

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF GEORGIA  
ATLANTA DIVISION**

TISSUE REGENERATION )  
TECHNOLOGIES, LLC and GENERAL )  
PATENT, LLC, )

Plaintiffs, )

v. )

THE ANTI-AGING GROUP, L.L.C. and )  
SEXUAL MD SOLUTIONS LLC, )

Defendants. )

Civil Action File No.  
\_\_\_\_:\_\_\_\_-CV-\_\_\_\_-\_\_\_\_

**Jury Trial Demanded**

**COMPLAINT**

COME NOW Plaintiffs Tissue Regeneration Technologies, LLC and General Patent, LLC and file this Complaint against Defendants The Anti-Aging Group, L.L.C. and Sexual MD Solutions LLC (collectively, the “Defendants”) and in support hereof show unto the Court the following:

**PARTIES**

1. Plaintiff Tissue Regeneration Technologies, LLC (“TRT”) is an Ohio limited liability company with its principal place of business located at 251 Heritage Walk, Woodstock, Georgia 30188.

2. Plaintiff General Patent, LLC is a Georgia limited liability company with its principal place of business located at 251 Heritage Walk, Woodstock, Georgia 30188.

3. Defendant The Anti-Aging Group, L.L.C. (“TAAG”) is a Florida limited liability company with its principal place of business located at 20800 W. Dixie Highway, Aventura, Florida 33180 and may be served with Summons and a copy of this Complaint by delivering the same to its registered agent, Mark White, at 20800 W. Dixie Highway, Aventura, Florida 33180.

4. Defendant Sexual MD Solutions LLC (“SMDS”) is a Florida limited liability company with its principal place of business located at 20800 W. Dixie Highway, Aventura, Florida 33180 and may be served with Summons and a copy of this Complaint by delivering the same to its registered agent, Mark White, at 20800 W. Dixie Highway, Aventura, Florida 33180.

#### **JURISDICTION AND VENUE**

5. This action arises under the Patent Act, 35 U.S.C. § 101 *et seq.*, including 35 U.S.C. §§ 271, 281, 283, 284, and 285, and the Lanham Act 15 U.S.C. §§ 1051 *et seq.* Accordingly, this Court has federal question jurisdiction pursuant to 15 U.S.C. § 1121 and 35 U.S.C § 281. This Court has original jurisdiction over this controversy pursuant to 28 U.S.C. §§ 1331 and 1338.

6. As explained below, Defendants have consented to jurisdiction and venue in this district.

7. Pursuant to the parties' Settlement and License Agreement entered into on September 17, 2018 ("License Agreement"), the parties explicitly and specifically consented to the jurisdiction and venue of this Court for disputes arising under the License Agreement. Additionally, this Court has personal jurisdiction over Defendants. Defendants have minimum contacts within the State of Georgia and in the Northern District of Georgia. Defendants have purposefully availed themselves of the privileges of conducting business in the State of Georgia and in the Northern District of Georgia. Defendants have sought protection and benefit from the laws of the State of Georgia. Defendants regularly and continuously conduct business in this District and have infringed or induced infringement, and continue to do so, in this District and Plaintiffs' causes of action arise directly from Defendants' business contacts and other activities in the State of Georgia and in the Northern District of Georgia. In addition, this Court has personal jurisdiction over Defendants because minimum contacts have been established with the forum and the exercise of jurisdiction would not offend traditional notions of fair play and substantial justice.

8. Defendants, directly and/or through their intermediaries, ship, distribute, make, use, import, offer for sale, sell, and/or advertise their products and

affiliated services in the United States, the State of Georgia, and the Northern District of Georgia. Moreover, Defendants' website advertises services in this District. *See*, <https://gainswave.com/directory/georgia/>. Defendants have committed patent infringement in the State of Georgia and in the Northern District of Georgia. Defendants solicit customers in the State of Georgia and in this District. Defendants also have customers who are residents of the State of Georgia and this District and who use Defendants' products in the State of Georgia and in this District.

#### **FACTUAL BACKGROUND**

9. This case involves claims of breach of the License Agreement and patent infringement under the Patent Act, 35 U.S.C. § 101 *et seq.*, based on the promotion, licensing, sale and use of Extracorporeal Shock Wave Technology ("ESWT") for various medical indications, specifically Erectile Dysfunction ("ED") and Peyronie's Disease ("PD") branded as GAINSWave® Treatment ("GAINSWave" or "the "Accused Method") in violation of U.S. Patent No. 7,601,127 (hereinafter, the "127 Patent") after termination of the License Agreement.

10. TRT is a medical technology company that develops, manufacturers, and sells ESWT devices used to treat a variety of medical conditions under the name SoftWave™ Acoustic Wave Therapy.

11. General Patent is an affiliate of TRT and is the owner of all patents at issue in this case. General Patent has granted exclusive, world-wide licenses to TRT to use and enforce the patent at issue in this case as necessary to protect and maintain TRT's business.

12. Originally conceived and operated as a research and development company, TRT began marketing and sales operations in 2008.

13. TRT is currently engaged in business throughout the United States. TRT also has a strong international presence through its German affiliate, MTS Europe GmbH.

14. TRT develops and manufactures its "SoftWave" devices through its German affiliate, MTS. The technology utilized in the devices can be categorized into two groups: (a) unfocused "SoftWaves" for soft tissue indications (*e.g.*, wounds) and (b) focused shockwaves for lithotripsy and bony indications (*e.g.*, non-healing fractures).

15. The patented SoftWave technology uses various lens configurations to produce pressure waves. These waves have a characteristic pressure profile of short rise-times reaching high amplitudes (comparable to a sonic boom). The pressure waves can be shaped through a reflector, which enables the transmission of either highly-focused shockwaves for use on urinary stones or non-union fractures, or soft-

focused or unfocused pressure waves (*i.e.*, SoftWaves) for most soft tissue indications.

16. Plaintiffs' SoftWave technology is distinguished from its competitors' shockwave technology in that TRT uses a patented parabolic (as opposed to an ellipsoid) reflector in the therapy head. This allows delivery of unfocused waves of acoustic energy over a broad target area.

17. The fact that TRT's SoftWave technology generates less pain, has a higher efficacy rate, and has a lower re-treatment rate further distinguishes it from its competitors' higher-energy, more focused shockwave systems.

18. As the industry leader, TRT's discovery that "soft waves" have the same or better clinical benefit as higher-energy focused shockwaves for most medical conditions has allowed it to further develop the idea into a useful format and secure patents protecting its inventions.

19. TRT's SoftWave technology provides a number of benefits, including but not limited to: (a) painless treatments not requiring the use of localized anesthesia; (b) the ability to treat larger surfaces, such as wounds, faster and more efficiently than competing shockwave devices; and (c) small, compact devices that are less expensive to manufacture than competing devices.

20. TRT currently has approval to distribute two devices in the United States: the LithoGold and VetGold systems.

21. General Patent was the first company to discover (and patent the inventions used to generate) the biologic response generated by unfocused SoftWave technology, including: (a) promotion of growth factors (e.g., VEGF, BPM, and OP); (b) promotion of nitric oxide; (c) improved vascularity; and (d) migration and differentiation of stem cells.

22. Although the individual inventors have assigned their patents and patent applications to General Patent, General Patent has, in return, granted TRT a sole and exclusive, royalty-free, perpetual, and irrevocable license to use and develop all of its patents and patent applications necessary for TRT's business.

23. Specifically, TRT is the exclusive licensee of United States Patent No. 7,601,127, entitled *Therapeutic Stimulation Of Genital Tissue Or Reproductive Organ Of An Infertility Or Impotence Diagnosed Patient*, (the "Patent-in-Suit") and possesses all right, title, and interest in the Patent-in-Suit, including the right to enforce the Patent-in-Suit, the right to license the Patent-in-Suit, and the right to sue Defendants for infringement and recover past, present and future damages, as described below. The Patent-in-Suit was duly and legally issued by the United States Patent and Trademark Office after full and fair examination.

24. TRT currently has product lines developed for the treatment of five distinct areas of care: (a) CardioGold™ – cardiac and vascular indications; (b) LithoGold™ – lithotripsy and urology indications; (c) OrthoGold™ – orthopedic

indications; (d) UroGold™ – urology indications; (e) VetGold™ – veterinary indications; and (f) DermaGold™ – wound care indications.

25. Currently, TRT’s three primary initiatives consist of: (a) selling approved devices throughout North America; (b) securing legal protection for its products and intellectual property; and (c) obtaining regulatory approval or clearance in the United States.

26. Defendants TAAG and SMDS are affiliated entities. They have the same address, registered agent, and officers. SMDS owns United States Trademark Registration Number 5,404,332 for the word mark GAINSWAVE (the “GAINSWAVE Trademark”) in International Class 044 and United States Classes 100 and 101 for “Extra corporeal shock wave therapy services; Medical services, namely, extra corporeal shock wave therapy for sexual wellness; Medical extra corporeal shock wave therapy services.” TAAG and SMDS are collectively referred to herein as “the GAINSWAVE defendants.”

27. On information and belief, the GAINSWAVE Defendants advertise, market, promote, and license a competing shockwave device by licensing the “GAINSWave” method to doctors throughout the United States, including doctors in this district, as well as to doctors in Canada, Bermuda, and Puerto Rico.<sup>1</sup>

28. Plaintiffs are engaged in commerce within the control of Congress.

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<sup>1</sup> See, <https://gainswave.com/directory/>.



29. Plaintiffs previously filed suit against the GAINSWAVE Defendants, as well as several of the providers located in this district, in the case styled *Tissue Regeneration Technologies, LLC and General Patent, LLC, Plaintiffs vs. The Anti-Aging Group, L.L.C.; Sexual Md Solutions LLC; Richard Gaines; Taylor Medical Wellness, Weight Loss, And Aesthetic Group; Eldred Taylor; Ava Bell-Taylor; Fayette Executive Health Services, Inc.; Health Gain Solutions; And Earl Eye*, CAFN 1:18-cv-03482-MLB (hereinafter GAINSWAVE I). Plaintiffs and the Gainswave Defendants settled GAINSWAVE I, and *inter alia*, entered into the License Agreement wherein the Gainswave Defendants were granted an exclusive license to the '127 Patent, which they could sublicense to their providers.

30. Plaintiffs provided the requisite notice of breach pursuant to the terms of the License Agreement.

31. Defendants failed to cure the breach and the License Agreement was terminated effective September 29, 2019.

32. Several provisions of the License Agreement survived termination of the License Agreement, including section 7.14, which provides:

<p><b>7.14. Covenant Not to Contest.</b> Licensee shall not file, join as a party in, and/or directly or indirectly assist any third party in challenging or attacking the validity, enforceability, or <b>infringement</b> of the Licensed Patent.. However, Licensor acknowledges and agrees that Licensee may fully comply with any and all legal process or obligations requesting or requiring disclosure of information related</p>
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to validity, enforceability, or infringement of the Licensed Patent. The notice requirements described in Section 5 shall apply.

33. In addition, section 7.15 survived termination, which provides:

**7.15. Choice of Law and Forum.** Any controversy or claim arising out of or relating to this Agreement shall be litigated in the U.S. District Court for the Northern District of Georgia. Any such dispute shall be governed by the law of the State of Georgia, unless arising from federal common or statutory law that does not apply the law of the states. GAINSWAVE expressly consents to the jurisdiction and venue of the U.S. District Court for the Northern District of Georgia. The Parties agree that the Northern District of Georgia will retain jurisdiction to enforce the Parties' Settlement Agreement, and as to any disputes related thereto, as necessary, and will request an order to that effect.

### COUNT I

#### Defendants' Intentional Breach of the Parties' License Agreement

34. Plaintiffs re-allege and incorporate by express reference the preceding Paragraphs as if fully restated and set forth herein.

35. After an arms-length negotiation with each parties' respective counsel involved in drafting and negotiating the terms, Plaintiffs and Defendants executed the License Agreement on or about September 17, 2018.

36. The License Agreement required, among other things, that Defendants make ongoing payments in the form of monthly license fees to Plaintiffs and to provide monthly reports showing the name, number and location of all Gainswave providers.

37. Defendants made the initial, up-front payment called for under the License Agreement, and several monthly payments, but never provided any reports as required and some monthly payments were made late.

38. Without reviewing the requisite reports due under the License Agreement, Plaintiffs are unable to verify whether the payments made by Defendants are accurate.

39. Defendants intentionally and knowingly decided not to pay all royalties owed to Plaintiffs under the License Agreement and to not provide any reports.

40. The last payment of royalties made by Defendants was on May 28, 2019, which was for the payment that was due on March 15, 2019. Despite receiving a written demand for payment and reports from Plaintiffs, Defendants never made another payment after May 28, 2019.

41. Plaintiffs are entitled to receive monthly reports for each and every month the Agreement was in force, through and including September of 2019

42. Plaintiffs are entitled to payment from defendants for all unpaid royalties owed through and including the end of September, 2019.

43. After numerous attempts to resolve the issue of Defendants' failure to pay the royalties owed, Plaintiffs provided formal notice to the Defendants on August 28, 2019 of the breach per the terms of the License Agreement and initiated the 30-day period for the breach to be cured.

44. Defendants failed to cure the breach.

45. On September 29, 2019, 31 days after notifying Defendants of the breach and Defendants failure to cure, the License Agreement terminated.

46. Certain provisions of the License Agreement expressly survive termination, including but not limited to the parties' chosen venue and jurisdiction and Defendants' covenant not to contest validity, enforceability and infringement of the '127 Patent.

47. Despite having not paid royalties for many months and having never provided any royalty reports, Defendants have continued to advertise on its website rights to Plaintiff's patented technology as recently as October 7, 2019, even after the License Agreement was terminated due to Defendants' intentional breach.

**COUNT II**  
**Patent Infringement (U.S. Patent No. 7,601,127)**

48. Plaintiffs re-allege and incorporate by express reference the preceding Paragraphs as if fully restated and set forth herein.

49. The '127 Patent was duly and legally issued by the USPTO on October 13, 2009 to its inventors, Reiner Schultheiss, Wolfgang Schaden, and John Warlick, and was initially assigned to General Patent, LLC.<sup>2</sup>

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<sup>2</sup> A true and accurate copy of the '127 Patent is attached hereto as **Exhibit A** and incorporated herein by express reference.

50. The '127 Patent recites claims directed to the stimulation of genital tissue for the treatment of, *inter alia*, impotence, through the use of an acoustic shockwave generator or source to emit acoustic shock waves directed towards genital tissue. The '127 Patent defines “impotence” as:

“impotence” an abnormal physical or psychological state of a male characterized by inability to copulate because of failure to have or maintain an erection—called also erectile dysfunction. In females it means a loss of sensation in the vaginal region and a resultant psychological lack of desire for sexual contact.

51. The GAINSWAVE Defendants promote, market, and grant licenses to their physician customers to independently provide a procedure under the trademark and trade name GAINSWAVE® to patients that incorporates Plaintiffs’ patented methods to treat erectile dysfunction and Peyronie’s Disease, among other things. Like the '127 Patent, “GAINSWave utilizes high frequency, low-intensity soundwaves to improve blood flow to the penis, remove micro-plaque, and stimulate the growth of new blood vessels. GAINSWave uses a specific protocol designed to optimize efficacy, safety and results.”<sup>3</sup>

52. The GAINSWAVE Defendants have infringed and continue to infringe the '127 Patent, either literally or under the doctrine of equivalents, by promoting, marketing, training, and licensing the use of infringing methods. Specifically, each

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<sup>3</sup> See, <https://gainswave.com/gainswave/>.

of the GAINSWAVE Defendants has infringed and continues to infringe one or more claims of the '127 Patent, including at least Claims 1, 3, and 7-9 (the "'127 Patent Claims") by: (a) promoting, marketing, and advertising the GAINSWAVE Procedure to potential customers who are medical providers; (b) licensing the GAINSWAVE Procedure to their medical provider customers; (c) training their medical provider customers to provide the GAINSWAVE Procedure; and (d) providing marketing and advertising support to their medical provider customers to create awareness and demand by patients for the GAINSWAVE Procedure. As such, the Defendants have infringed the '127 Patent by utilizing the methods claimed and disclosed in the '127 Claims.<sup>4</sup>

53. Each of the GAINSWAVE Defendants has intentionally induced and continues to induce infringement of the '127 Patent Claims in this district and elsewhere in the United States, by their intentional acts which have successfully, among other things, encouraged, instructed, enabled, and otherwise caused others to use the GAINSWAVE Procedure in an infringing manner. Despite knowledge of the '127 Patent as early as July 20, 2018, the date of their receipt of the complaint in GAINSWAVE I, the GAINSWAVE Defendants continue to encourage, instruct, enable, and otherwise cause their customers to use their systems and methods, in a manner which infringes the '127 Patent claims. The provision of and licensing of

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<sup>4</sup> See **Exhibit B** attached hereto and incorporated herein by express reference.

the GAINSWAVE Procedure provides Defendants with a source of revenue and business focus. Each of the GAINSWAVE Defendants has specifically intended their customers to use the GAINSWAVE Procedure in such a way that infringes the '127 Patent. Each of the GAINSWAVE Defendants knew that their actions, including but not limited to, making the GAINSWAVE Procedure available for license and sale under their trademarked brand, would induce, has induced, and will continue to induce infringement by their customers by continuing to promote, advertise, train, support, and instruct said customers on using the GAINSWAVE Procedure.<sup>5</sup>

54. The GAINSWAVE Defendants' aforesaid activities have been without authority and/or license from Plaintiffs on or after September 30, 2019.

55. Plaintiffs are entitled to recover from each of the GAINSWAVE Defendants the damages sustained by Plaintiffs as a result of each Defendant's wrongful acts in an amount subject to proof at trial, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

56. Defendants' infringement of Plaintiff's rights under the '127 Patent will continue to damage Plaintiff, causing irreparable harm to Plaintiff for which there is no adequate remedy at law, unless enjoined by this Court.

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<sup>5</sup> See **Exhibit B** attached hereto and incorporated herein by express reference.

57. As one of the bargained for paragraphs of the Agreement, the Defendants agreed that neither of them would directly or indirectly challenge the validity, enforceability or infringement by them of '127 Patent. Defendants are thus estopped from denying the claims in this Count II.

**JURY DEMAND**

58. Plaintiffs demand a trial by jury on all issues.

WHEREFORE Plaintiffs Tissue Regeneration Technologies, LLC and General Patent LLC pray upon this Court for the following relief:

- A. That summons issue and Defendants be served according to law;
- B. That Plaintiffs recover from Defendants all past and future damages caused by their breach of the Settlement and License Agreement;
- C. An adjudication that one or more claims of the Patent-in-Suit has been infringed, either literally and/or under the doctrine of equivalents, by each of the GAINSWAVE Defendants;
- D. An adjudication that Defendants' infringement of the Patent-in-Suit is willful;
- E. An adjudication that each of the GAINSWAVE Defendants has induced infringement of one or more claims of the Patent-in-Suit;
- F. An award of damages to be paid by the GAINSWAVE Defendants adequate to compensate Plaintiffs for Defendants' past infringement and any



continuing or future infringement up until the date such judgment is entered, including interest, costs, and disbursements as justified under 35 U.S.C. § 284 and, if necessary to adequately compensate Plaintiffs for Defendants' infringement, an accounting of all infringing sales including, but not limited to, those sales not presented at trial;

G. A grant of permanent injunction pursuant to 35 U.S.C. § 283, enjoining Defendants and their respective officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise, from further acts of infringement with respect to any one or more of the claims of the Patents-in-Suit;

H. That this Court declare this to be an exceptional case and award Plaintiffs their reasonable attorneys' fees and costs in accordance with 35 U.S.C. § 285; and

I. Any such other and further relief deemed just and proper by this Court.

This 28th day of October, 2019.

*Signatures appear on following page*

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**LOCAL RULE 7.1D CERTIFICATION**

By signature below, counsel certifies that the foregoing document was prepared in Times New Roman, 14-point font in compliance with Local Rule 5.1B.

*/s/ Randy Edwards*

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