspicious tumors.

Our Advanced 4-Step Treatment Protocol

1. **3T Multi-Parametric MRI – BlueLaser™** qualifies appropriate candidates for laser ablation based on a detailed prostate map from our multi-parametric MRI, and targeted biopsy of suspicious prostate tissue.

Our multiparametric software is equally advanced, and provides sophisticated visual data on the key parameters (T2 weighting, Diffusion Weighting, Dynamic Contrast Enhancement) that differentiate healthy tissue from cancer and from benign prostate conditions such as BPH (benign prostatic hyperplasia).

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Multiparametric magnetic resonance imaging (mpMRI) is demonstrating immense value for detecting and diagnosing prostate cancer. The parameters, or imaging sequences, each highlight various features that distinguish healthy from diseased tissue in the prostate. Special software processes the feedback information during each MRI sequence in a unique way that shows up on a computer monitor. The parameters are meant to be correlated with each other, and the first two (T2-weighted and diffusion weighted) are considered the workhorse of prostate MRI when used in combination.

20. SPC's software in the MRI imaging system creates a three-dimensional model of the prostate. This model includes regions of interest representing the presence of malignant tissue (which relate to variable "a") and healthy tissue (which relate to variable "b").

What mpMRI can do for you

mpMRI gives high resolution 3-dimensional images of the prostate gland showing healthy and unhealthy tissue. If no suspicious tumor is present, a biopsy is not needed and the situation can be monitored by imaging at prescribed intervals if PSA remains high.

21. Defendant describes the MRI-guided Prostate Ablation procedure on its website (https://sperlingprostatecenter.com/focal-laser-ablation-new-york-city/).

22. Defendant captures and processes MR images including T2 weighted ("T2W"), diffusion weighted ("DWI"), and dynamic contrast enhanced images.

23. T2W, DWI, and dynamic contrast enhanced images are the components of a multiparametric MRI ("mpMRI").

24. According to Defendant, mpMRI imaging "is demonstrating immense value for detecting and diagnosing prostate cancer. These parameters, or imaging sequences each highlight various features that distinguish healthy from diseased tissue in the prostate."

25. At least one additional dynamic contrast enhanced image is obtained using a T1 weighted pulse sequence to produce DCE images.

26. During the course of the treatment procedure, Defendant generates an apparent diffusion coefficient map ("ADC") using the MRI system.

27. An ADC map displays ADC values for each voxel in an MR image.

28. Defendant administers an intravenous contrast agent (a gadolinium-based contrast agent) during the procedure (typically before the T1W pulse sequence).

29. During the MRI-Guided Laser Ablation procedure, Defendant uses specialized software to generate a permeability map by calculating a k_{trans} value for

each pixel/voxel.

30. PI-RADS is set of guidelines and a scoring system for prostate MRI that serves a standard for care in the field. It is designed to promote global standardization and diminish variation in the acquisition, interpretation, and reporting of prostate mpMRI examinations.

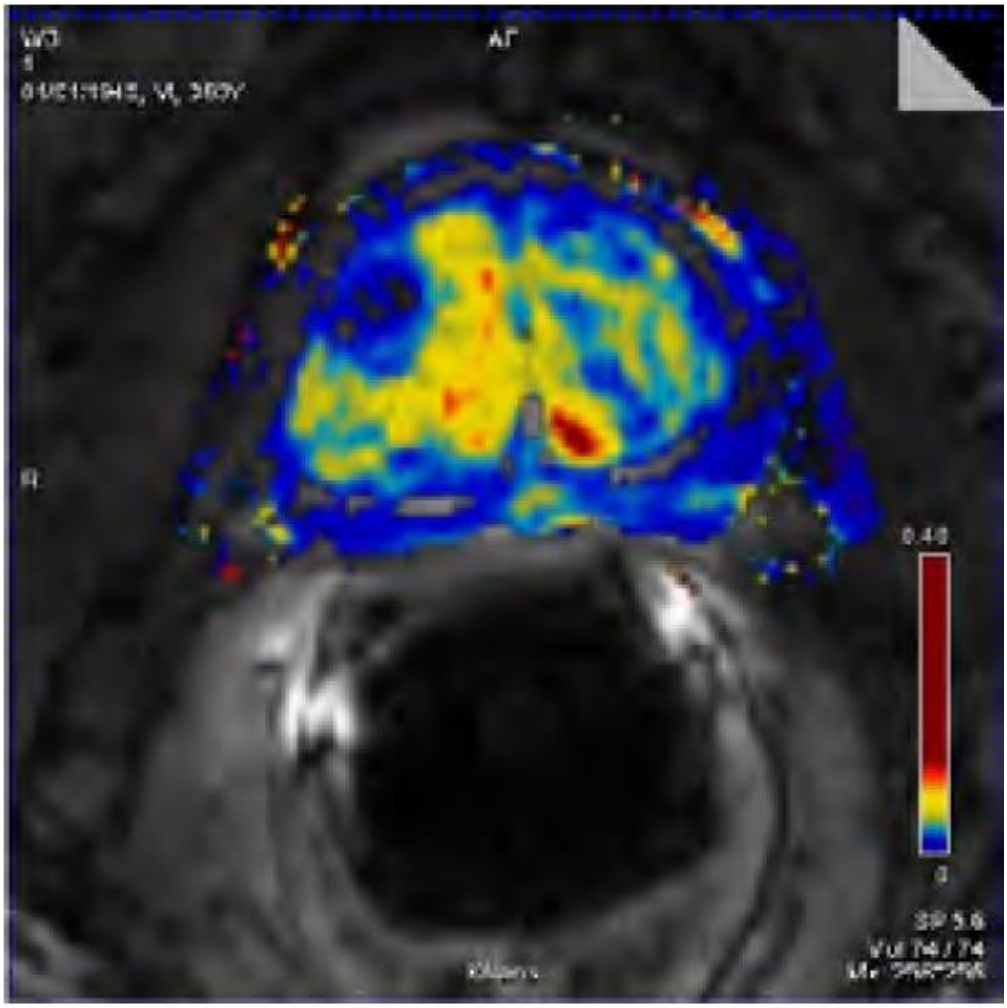
31. Defendant generally follows PI-RADS and employs the PI-RADS scoring system in performing biopsy procedures.

32. To generate a permeability map, Defendant processes DCE datasets using a quantitative analysis that includes determining the permeability of a pixel/voxel by fitting the observed contrast perfusion characteristics to a pharmacokinetic model, either a modified Brix pharmacokinetic model or substantial equivalent, to relate the change in signal intensity to permeability (k_{trans} value).

33. The ’562 Patent describes deriving permeability from a 2-compartment pharmacokinetic model to represent the transfer constant of the contrast agent from the vascular compartment to the tissue compartment. ’562 at 8:41-45.

34. By weighting pre-determined regions of the permeability map to automatically generate a value to determine the size, location, and orientation of prostate regions of interest, Defendant’s specialized software generates an image display representing the prostate with a color overlay.

35. Below is an example of the image output:



36. These weighted values help determine the location of a prostate tumor by highlighting tissue volumes characterized by high transfer rate of contrast agent from blood plasma into the tissue indicative of malignancy.

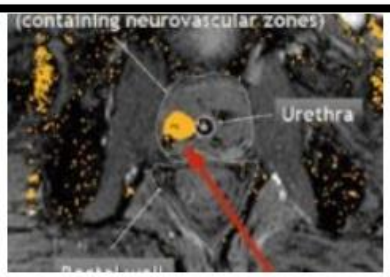
37. Defendant's specialized software automatically identifies regions of interest to delineate malignant tissue to target for biopsy.

38. Upon identifying a region of interest, Defendant's specialized software

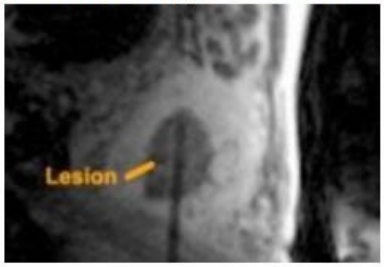
is used to refine the boundaries of the region by setting a window of permeability values.

39. During the MRI-Guided Laser Ablation procedure, Defendant provides a laser fiber to deliver ablation energy to the malignant tissue

1. Pre-procedure MRI confirms placement of applicator in the target tissue.



2. The thin (1.6mm) laser fiber is then placed into the tumor under MRI guidance. The laser is activated to begin heating of the tumor. Using MR images and software from Visualase allows the physician to see the tissue heating during laser irradiation, and control how much energy is delivered. During the procedure the MRI is also used to monitor temperature-sensitive changes in the prostate tissue. The result is unparalleled control over how much energy is delivered. At the same time, the destruction of tissue and tumor is confirmed. Typically, the laser procedure takes about an hour.



3. Results are confirmed with MR images.

40. SPC's MRI-Guided Focal Laser Ablation procedures are performed under real time MRI to precisely guide laser energy to the middle of the malignant tissue. The laser energy is being monitored during the procedure.

THE 3T MULTI-PARAMETRIC MRI – BLUELASER™ GUIDED PROSTATE LASER ABLATION PROCEDURE

During the procedure Dr. Sperling uses real-time MRI to visualize the tumor, guide precise placement of the latest and most powerful laser fiber, and accurately ablate (destroy) tumors while protecting healthy tissue with "safety zones." This preserves urinary and sexual function. It is FDA cleared.

41. Claim 15 of the ’562 Patent recites:

a. taking real-time, non-invasive MRI imaging data;

b. executing a software program on the received generated MR image data to provide an indication of differentiation between malignant and non-malignant tissues of prostate by steps comprising:

i. inputting variable “a” to represent the presence of malignant tissue and variable “b” to represent the absence of malignant tissue in accordance with T2 weighted, diffusion weighted and dynamic contrast enhanced images further acquired by the MRI device spanning the prostate tissue; and

ii. using a T1 weighted pulse sequence to obtain at least one additional dynamic contrast enhanced image;

c. generating an apparent diffusion coefficient map (ADC) on the MRI device;

d. administering an intravenous contrast agent;

e. generating a permeability map sing a modified Brix pharmacokinetic model; and

f. automatically generating a value, by weighting pre-determined regions of the permeability map, to determine the size, location and orientation of the malignant and non-malignant tissue of the prostate represented on an image display;

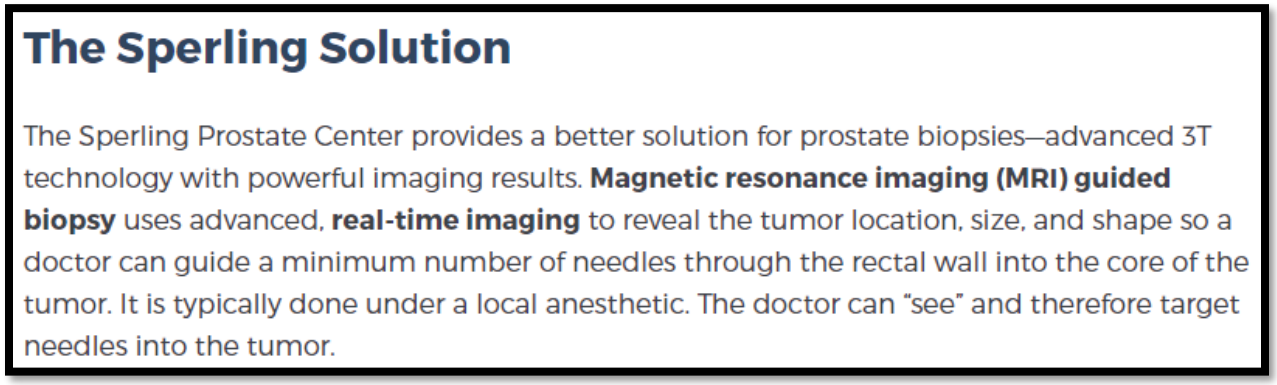
g. providing a resection medical tool to deliver focal therapy of excision of tissue to the malignant tissue of the prostate in accordance with the determined size, location and orientation of at least the malignant tissue;

h. monitoring in real-time the amount and location of tissue removed and comparing the tissue removing focal therapeutic treatment to determined size, location and orientation of the malignant tissue.

42. SPC developed and performs an MRI-Guided Prostate Biopsy Procedure that infringes claim 15 of the ’562 Patent to perform an in-bore real time

MRI-guided biopsy of the prostate. According to SPC, its MRI-guided biopsy procedure is done live and in real time, yields MR images that are free from inaccuracy or distortion, enables radiologists to see the live target, and may use a radiologist already experienced in reading and interpreting MRI images.

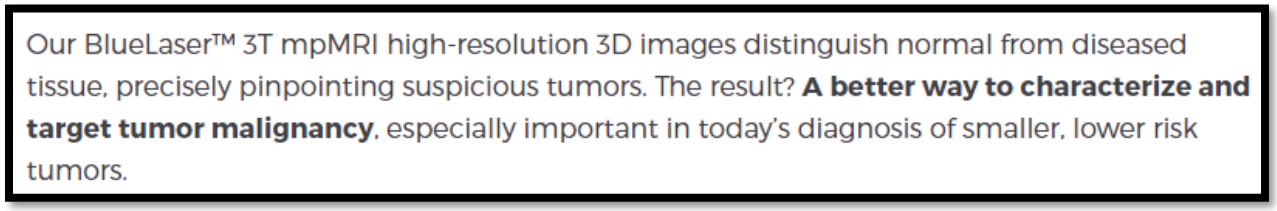
43. Defendant uses a Siemens MRI imaging system to generate a series of MR images through the prostate in real-time.



The Sperling Solution

The Sperling Prostate Center provides a better solution for prostate biopsies—advanced 3T technology with powerful imaging results. **Magnetic resonance imaging (MRI) guided biopsy** uses advanced, **real-time imaging** to reveal the tumor location, size, and shape so a doctor can guide a minimum number of needles through the rectal wall into the core of the tumor. It is typically done under a local anesthetic. The doctor can "see" and therefore target needles into the tumor.

44. SPC uses software together with its MRI equipment (e.g., Siemens Skyra MRI imaging system) to differentiate between malignant and non-malignant tissue. SPC's technique can distinguish normal from diseased tissue by precisely locating suspicious tumors.



Our BlueLaser™ 3T mpMRI high-resolution 3D images distinguish normal from diseased tissue, precisely pinpointing suspicious tumors. The result? **A better way to characterize and target tumor malignancy**, especially important in today's diagnosis of smaller, lower risk tumors.

Our multiparametric software is equally advanced, and provides sophisticated visual data on the key parameters (T2 weighting, Diffusion Weighting, Dynamic Contrast Enhancement) that differentiate healthy tissue from cancer and from benign prostate conditions such as BPH (benign prostatic hyperplasia).

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of a multiparametric MRI ("mpMRI").

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53. Defendant administers an intravenous contrast agent (a gadolinium-based contrast agent) during the procedure (typically before the T1W pulse sequence).

54. During the MRI-Guided Biopsy procedure, Defendant uses specialized software to generate a permeability map by calculating a k_{trans} value for each pixel/voxel.

55. PI-RADS is set of guidelines and a scoring system for prostate MRI that serves a standard for care in the field. It is designed to promote global standardization and diminish variation in the acquisition, interpretation, and reporting of prostate mpMRI examinations.

56. Defendant generally follows PI-RADS and employs the PI-RADS scoring system in performing fusion biopsy procedures.

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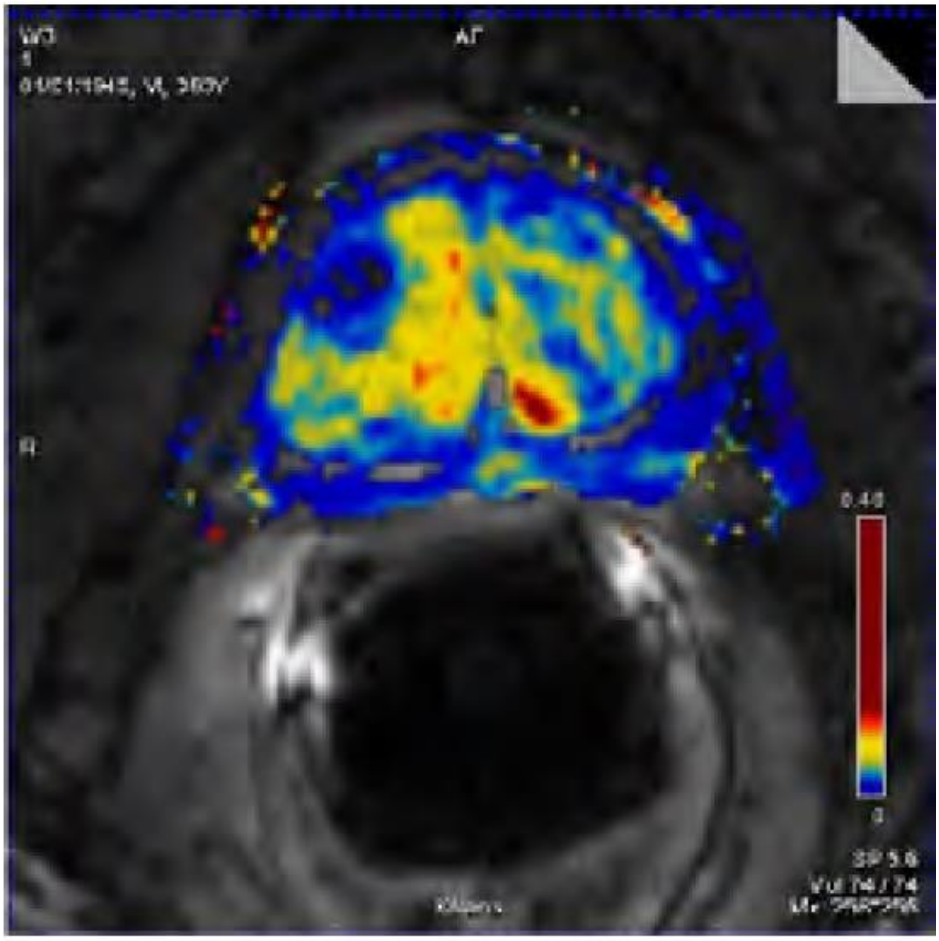

61. These weighted values help determine the location of a prostate tumor by highlighting tissue volumes characterized by high transfer rate of contrast agent from blood plasma into the tissue indicative of malignancy.

62. Defendant's specialized software automatically identifies regions of interest to delineate malignant tissue to target for biopsy.

63. Upon identifying a region of interest, Defendant's specialized software is used to refine the boundaries of the region by setting a window of permeability values.

64. During the biopsy procedure, Defendant provides a biopsy needle to deliver focused therapeutic excision of tissue in accordance with the determined size, location, and orientation of the identified tissue region.

65. SPC MRI-Guided Biopsies are performed under real time MRI to precisely guide the biopsy needle to the middle of the determined location of malignant tissue.

66. According to Defendant, this computer-aided tumor detection allows the biopsy removal to be performed right in the middle of the tumor, enabling the procedure to obtain the right tissue.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 8,548,562

67. Obsidian Medical incorporates the preceding paragraphs by reference as if set forth herein.

68. Obsidian Medical is the exclusive licensee of the ’562 Patent titled “System and Method of Guided Treatment within Malignant Prostate Tissue.”

69. As the exclusive licensee of the ’562 Patent, Obsidian Medical holds all substantial rights in and under the ’562 Patent, including the right to grant sublicenses, exclude others, and to enforce, sue, and recover damages for past and future infringement.

70. The United States Patent Office granted the ’562 Patent on October 1,

2013, after a full and fair examination.

71. The ’562 Patent is valid, enforceable and was duly issued in full compliance with Title 35 of the United States Code.

72. Defendant has directly infringed, and continues to infringe, the ’562 Patent, literally or under the doctrine of equivalents, by practicing and/or directing and controlling the practice of one or more claims of the ’562 Patent, including at least claim 1 and 10 by performing MRI-Guided Prostate Laser Ablation Procedures and at least claim 15 by performing MRI-Guided Prostate Biopsy procedures during as described above.

73. Defendant has been on notice that Obsidian Medical contends that its MRI-Guided Prostate Biopsy and MRI-Guided Laser Ablation Procedures infringe the ’562 Patent.

74. Obsidian Medical has been damaged as a result of Defendant’s infringing conduct described in this count.

75. Defendant is liable to Obsidian Medical in an amount that adequately compensates it for its infringement, which amount, by law, can be no less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

76. As a result of Defendant’s ongoing infringing conduct described in this complaint, Obsidian Medical will continue to be damages unless Defendant is

enjoined from further infringement.

NOTICE

77. Obsidian Medical does not currently distribute, sell, offer for sale, or make its own products embodying the ’562 Patent.

78. Obsidian Medical provided actual notice of infringement to Defendant on multiple occasions starting in 2020. Defendant never responded, necessitating this action.

NOTICE OF REQUIREMENT OF LITIGATION HOLD

79. Defendant is hereby notified it is legally obligated to locate, preserve, and maintain all records, notes, drawings, documents, data, communications, materials, electronic recordings, audio/video/photographic recordings, and digital files, including edited and unedited or “raw” source material, and other information and tangible things that Defendant knows, or reasonably should know, may be relevant to actual or potential claims, counterclaims, defenses, and/or damages by any party or potential party in this lawsuit, whether created or residing in hard copy form or in the form of electronically stored information (hereafter collectively referred to as “Potential Evidence”).

80. As used above, the phrase “electronically stored information” includes without limitation: computer files (and file fragments), e-mail (both sent and received, whether internally or externally), information concerning e-mail

(including but not limited to logs of e-mail history and usage, header information, and deleted but recoverable e-mails), text files (including drafts, revisions, and active or deleted word processing documents), instant messages, audio recordings and files, video footage and files, audio files, photographic footage and files, spreadsheets, databases, calendars, telephone logs, contact manager information, internet usage files, and all other information created, received, or maintained on any and all electronic and/or digital forms, sources and media, including, without limitation, any and all hard disks, removable media, peripheral computer or electronic storage devices, laptop computers, mobile phones, personal data assistant devices, Blackberry devices, iPhones, video cameras and still cameras, and any and all other locations where electronic data is stored. These sources may also include any personal electronic, digital, and storage devices of any and all of Defendant's agents, resellers, or employees if Defendant's electronically stored information resides there.

81. Defendant is hereby further notified and forewarned that any alteration, destruction, negligent loss, or unavailability, by act or omission, of any Potential Evidence may result in damages or a legal presumption by the Court and/or jury that the Potential Evidence is not favorable to Defendant's claims and/or defenses. To avoid such a result, Defendant's preservation duties include, but are not limited to, the requirement that Defendant immediately notify its agents and employees to halt

and/or supervise the auto-delete functions of Defendant's electronic systems and refrain from deleting Potential Evidence, either manually or through a policy of periodic deletion.

JURY DEMAND

Obsidian Medical hereby demands a trial by jury on all claims, issues and damages so triable.

PRAYER FOR RELIEF

Obsidian Medical prays for the following relief:

a. That Defendant be summoned to appear and answer;

b. That the Court enter an order declaring that Defendant has infringed U.S. Patent No. 8,548,562;

c. That the Court grant Obsidian Medical judgment against Defendant for all actual, consequential, special, punitive, increased, and/or statutory damages, including, if necessary, an accounting of all damages; pre and post-judgment interest as allowed by law; and reasonable attorneys' fees, costs, and expenses incurred in this action;

d. That Obsidian Medical be granted such other and further relief as the Court may deem just and proper under the circumstances.

Filed: April 13, 2022 Respectfully submitted,

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