UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LUMENIS LTD.,
Petitioner,

v.

BTL HEALTHCARE TECHNOLOGIES A.S.,
Patent Owner.

_____

Case IPR2021-01285
Patent No. 10,709,894

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PETITION FOR *INTER PARTES* REVIEW

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1004	U.S. Patent Application Publication No. 2015/0165226 ("Simon")
1005	U.S. Patent Application Publication No. 2014/0148870 ("Burnett-'870")
1006	Chris Hovey et al., *The Guide To Magnetic Stimulation*, Magstim, July 21, 2006, Affidavit ("Magstim")[1]
1007	U.S. Patent Application Publication No. US20050216062 ("Herbst")
1008	U.S. Pat. No. 7,396,326 ("Ghiron")
1009	U.S. Pat. No. 10,675,819 ("Li")
1010	U.S. Pat. Pub. No. 2014/0277219A1 ("Nanda")
1011	Alain-Yvan Belanger, *Therapeutic Electrophysical Agents*, 3d Edition, Wolters Kluwer (2015), Declaration ("Belanger")
1012	U.S. Pat. Pub. No. 2012/0245483 ("Lundqvist")
1013	U.S. Patent Application Publication No. 2010/0168501 from Application No. 12/508,529 ("Burnett-'529")

[1] All pinpoint citations to Magstim, throughout this document and the corresponding expert declaration, refer to the page number originally in Magstim itself (*i.e.*, in the bottom middle portion of Magstim).

Exhibit (Ex-)	Description
1014	Gorgey et al., *Effects of Electrical Stimulation Parameters on Fatigue in Skeletal Muscle*, J. Orthop. & Sports Phys. Therapy Vol. 39: 9 (2009) ("Gorgey")
1015	Stevens et al., *Neuromuscular Electrical Stimulation for Quadriceps Muscle Strengthening After Bilateral Total Knee Arthroplasty: A Case Series*, Journal of Orthopaedic & Sports Physical Therapy, 34(1):21-29 (2004) ("Stevens")
1016	Doucet et al., *Neuromuscular Electrical Stimulation for Skeletal Muscle Function*, Yale Journal of Biology & Medicine 85:201-215 (2012) ("Doucet")
1017	Abulhasan et al., *Peripheral Electrical and Magnetic Stimulation to Augment Resistance Training*, Journal of Functional Morphology and Kinesiology, 1(3):328-342 (2016) ("Abulhasan")
1018	Remed, Salus Talent Brochure (2010) ("Salus")
1019	Iskra Medical, TESLA Stym Website (2013) ("TESLA Stym")
1020	510(k) Summary, No. K163165, AM-100 (2017) ("AM-100")
1021	510(k) Summary, No. K160992, HPM-6000 (2016) ("HPM-6000")
1022	U.S. Pat. Pub. No. 2003/0158585 ("Burnett '585")
1023	U.S. Provisional Patent Application Ser. No. 60/848,720 ("Burnett-Provisional-'720")
1024	U.S. Pat. No. 6,701,185 ("Burnett-'185")
1025	U.S. Pat. Pub. No. 2008/0306325 ("Burnett-'325")
1026	U.S. Pat. No. 6,155,966 ("Parker")
1027	U.S. Pat. No. 5,344,384 ("Ostrow")
1028	Andrey Gennadievich Belyaev, *Effect of Magnetic Stimulation on the Strength Capacity of Skeletal Muscle* (2015) (Ph.D. dissertation,

Exhibit (Ex-)	Description
	Federal State Budgetary Educational Institution of Higher Professional Education "Velikiye Luki State Academy of Physical Culture and Sport") (English translation) ("Belyaev")
1029	Andrey Gennadievich Belyaev, *Effect of Magnetic Stimulation on the Strength Capacity of Skeletal Muscle* (2015) (Ph.D. dissertation, Federal State Budgetary Educational Institution of Higher Professional Education "Velikiye Luki State Academy of Physical Culture and Sport") (Russian)
1030	U.S. Pat. No. 7,024,239 ("George")
1031	U.S. Pat. No. 5,181,902 ("Erickson")
1032	U.S. Pat. Pub. No. 2006/0199992 ("Eisenberg")
1033	U.S. Pat. No. 5,718,662 ("Jalinous")
1034	U.S. Pat. No. 5,061,234 ("Chaney")
1035	U.S. Pat. No. 10,271,900 ("Marchitto-'900")
1036	U.S. Pat. Pub. No. 2016/0184601 ("Gleich")
1037	Judith Woehrle et al., *Dry Needling and its Use in Health Care – A Treatment Modality and Adjunct for Pain Management*, J. Pain & Relief, 4(5):1-3 (2015) ("Woehrle")
1038	U.S. Patent Publication No. 2015/0157873 ("Sokolowski")
1039	U.S. Patent No. 7,744,523 ("Epstein")
1040	U.S. Pat. No. 6,738,667 ("Deno")
1041	U.S. Pat. No. 6,871,099 ("Whitehurst")
1042	U.S. Patent Application Publication No. US20050075701 ("Shafer-'701")

Exhibit (Ex-)	Description
1043	U.S. Patent Application Publication No. US20050075702 ("Shafer-'702")
1044	D. Suarez-Bagnasco et al., *The Excitation Functional for Magnetic Stimulation of Fibers*, 32nd Ann. Int'l Conf. of the IEEE EMBS, 4829–33 (2010) ("Suarez-Bagnasco")
1045	Zhi-De Deng et al., *Electric field depth-focality tradeoff in transcranial magnetic stimulation: simulation comparison of 50 coil designs*, Brain Stimulation, 6(1):1-13 (2013) ("Zhi-De-Deng-Electric")
1046	Zhi-De Deng, *Electromagnetic Field Modeling of Transcranial Electric and Magnetic Stimulation: Targeting, Individualization, and Safety of Convulsive and Subconvulsive Applications*, (2013) (Ph.D. dissertation, Columbia University) ("Zhi-De-Deng-Electromagnetic")
1047	U.S. Patent Application Publication No. 2011/0190569 ("Simon-'569")
1048	U.S. Patent Application Publication No. 2011/0152967 ("Simon-'967")
1049	U.S. Patent Application Publication No. 2011/0125203 ("Simon-'203")
1050	U.S. Patent Application Publication No. 2011/0046432 ("Simon-'432")
1051	U.S. Patent No. 9,089,719 ("Simon-'719")
1052	U.S. Patent No. 9,037,247 ("Simon-'247")
1053	U.S. Patent No. 8,868,177 ("Simon-'177")
1054	File History of U.S. Patent Application No. 12/859,568 (excerpts) ("File-history-'568")

Exhibit (Ex-)	Description
1055	File History of U.S. Patent Application No. 12/964,050 (excerpts) ("File-history-'050")
1056	File History of U.S. Patent Application No. 13/005,005 (excerpts) ("File-history-'005")
1057	File History of U.S. Patent Application No. 13/024,727 (excerpts) ("File-history-'727")
1058	*Allergan, Inc. et al v. BTL Medical Technologies SRO et al*, PGR2021-00017, Paper 16 (Institution Denial Decision on §112(f)) ("PGR2021-00017-ID")
1059	*Allergan, Inc. et al v. BTL Medical Technologies SRO et al*, PGR2021-00020 (PTAB, Filed Dec. 14, 2020), Paper 16 (Institution Denial Decision on §112(f)) ("PGR2021-00020-ID")
1060	*Reserved*
1061	U.S. Patent Application Publication No. 2015/0025299 ("Edoute")
1062	International Application Publication No. WO 2015/179571 ("Errico")
1063	U.S. Patent Application Publication No. 2011/0172735 ("Johari")
1064	U.S. Patent Application Publication No. 2013/0123765 ("Zarsky")
1065	U.S. Patent No. 6,200,259 ("March")
1066	U.S. Patent Application Publication No. 2020/0155221 ("Marchitto-'221")
1067	U.S. Patent Application Publication No. 2006/0187607 ("Mo")
1068	Declaration of Jonathan Bradford

I. INTRODUCTION

Lumenis Ltd. ("Petitioner") respectfully requests IPR of Claims 18-30 ("Claims") of U.S. 10,709,894 ("'894") pursuant to §§311-319 and §42.100.

'894 is directed to electrical stimulation of body tissues using magnetic field. '894, 1:64–2:5. Its exemplary device includes two applicators placed on a patient's body causing tissues to contract, thereby "toning' them. '894, 5:38–40; *see also id.*, 5:54–56; 17:4–5; 26:3–5. Figure 12 (annotated) shows each applicator has a circuit that contains a capacitor to discharge energy to a magnetic field generating coil. '894, 17:40–18:15. Bikson, ¶¶46-47, 103-110.

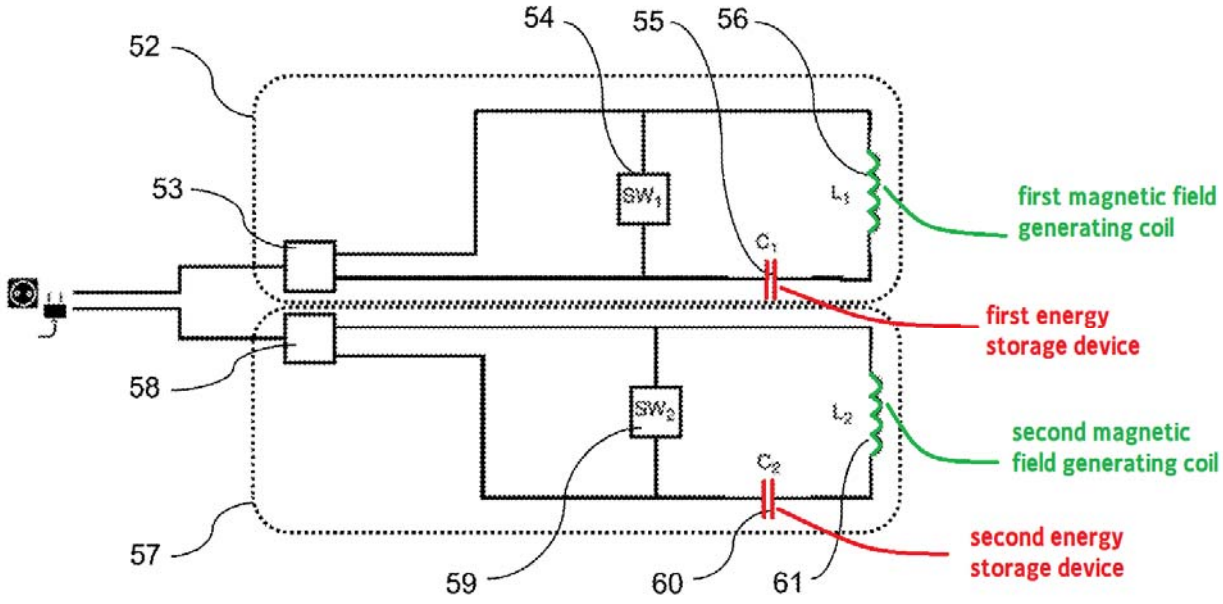


Figure 12

'894 explains that "magnetic methods" were already in use. '894, 2:44–47. Although the Claims are lengthy, reciting parameters and components, these

elements are conventional features well known in the art. Bikson, ¶¶46-102.

Simon discloses a magnetic device with two applicators for stimulating muscles during rehabilitation. Simon, *Abstract,* [0053]-[0054], [0197]. Bikson, ¶¶119-129, 208. **Burnett-'870** discloses a device with multiple applicators comprising coils to generate magnetic field to stimulate muscle. Burnett-'870, *Abstract*, Fig. 9B, [0114]. Bikson, ¶¶209-225, 341. **Magstim** discloses fundamentals of magnetic field, including the parameters and components recited in the Claims. Magstim, 1, 3-4. Bikson, ¶¶226-232. **Edoute** discloses stimulating tissues using both magnetic pulses and radiofrequency. Edoute, [0243], [0328]. Bikson, ¶¶349-357.

II. MANDATORY NOTICES UNDER 37 C.F.R. §42.8

A. Real Party-in-Interest

Lumenis Ltd. is the real party-in-interest. No other party had access to or control over the present Petition, and no other party funded or participated in preparation of the present Petition.

B. Related Matters

Petitioner is concurrently filing another petition (IPR2021-01278) challenging claims 1-17 of the '894 patent. Due to word-count constraints and the large number of claims, requiring 12,508 words in IPR2021-01285 and 13,527 words in IPR2021-01278, claims 18-30 are presented separately herein. *See* PTAB

Consolidated Trial Practice Guide, November 2019, 59-61 (permitting parallel petitions in certain circumstances, such as a large number of claims).

The '894 patent is not the subject of any other co-pending litigation. However, the '894 patent was the subject of the following litigations that were stayed or resolved and did not involve or relate to the Petitioner:

- *Certain Non-Invasive Aesthetic Body Contouring Devices, Components Thereof, and Methods of Using the Same*, Inv. No. 337-TA-1219 (ITC, Filed Aug. 5, 2020) (the "ITC Case") (settled);
- *BTL Industries, Inc. v. Allergan Ltd. et al*, No. 1-20-cv-01046 (D. Del., Filed Aug. 5, 2020) (settled);
- *Allergan, Inc. et al v. BTL Medical Technologies SRO et al*, PGR2021-00022 (PTAB, Filed Dec. 14, 2020) ("Allergan's PGR") (§112 grounds and §103 grounds primarily based on on-sale bar and public use of a device; settled prior to institution decision);
- *Allergan, Inc. et al v. BTL Medical Technologies SRO et al*, PGR2021-00023 (PTAB, Filed Dec. 14, 2020) ("Allergan's PGR") (Presented a different set of §103 grounds than those presented in this Petition; settled prior to institution decision).

C. Lead and Back-Up Counsel

Lead Counsel	Backup Counsel
Scott A. McKeown Reg. No. 42,866 **ROPES & GRAY LLP** 2099 Pennsylvania Avenue, NW Washington, D.C. 20006-6807 Phone: +1-202-508-4740 Fax: +1-617-235-9492 scott.mckeown@ropesgray.com **Mailing address for all PTAB correspondence:** ROPES & GRAY LLP IPRM—Floor 43 Prudential Tower 800 Boylston Street Boston, Massachusetts 02199-3600	James L. Davis, Jr. Reg. No. 57,325 (Back-up) Keyna Chow *Pro Hac Vice* (Back-up) **ROPES & GRAY LLP** 1900 University Avenue, 6th Floor East Palo Alto, CA 94303-2284 Phone: 650-617-4000 Fax: 617-235-9492 James.l.davis@ropesgray.com Keyna.Chow@ropesgray.com

Petitioner consents to electronic service of documents to the email addresses of the counsel identified above.

III. PAYMENT OF FEES

The undersigned authorizes the Office to charge the fee required by §42.15(a) for this Petition for review to Deposit Account No. 18-1945, under Order No. 116610-0002-656. Any additional fees that might be due are also authorized.

IV. REQUIREMENTS FOR *INTER PARTES* REVIEW

A. Grounds for Standing

Pursuant to §42.104(a), Petitioner certifies '894 is available for IPR.

Petitioner is not barred or estopped from requesting IPR challenging the Claims on the grounds herein.

B. Identification of Challenge

Pursuant to §§42.104(b), Petitioner requests the Board cancel the Claims as unpatentable.[2]

1. Specific Art on Which the Challenge is Based

Name	Exhibit	Filed	Published	Prior art
Simon	1004	3/3/2015	6/18/2015	§102(a)(1)-(2)
Burnett-'870	1005	11/20/2013	5/29/2014	§102(a)(1)-(2)
Magstim	1006	--	7/21/2006	§102(a)(1)
Edoute	1061	9/18/2014	1/22/2015	§102(a)(1)-(2)

a. §§314(a) and 325(d) are inapplicable

Simon and **Magstim**[3] were not before Examiner; **Burnett-'870** and **Edoute**[4] were cited in an IDS among hundreds of references, but not otherwise

[2] The art predates '894's earliest priority date; Petitioner takes no position as to the priority claims.

[3] Although **Magstim** (not previously cited or considered) and the operating manuals (cited but not applied to reject claims) are from the same company, the respective disclosures are substantially different—**Magstim** is a guide that teaches stimulation principles, techniques, and applications claimed in '894, while the manuals describe product operations.

[4] A related application (US2011/0130618) to **Edoute** was cited by the Examiner (Ex-1003, 199), but the Examiner never applied that application to the pending claims in the sole rejection (Ex-1003, 196-198) during prosecution and did not issue another rejection after the applicant cancelled the original set of claims and submitted new ones; thus the ground relying on **Edoute** is not the same or

identified or applied to reject claims during prosecution. Examiner never considered the testimony of Dr. Bikson (Ex-1002) regarding these documents. Ex-1003.

Although '894 was previously litigated in the ITC, Petitioner had no involvement or input to those proceedings, nor any relationship to any party challenging the patent therein. '894 invalidity was not decided before the matter was settled. This petition presents unique grounds not presented in PGR2021-00023 (settled prior to institution decision)—neither **Simon, Burnett-'870, nor Edoute** was asserted; and **Magstim**[5] is not applied the same way as in any prior ground, which prevent application of §§314(a) and 325(d) denial.

2. Statutory Grounds on Which the Challenge is based

Ground	Statute	Claim(s)	Prior Art
1	§103	18-21, 23-30	Simon
2	§103	18-30	Burnett-'870 in view of Magstim
3	§103	18-21, 23-30	Simon in view of Burnett-'870
4	§103	22	Simon in view of Edoute

substantially the same as the art and arguments raised during '894's prosecution. *Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GMBH*, IPR2019-01469, Pap. 6, *8-9. Moreover, the Examiner erred in a manner material to the patentability of claim 22 by failing to reject the pending claim over a combination of references teaching magnetic-and-radiofrequency stimulation.

[5] **Magstim** served as a primary reference in the PGR for disclosing two applicators; in contrast, **Magstim** is asserted here as a secondary reference for disclosing basic magnetic field parameters and applications.

See §VIII.

V. BACKGROUND

A. '894 Patent

'894 is directed to producing a time-varying magnetic field to remodel or improve muscles. '894, 3:26–29, 3:46–49, 3:64–4:6. It discloses a device with applicators that may be positioned on target body regions using an "adjustable belt." '894, 11:4–6, 17:4-5, Figs. 15-16. Bikson, ¶¶103-104.

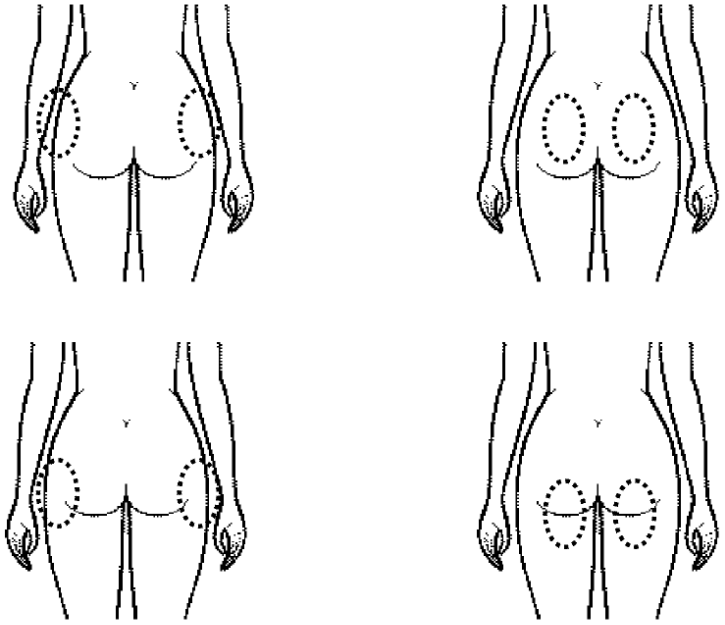


Figure 15

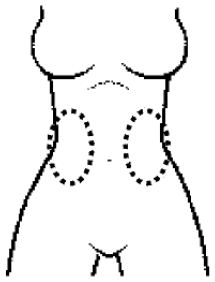


Figure 16

The device includes a "control unit" to regulate magnetic field parameters and uses a "casing" with a "cooling media" for the applicators. '894, 2:34–37, 10:40–44, 13:14–18. Its circuits have energy storage devices (*i.e.*, capacitors) that discharge energy to coils. '894, 18:6–9. Bikson, ¶¶105-106.

The coils generate "impulses" (*i.e.*, "magnetic stimulus") to cause muscle contractions. '894, 4:1–11, 5:54–56. Figure 8 shows that these impulses are biphasic and sinusoidal:

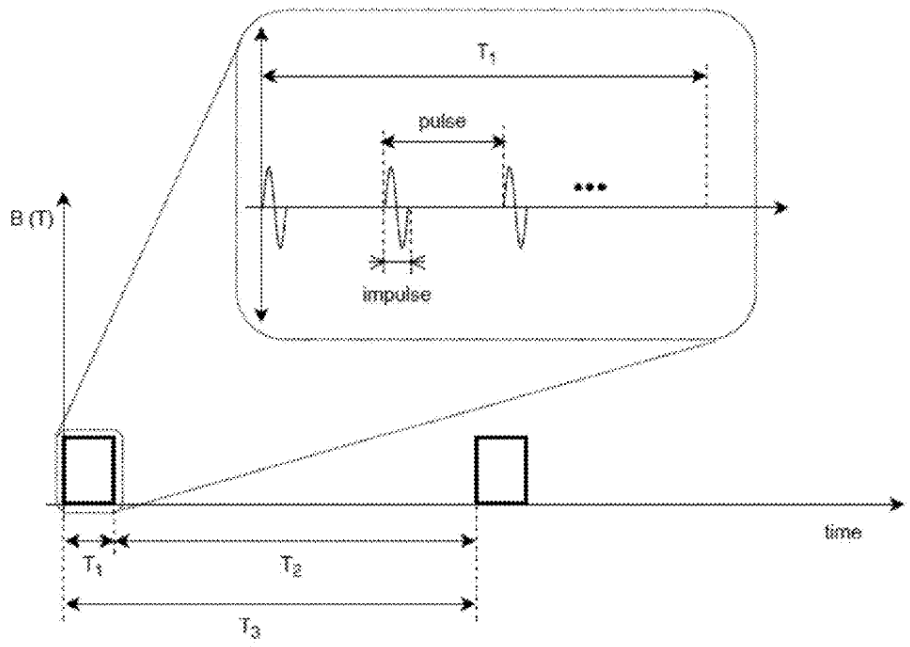


Figure 8

'894, Fig. 8, 5:54–56, 99:30–33. A "pulse" is defined by the period of treatment between the beginning of a first impulse and the beginning of a second impulse. '894, 5:57–61. Bikson, ¶¶107-110.

B. Prosecution History

'894 issued from U.S. Application No. 16/673,784, filed 11/4/2019. Ex-1003, 1–187. USPTO granted Track 1, prioritized status on 11/25/2019. Ex-1003, 192–193. Bikson, ¶111.

The Examiner issued a non-final rejection of then-pending claims 1 and 2,

each of which was less than 20 words in length, as anticipated by Lin (US6,213,933), on 12/16/2019. Ex-1003, 194–198. Appellant canceled then-pending claims 1 and 2, and submitted 30 new claims in an Amendment filed 3/16/2020. Ex-1003, 243–256. The Examiner issued no art-based rejections against the claims, before allowing them on 4/7/2020. Ex-1003, 263–273. Bikson, ¶¶112-116.

VI. LEVEL OF ORDINARY SKILL IN THE ART

On or before 7/1/2015, a POSITA would have had a bachelor's degree in biomedical engineering, electrical engineering, physics, or related field, and two or more years of professional experience working with the design, development, and/or use of devices that apply electromagnetic energy to stimulate biological tissue. Additional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education. Bikson, ¶¶1-45.

VII. CLAIM CONSTRUCTION

Claim terms subject to IPR are to be construed according to the *Phillips* standard applied in district court. §42.100(b). Petitioner applies the plain and ordinary meanings of terms. Only terms necessary to resolve the controversy must be construed. *Nidec Motor v. Zhongshan Broad Ocean Motor*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Bikson, ¶¶117-118. Pursuant to §42.104(b)(3), regarding

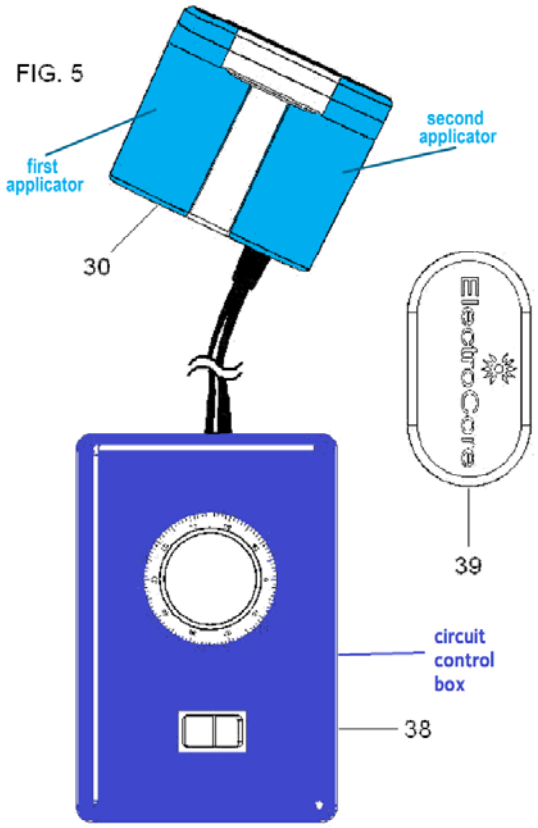
the term "control unit," the Board has denied institution on Allergan's PGRs of related patents (sharing substantially the same or similar specification) determining that the term is not indefinite and does not invoke §112(f). PGR2021-00017-ID, 10-16; PGR2021-00020-ID, 10-16.

VIII. GROUNDS OF UNPATENTABILITY

A. Ground 1: Claims 18-21, 23-30 are rendered obvious by Simon

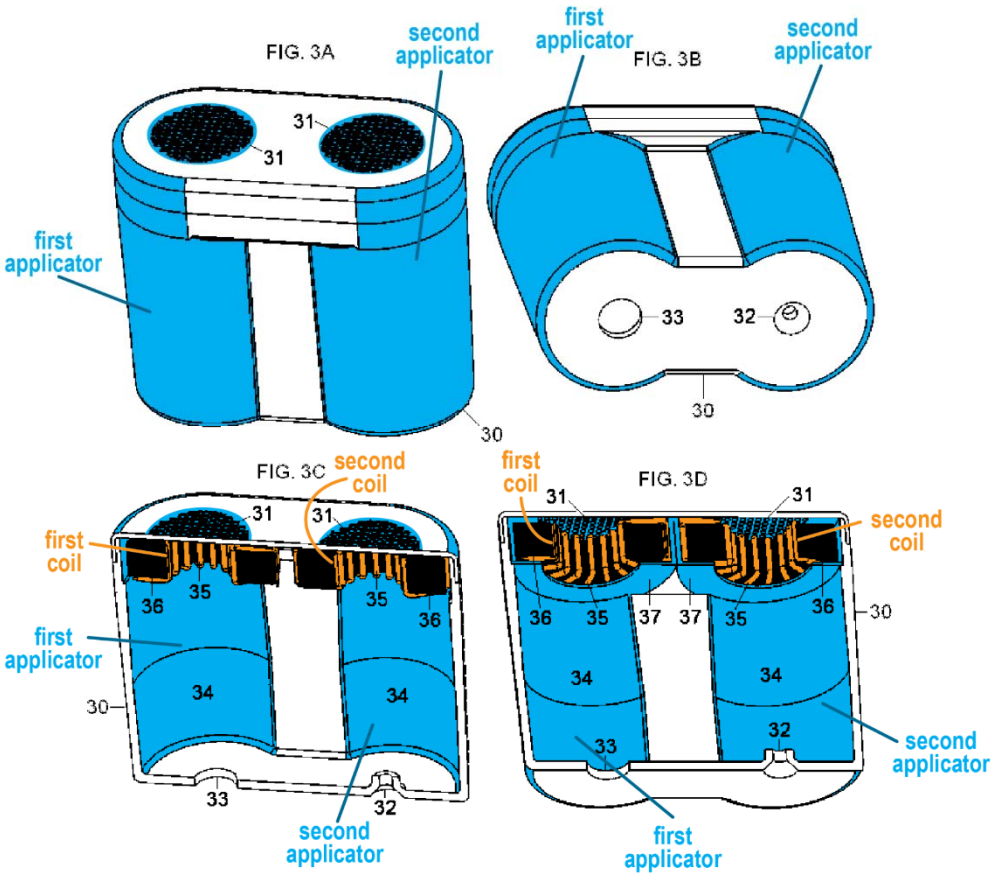
1. Simon Overview

Simon discloses a magnetic stimulator for muscle "[r]ehabilitation." Simon, title, [0002], [0197].



Simon, Fig. 5, [0103]. Figures 3A-3D (annotated) show **Simon's** stimulator with

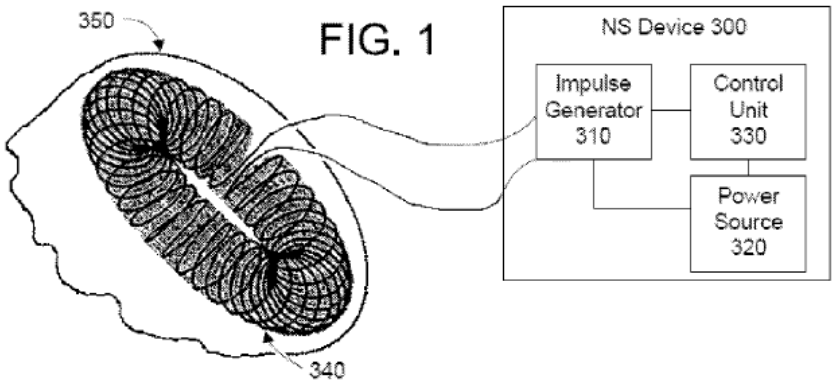
two **applicators** situated within a "housing," each **applicator** containing a "**coil**" that generates a time-varying magnetic field when a capacitor is "discharged." Simon, [0012], [0045], [0047], [0098]. Bikson, ¶¶120-121.



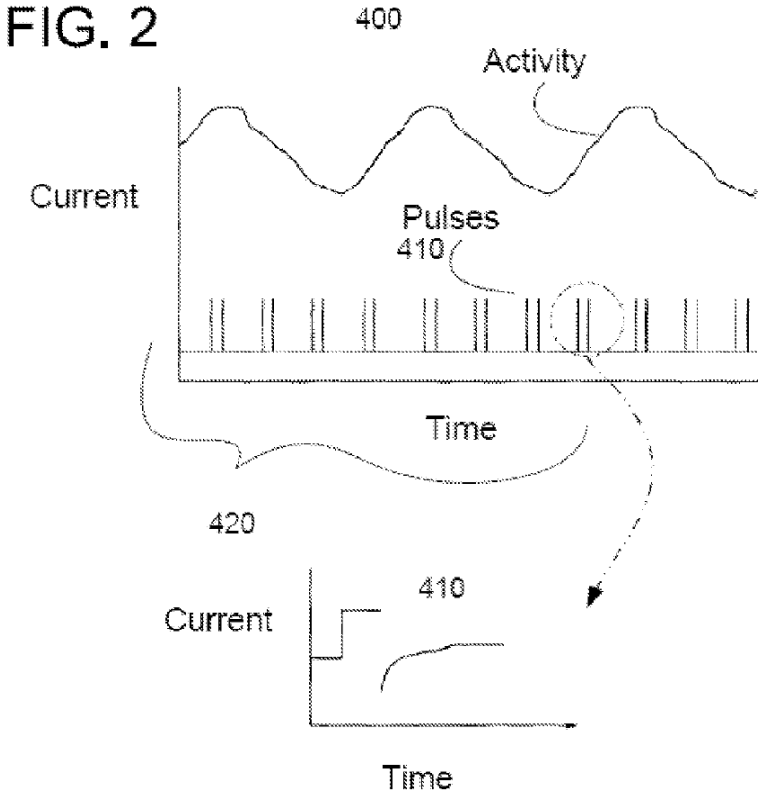
Each **coil** "induces an electromagnetic field" to apply "electrical impulses" to muscles within target body regions (*e.g.*, abdomen). Simon, [0024], [0027]-[0028], [0035], [0053]. Simon's stimulator may contain more than two **applicators**, with varying shapes and configurations for different applications based on the "anatomical location of the stimulation and determining the appropriate pulse configuration." Simon, [0031], [0100]-[0102], Fig. 4C-4D.

Bikson, ¶122.

Simon's device has an "impulse generator," containing a capacitor and connected to a "control unit" causing the impulse generator to generate a signal for each **coil**. Simon, [0019], [0057], Fig. 1. The control unit controls the capacitor via switching. Simon, [0019]. The impulse generator may contain a "bank of capacitors" discharged to coils at different times such that multiple, and serial pulses may be generated. Simon, [0019], [0063]. Bikson, ¶¶123-124.



Simon's coils generate consecutive "energy impulses" to stimulate tissue:



Simon, Fig. 2, [0002], [0029], [0035]. **Simon** teaches adjustable parameters for the stimulation signal including frequency, pulse amplitude, and repetition rate. Simon, [0059], [0063]-[0064], [0104]. Bikson, ¶125.

Simon aims to "significantly less[en] pain or discomfort" during treatment. Simon, [0016], [0123]. Applied current may be "increased gradually, first to a level wherein the patient feels sensation," then "set to a level." Simon, [0123]. **Simon** recognizes magnetic stimulator coils "overheat" during "extended" use, so it discloses solutions such as "cool[ing] the coils" with flowing water, air, or "ferrofluids." Simon, [0020]. Bikson, ¶¶126-127.

To the extent argued **Simon** lacks disclosure of connecting tubes for flowing

oil to applicators, a POSITA would have found it obvious to modify Simon to use connecting tubes in order to cool applicators to avoid coils "overheat[ing]" when used over an extended period of time, such as for muscle "rehabilitation." Simon, [0020], [0197]. **Simon** leaves the exact cooling details to a POSITA, who would have been motivated to use connecting tubes for oil to flow from a source to the applicator and provide cooling, as it is necessary to circulate cooling fluid and conduits were well-known for such purposes. Such a routine change in device cooling would predictably work and provide the expected functionality. Bikson, ¶128.

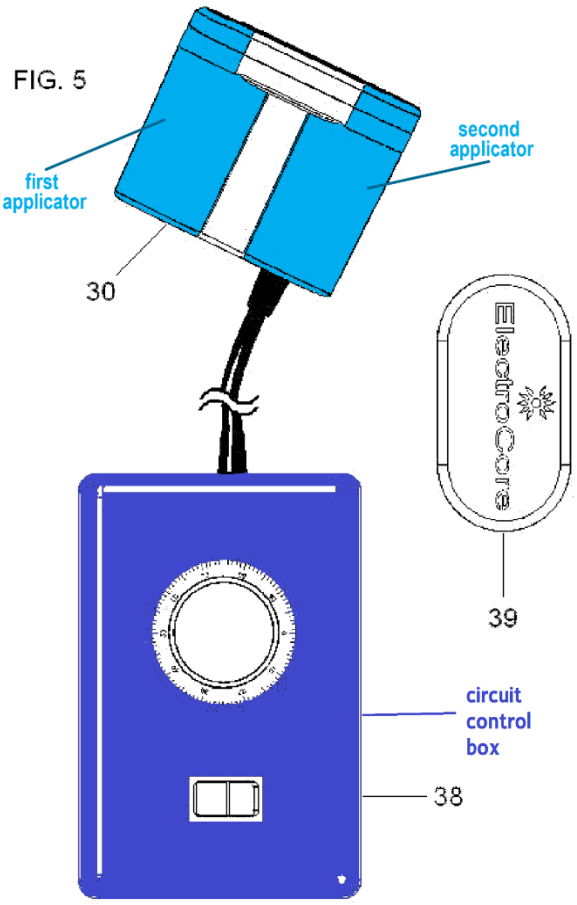
To the extent argued that **Simon** does not explicitly disclose ramp-down required for trapezoidal/triangular envelopes, a POSITA would have been motivated and found it obvious to ramp down the current after it has been ramped-up forming a triangular or trapezoidal envelope (Simon, [0123]) to mimic muscle contraction and relaxation as was known in the art. *See, e.g.*, Belanger, 239 (disclosing to apply trapezoidal envelope to mimic the "gradual build up and relaxation phases" during "voluntary muscle contraction" for "smooth" contraction to increase patient comfort); Herbst [0030]; [0047] ("[s]awtooth" with "rise and fall ramp"; "[a]rbitrary waveform"). **Simon** teaches applying stimulation in a manner avoiding "discomfort," and once current is increased, it must either be ramped down gradually or abruptly cut off, such that a POSITA would have had a

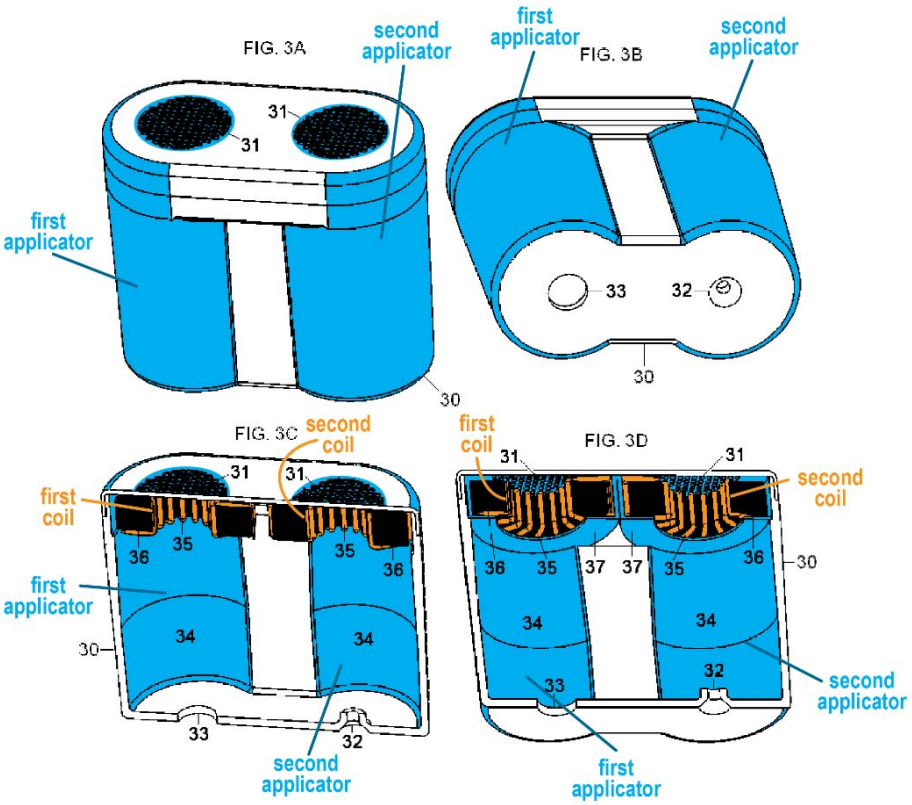
finite number of options to gradually relax the muscle. Simon, [0016]. Simon discloses that stimulator "power" may be "modulate[d]," impacting "intensity of stimulation." Simon, [0113], [0195]. Such a routine change in signal amplitude, which **Simon** discloses is "adjustable," would predictably work and provide the expected functionality based on the explained teachings. Simon, [0063]. Bikson, ¶129.

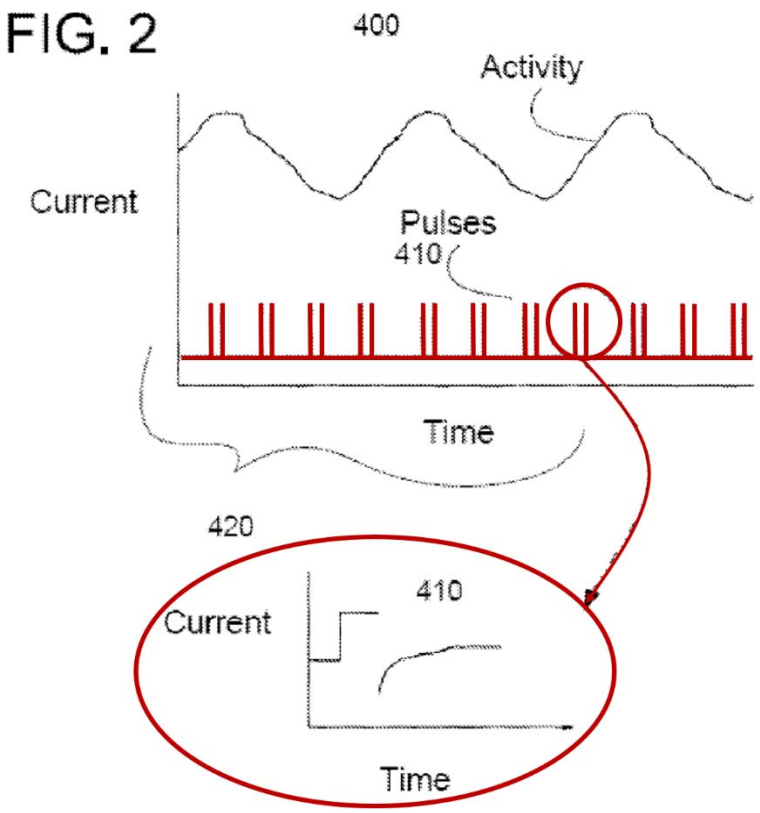
2. Claim Charts

a. Independent Claim 18

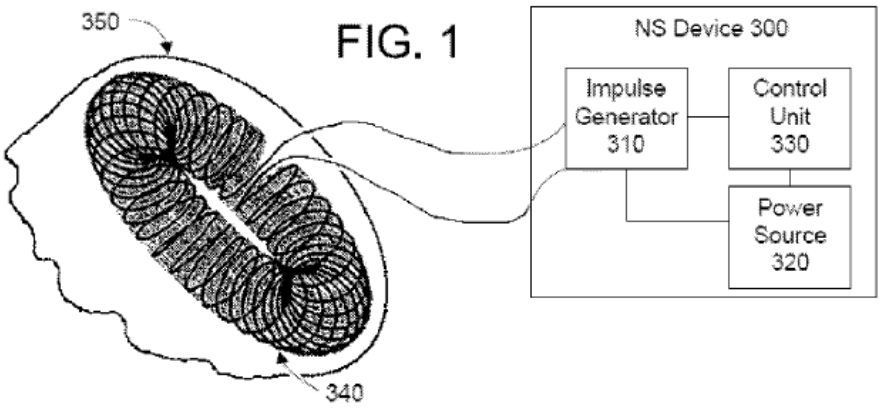
Claim Elements	Simon
[18.pre] A device for treating a patient, the device comprising:	**Simon discloses a device** (*e.g.*, "apparatus") **for treating a patient.** **Simon** discloses "treatment[s]" such as "[m]agnetic stimulation devices and methods of therapy" for treating muscles, e.g., through muscle "rehabilitation" or for muscle "injury." Simon, title, Abstract, [0005], [0023], [0054], [0197]. Bikson ¶¶48-76. **Simon** discloses an "apparatus" that induces a "time-varying magnetic field" to apply "energy" to a target region within a "patient." Simon, Abstract, [0015], [0023]-[0024], [0053]. The apparatus are placed on "abdomen" in order to produce an "intended beneficial physiological effect." Simon, [0035]-[0036]. Bikson, ¶¶130-131.
[18.a] a first energy storage device;	**Simon discloses a first energy storage device** (*e.g.*, "capacitor" in "impulse generator")**.** **Simon's** device contains an "impulse generator" containing a "capacitor," which stores energy when "[charged]…under the control of a control unit." Simon, [0019], [0025]. The capacitor is "discharged" through each coil when a user

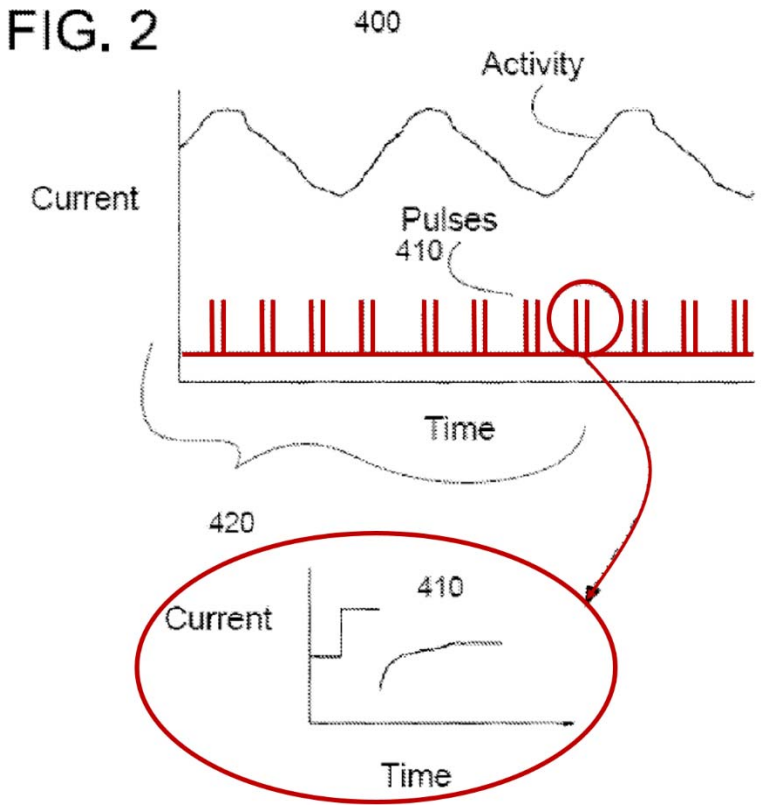
Claim Elements	Simon
	wishes to "apply [a] stimulus." Simon, [0025], Fig. 3A-D. Bikson ¶¶132-134, 83-86.
[18.b] a first applicator comprising a first magnetic field generating device disposed within the first applicator, wherein the first magnetic field generating device is configured to generate a first time-varying magnetic field,	**Simon discloses a first applicator** (*e.g.*, first applicator of "stimulator 30") **comprising a first magnetic field generating device** (*e.g.*, "coil") **disposed within the first applicator, wherein the first magnetic field generating device is configured to generate a time-varying magnetic field.** **Simon** discloses a "stimulator 30" containing **applicators** and connected to "**circuit control box** 38":  Simon, Fig. 5 (annotated); [0103].

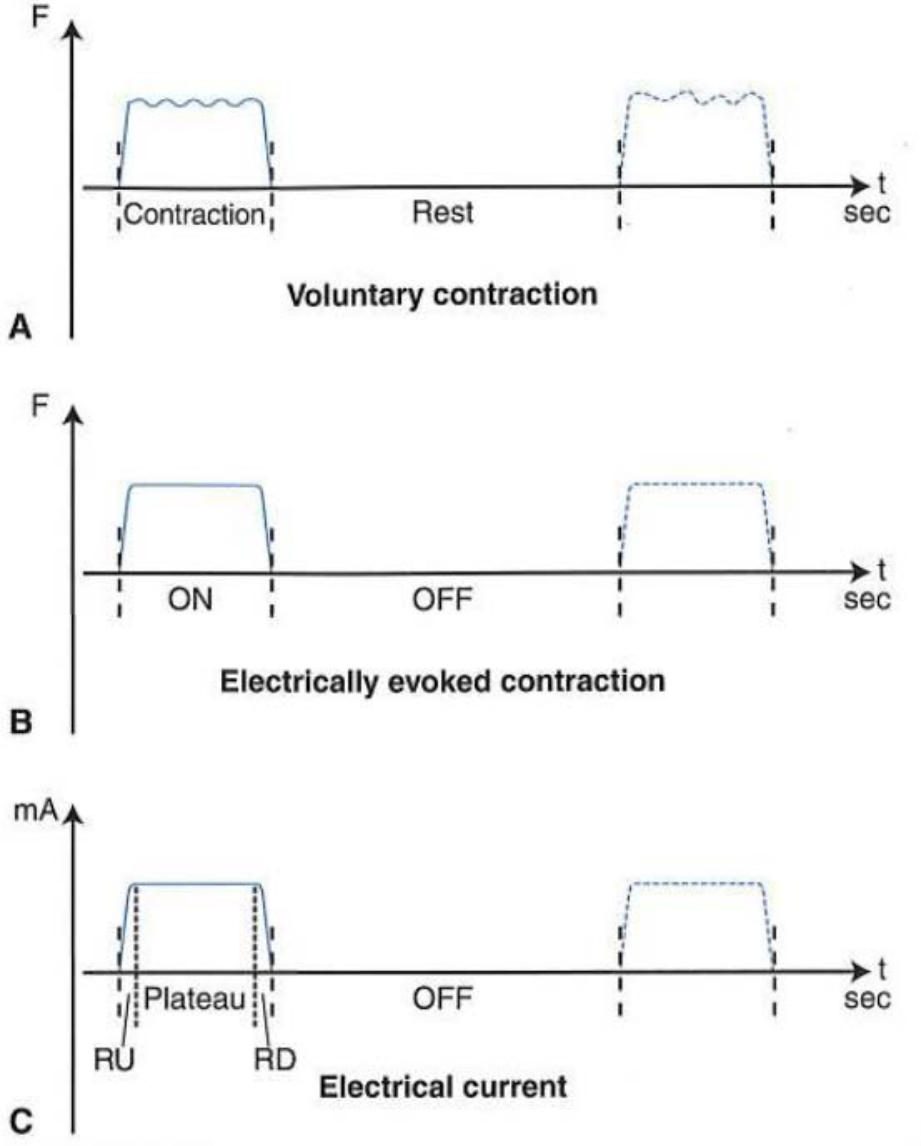
Claim Elements	Simon
	The stimulator may have two **applicators** "that lie side-by-side," each containing a "**coil[]**" disposed in "its own housing":  Simon, Fig. 3A-D (annotated), [0031], [0098]. The stimulator induces a "time-varying magnetic field" to apply "energy" to a target region within a "patient." Simon, Abstract, [0015], [0023]-[0024], [0053]. **Simon** further discloses the stimulator "positioned…on or near a patient's…abdomen…" and cites prior art "abdomen" treatment. Simon, [0035], [0105], [0175]. **Simon** is not limited to two **applicators**; the shapes and configurations may vary based on, *e.g.*, "anatomical location of the stimulation." Simon, [0031], [0100]-[0102], Fig. 4C-4D. Bikson, ¶¶135-139, 48-86.
[18.c] the first time-varying magnetic field	**Simon discloses the first time-varying magnetic field comprises: a first plurality of magnetic pulses** (*e.g.*, "pulse"/"impulse") **having a first magnetic flux density; a**

Claim Elements	Simon
comprising: a first plurality of magnetic pulses having a first magnetic flux density; a second plurality of magnetic pulses having a second magnetic flux density; and a third plurality of magnetic pulses having a third magnetic flux density; and	**second plurality of magnetic pulses having a second magnetic flux density; and a third plurality of magnetic pulses having a third magnetic flux density.** *See* [18.pre]-[18.b]—**Simon** illustrates a plurality of consecutive "impulse[s] 410" (*i.e.*, the claimed pulses) in an "exemplary electrical voltage/current profile for a stimulating, blocking and/or modulating impulse" resulting in biological "activity" such as tissue stimulation:  Simon, Fig. 2 (depicting **impulses** 410), [0060]-[0061]. **Simon** discloses that "current passing through the coil produces a magnetic field" within the core of about 0.1 to 2 Tesla" (Tesla being unit of flux density). Simon, [0030], [0104] ("magnetic field strength"). **Simon's** "stimulator" is "adjustable in regard to amplitude, duration, repetition rate and other variables,"—a POSITA

Claim Elements	Simon
	would have understood "amplitude" to refer to "magnetic flux density," thus providing multiple flux densities, *e.g.*, varying "parameters" to "obtain a beneficial response" or adjusting stimulation to a point where before the patient experiences "discomfort." Simon, [0020], [0063], [0103], [0123], [0141]; Bikson, ¶¶53-58, 92-99. *E.g.*, **Simon's** device "parameters" may be selected "to influence the therapeutic result," or "automatically adjusted by feedback." Simon, [0123], [0063]. A POSITA would have been motivated to use first/second/third magnetic flux densities when ramping-up, plateauing, and ramping-down to mimic natural muscle contraction—*see* [20]. Herbst, incorporated into **Simon**, discloses a "modulator" coupled to "amplitude control unit" to modify the signal's amplitude. Herbst, [0033], [0047], [0072], Fig. 1. Because **Simon's** coil is "wound around" (*i.e.*, touching) the core, magnetic field flux density at the core is also at surfaces of the coils. Simon, [0029]. **Simon** indicates that "coil" refers to current-carrying wire *and* to "core material," so flux density at the core is also the flux density at surfaces of the coils. Simon, [0015]. It was also known in the art to measure magnetic field strength at the coil surface where stimulus strength is at its highest. *E.g.*, Magstim, 8. Bikson, ¶¶140-146, 53-58, 92-99.
[18.d] a control unit configured to control the generation of the first time-varying magnetic field such that:	**Simon discloses a control unit** (*e.g.*, "control unit") **configured to control the generation of the first time-varying magnetic field.** *See* [18.b]-[18.c]—**Simon's** device has "an impulse generator" coupled to a "power source" and "control unit":

Claim Elements	Simon
	 Simon, Fig. 1, [0054]. The "control unit" controls the "impulse generator" which stores energy by charging a capacitor to "generate a signal for each of the device's magnetic stimulation coils." Simon, [0019], [0057]. Control is based on "feedback" from "externally supplied physiological or environmental signals." Simon, [0058]. A user may "operate the system" by typing "instructions" for the control unit and may view results on a "monitor." Simon, [0058]. Bikson, ¶¶147-149, 58.
[18.e] the first plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; the second plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular	**Simon teaches the first plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; the second plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; and the third plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope.** *See* [18.c]—**Simon** illustrates sequential "impulse[s] 410" forming a "pulse train 420 to the stimulator coil(s)":

Claim Elements	Simon
envelope; and the third plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope,	 Simon, Fig. 2, [0060]-[0061]. **Simon** discloses a trapezoidal envelope formed by increasing stimulation power "gradually, first to a level where in the patient feels sensation from the stimulation," then it is "set to a level" less than one that would cause "discomfort." Simon, [0123], [0141], [0147], [0154], [0168], [0182], [0057]-[0058]. **Simon** discloses that stimulator "power" may be "modulate[d]," impacting "intensity of stimulation." Simon, [0113], [0195]. Moreover, **Simon** discloses that "frequency and other parameters" may be selected "to influence the therapeutic result," or "automatically adjusted by feedback." Simon, [0123], [0063]. POSITAs would have been motivated and found it obvious to use trapezoidal envelopes—*see* §VIII.A.1. For example, it was known to use repeated trapezoidal envelopes for patient comfort, *e.g.*, mimic natural voluntary contraction:

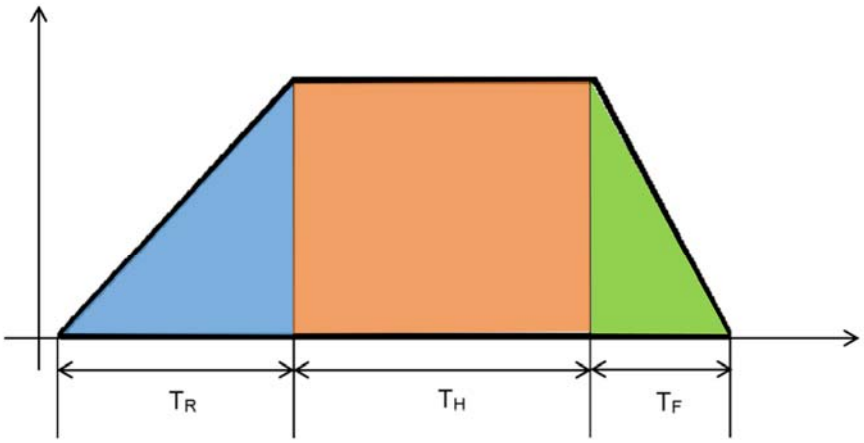
Claim Elements	Simon
	 Belanger, 236, Fig. 13-15; Herbst, [0030]-[0031] ("signals of different shape"); [0047] ("rise and fall ramp;" "[a]rbitrary waveform"). Bikson, ¶¶150-155, 58, 92-99.
[18.f] wherein the first applicator is configured to be positioned at a body region of the patient, wherein	**Simon discloses the first applicator** (*e.g.,* first applicator of "stimulator 30") **is configured to be positioned at a body region of the patient, wherein the body region comprises the patient's buttocks or abdomen.**

Claim Elements	Simon
the body region comprises the patient's buttocks or abdomen,	*See* [18.b]—**Simon** discloses a two-applicator stimulator "positioned…on…abdomen…" and cites prior art "abdomen" treatment. Simon, [0035], [0105], [0175]. Bikson, ¶¶156-157, 78-80.
[18.g] wherein each of the first, second, and third pluralities of magnetic pulses has a repetition rate in a range of 1 to 300 Hz,	**Simon discloses each of the first, second, and third pluralities of magnetic pulses** (*e.g.*, "pulse"/"impulse") **has a repetition rate in a range of 1 to 300 Hz** (*e.g.,* "15 to 50 Hz")**.** *See* [18.a]–[18.c]—**Simon** discloses that the "magnetic stimulator" may have "high repetition rates" and is "adjustable in regard to amplitude, duration, repetition rate..." Simon, [0020], [0063]. **Simon** further discloses "modulating impulse signal" at a "frequency…about 1 Hz or greater, such as between about 15 Hz to 50 Hz, more preferably around 25 Hz," which is the repetition rate for the impulses. Simon, [0064]; *see also id.,* [0030], [0033], cl. 8. Herbst, incorporated into **Simon**, discloses setting repetition rates for multiple output channels. Herbst, [0037]. Bikson, ¶¶158-161, 56, 92-99.
[18.h] wherein the first, second, and third magnetic flux densities are each in a range of 0.5 to 7 Tesla, and	**Simon discloses the first, second, and third magnetic flux densities are each in a range of 0.5 to 7 Tesla** (e.g., "0.1 to 2 Tesla"). *See* [18.a]–[18.c]—**Simon's** "magnetic field within the core of about 0.1 to 2 Tesla" is within the claimed range. Simon, [0030], [0104]. Bikson, ¶¶162-163.
[18.i] wherein the first magnetic field generating device is configured to apply the first time-varying magnetic field to muscle fibers,	**Simon discloses the first magnetic field generating device** (*e.g.*, "coil") **is configured to apply the first time-varying magnetic field to muscle fibers, neuromuscular plates, or nerves innervating muscle fibers in the body region** (*e.g.*, "abdomen") **such that muscles of the body region contract.** *See* [18.pre], [18.b], [18.e]-[18.f]—**Simon** discloses placing applicators in contact with abdomen. The resulting consecutive "electrical impulses" interact with "one or more

Claim Elements	Simon
neuromuscular plates, or nerves innervating muscle fibers in the body region such that muscles of the body region contract.	nerves, muscles, to achieve a therapeutic result" such as to "stimulat[e] tissue and/or one or more nerve fibers within the patient." Simon, Abstract, [0012], [0053], [0060]-[0061], Fig. 2. **Simon** further discloses that stimulation "involves the induction, by a time-varying magnetic field, of electrical fields and current within tissue"; and that a magnetic field "induc[es] at a distance an electric field and electric current within electrically-conducting bodily tissue," including "muscles." Simon, [0015], [0053], [0083], [0105]. **Simon** teaches—as was well-known—that muscles "contract" while stimulated. Simon, [0158], [0194]-[0195]. It was well-known and conventional that using biphasic pulsed current to stimulate muscles causing them to contract would allow them to be strengthened—getting "larger and stronger," thereby toning them. *See, e.g.,* Belanger, 234. Accordingly**, Simon** teaches applying consecutive impulses of the first and second magnetic field to muscle fibers causing them to contract. Bikson, ¶¶164-167, 48-76.

b. Dependent Claims 19-30

Claim Elements	Simon
[19] The device of claim 18, wherein: the first plurality of magnetic pulses forms a triangular envelope, the second plurality of magnetic pulses forms a rectangular envelope, and the third plurality of magnetic pulses	**Simon teaches the first plurality of magnetic pulses forms a triangular envelope, the second plurality of magnetic pulses forms a rectangular envelope, and the third plurality of magnetic pulses forms a triangular envelope.** *See* [18.pre], [18.d]-[18.e]—**Simon** discloses "parameters" including "amplitude" are programmable. Simon, [0062]. **Simon** discloses increasing stimulation power "gradually, first to a level where in the patient feels sensation from the stimulation," then it is "set to a level" less than one that would cause "discomfort." Simon, [0123], [0141], [0147], [0154], [0168], [0182], [0057]-[0058].

Claim Elements	Simon
forms a triangular envelope.	**Simon** teaches a trapezoidal envelope (*see* [18.e]) which consists of a **first triangular envelope (blue)**, **second rectangular envelope (orange)**, and **third triangular envelope (green)** as shown in '894 Fig. 13 (annotated):  Figure 13 *See* '894, Fig. 28b, 30:16-18 (waveform similar to T_R above labeled "triangular shaped envelope 2802"), Fig. 29b, 30:42-43 (same). To the extent argued the triangular/rectangular envelopes must be separated, **Simon** further discloses that "frequency and other parameters" may be selected "to influence the therapeutic result," or "automatically adjusted by feedback." Simon, [0123], [0063]. **Simon** teaches applying stimulation in a manner avoiding "discomfort," and once current is increased, it must either be ramped down gradually (forming triangular envelope) or abruptly cut off, such that a POSITA would have had a finite number of options and would have chosen the ramp-down option to avoid discomfort, resulting in a triangular envelope. Simon, [0016]. Such ramp modulation is known in the art. *See, e.g.*, Johari, Abstract [0038] (disclosing "a ramp up of 4 seconds and a ramp down of four seconds" for muscle stimulation). Moreover, **Simon** teaches a trapezoidal envelope (*see* [18.e]) with varying "train duration" (Simon, [0059]); as duration

Claim Elements	Simon
	diminishes, a trapezoidal envelope becomes triangular. Bikson, ¶¶168-170, 92-99. A rectangular envelope includes stimulation on/off without ramping; a POSITA would have been motivated and found it obvious to do so when an optimal stimulation level is known and at a lower amplitude where ramping up/down is not necessary for patient comfort. For example, Simon discloses the amplitude is "programmable"/"adjustable." Simon, [0062]-[0063]; *see* Burnett-'870, [0070] (amplitude is "varied"), [0085], (stimulation corresponds to "optimal therapy level"). **Simon** discloses using a treatment plan with various adjustable parameters over time. Simon, [0062], [0103], [0168], [0182]. A POSITA would have been motivated and found it obvious to use a treatment sequence with a triangular envelope, then a rectangular envelope, followed by another triangular envelope, for a treatment plan requiring a higher stimulation amplitude at the beginning and the end, and a lower stimulation amplitude in the middle, such that ramping is provided for the first and third periods for patient comfort but not needed for the middle portion. A POSITA would have understood that high, then low, then high-amplitude stimulation would be similar to the on-off-on sequence used to "prevent muscle fatigue." Belanger, 244. Bikson, ¶¶168-174, 92-99.
[20] The device of claim 19, wherein the control is further configured to control the generation of the time-varying magnetic field such that: an amplitude of the first magnetic flux	**Simon discloses the control unit** (*e.g.*, "control unit") **is further configured to control the generation of the time-varying magnetic field such that: an amplitude of the first magnetic flux density increases over a first time period; an amplitude of the second magnetic flux density remains constant over a second period of time; and an amplitude of the third magnetic flux density decreases over a third time period.** *See* [18.c]–[18.e], [18.h], [19]. Bikson, ¶¶175-176, 58, 92-99.

Claim Elements	Simon
density increases over a first time period; an amplitude of the second magnetic flux density remains constant over a second period of time; and an amplitude of the third magnetic flux density decreases over a third time period.	
[21] The device of claim 20 wherein the control unit is further configured to control the generation of the time-varying magnetic field such that no magnetic pulses are generated between the first time period and the second time period and between the second time period and the third time period.	**Simon discloses the control unit** (*e.g.*, "control unit") **is further configured to control the generation of the time-varying magnetic field such that no magnetic pulses are generated between the first time period and the second time period and between the second time period and the third time period.** *See* [18.c]–[18.e], [18.g]-[18.h], [19]. **Simon** also discloses an adjustable "duty cycle," *i.e.* stimulation on/off ratio indicating periods with no pulses, and acknowledges a "10 seconds on, 10 seconds off" treatment cycle. Simon, [0062], [0064], [0111]. Moreover, **Simon** discloses "inter-stimulus interval[s]," *i.e.*, space between impulses. Simon, cls. 9-10; [0030], [0033], [0059], [0104]; *see also* Herbst, [0037] ("two…pulses" with "adjustable delay between them"). Moreover, it was well-known in the art that there is a time period between pulses. *See, e.g.,* Magstim, 10, 11 (discussing interpulse spacing); *see also* Burnett '585, [0073] (disclosing impulse duration less than the time period between two impulses). Bikson, ¶¶177-180, 52.

Claim Elements	Simon
[23] The device of claim 18 wherein the first plurality of magnetic pulses forms a trapezoidal envelope, the second plurality of magnetic pulses forms a trapezoidal envelope, and the third plurality of magnetic pulses forms a trapezoidal envelope.	**Simon teaches the first plurality of magnetic pulses forms a triangular envelope, the second plurality of magnetic pulses forms a rectangular envelope, and the third plurality of magnetic pulses forms a triangular envelope.** *See* [18.c]–[18.e], [18.h], [19]. Bikson, ¶¶181-182, 92-99.
[24] The device of claim 23, wherein the control unit is further configured to control the generation of the time-varying magnetic field such that no magnetic pulses are generated for a first period of time between the first plurality of magnetic pulses and the second plurality and for a second period of time between the second plurality of magnetic pulses and the third plurality of magnetic pulses	**Simon teaches the control unit** (*e.g.*, "control unit") **is further configured to control the generation of the time-varying magnetic field such that no magnetic pulses are generated for a first period of time between the first plurality of magnetic pulses and the second plurality and for a second period of time between the second plurality of magnetic pulses and the third plurality of magnetic pulses.** *See* [21]. Bikson, ¶¶183-184, 52.

Claim Elements	Simon
and the third plurality of magnetic pulses.	
[25] The device of claim 18, further comprising a spacer configured to space the applicator away from the patient's skin during a treatment.	**Simon discloses a spacer** (*e.g.*, "interface material") **configured to space the applicator from the patient's skin during a treatment.** **Simon** discloses "interface material" "interpose[d]" (*i.e.*, spacing) between the applicator and patient's skin. Simon, [0032]. For example, this may comprise "hydrogel," "MYLAR®." Simon, [0032]. **Simon** additionally discloses placing conducting medium "within a conducting deformable elastomeric balloon" between applicator and skin. Simon, [0032]. **Simon** further discloses it was known in the art to "place[] foam pads on the skin at the site of stimulation," *i.e.*, spacing applicator from skin, to "reduce the pain" of treatment." Simon, [0022]. Bikson, ¶¶185-187.
[26] The device of claim 18, further comprising a belt, wherein the first applicator is configured to be positionable along the belt.	**Simon teaches a belt** (*e.g.*, "[s]traps, harnesses")**, wherein the first applicator is configured to be positionable** (*e.g.*, "maintain[ed]…in position") **along the belt.** **Simon** discloses fixing a stimulator having two applicators to body regions (*e.g.,* "abdomen" and "forearm") with "[s]traps, harnesses, or frames," *i.e.*, a belt, to "maintain the stimulator in position." Simon, [0147], [0154], [0168], [0182], [0194]. For example, **Simon** discloses "using a strap" to hold stimulator coils "against the patient." Simon, [0194]. Moreover, it was well-known to position applicators on a belt (*e.g.*, **Burnett-'870's** "adjustable" "belt"/"band"/"strap") to provide flexibility, *e.g.*, placing applicators on different muscles for a broad range of applications/treatments. Simon,

Claim Elements	Simon
	[0123], Burnett-'870, [0007], [0114], [0209]. Bikson, ¶¶188-190, 78-84.
[27.a] The device of claim 18, wherein the device further comprises a second applicator comprising a second magnetic field generating device disposed within the second applicator, wherein the second magnetic field generating device is configured to generate a second time-varying magnetic field,	**Simon discloses a second applicator** (*e.g.*, "applicator") **comprising a second magnetic field generating device** (*e.g.*, "coil") **disposed within the second applicator, wherein the second magnetic field generating device is configured to generate a second time-varying magnetic field.** *See* [18.pre]-[18.b]—**Simon** discloses two or more applicators; the shapes and configurations vary based on "anatomical location of the stimulation." Simon, [0031], [0100]-[0102], Fig. 4C-4D. A capacitor is "discharged" through each coil when a user wishes to "apply [a] stimulus." Simon, [0019], [0025]. **Simon** discloses charging "bank of capacitors," which are "discharged through the coil[s]." Simon, [0019]. **Simon** discloses "first and second time-varying magnetic fields" are generated by "first and second coils." Simon, [0025]. **Simon** teaches an implementation according to Herbst's teaching (incorporated) to use "a plurality of []signal generators, each producing a signal" for a corresponding output. Simon, [0063]; Herbst, [0017], [0037], [0070]. Accordingly, POSITAs would understand that **Simon** teaches individual capacitors may be discharged into corresponding coils such that separate pulses may be provided to the two coils. Bikson, ¶¶191-193, 78-86.
[27.b] the second time-varying magnetic field comprising: a fourth plurality of magnetic pulses having a fourth magnetic flux density; a fifth plurality of magnetic pulses	**Simon discloses the second time-varying magnetic field comprising: a fourth plurality of magnetic pulses having a fourth magnetic flux density; a fifth plurality of magnetic pulses having a fifth magnetic flux density; and a sixth plurality of magnetic pulses having a sixth magnetic flux density.** *See* [18.c]. Bikson, ¶¶194-195, 50-63.

Claim Elements	Simon
having a fifth magnetic flux density; and a sixth plurality of magnetic pulses having a sixth magnetic flux density;	
[27.c] wherein the control unit is further configured to control the generation of the second time-varying magnetic field such that: the fourth plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; the fifth plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; and the sixth plurality of magnetic pulses forms one of a trapezoidal	**Simon teaches the control unit** (*e.g.*, "control unit") **is further configured to control the generation of the second time-varying magnetic field such that: the fourth plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; the fifth plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; and the sixth plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope.** *See* [18.c]-[18.e]. Bikson, ¶¶196-197, 50-63, 92-99.

Claim Elements	Simon
envelope, a rectangular envelope, or a triangular envelope.	
[28] The device of claim 27, wherein the control unit is further configured to control the generation of the second time-varying magnetic field such that the magnetic pulses of the second time-varying magnetic field are generated synchronously with the magnetic pulses of the first time-varying magnetic field.	**Simon teaches the control unit** (*e.g.*, "control unit") **is further configured to control the generation of the second time-varying magnetic field such that the magnetic pulses of the second time-varying magnetic field are generated synchronously with the magnetic pulses of the first time-varying magnetic field.** *See* [18.pre]-[18.d]—Because switches are individually controlled by **Simon's** control unit, both switches may be switched synchronously. Synchronous modes in stimulators were well–known and conventional. *See* Belanger, 220 ("stimulation modes (synchronous, reciprocal, overlap)"), 242-243, 246; Burnett-'870, [0086]-[0087] ("coils…activated simultaneously"). Bikson, ¶¶198-199, 58, 92-100.
[29] The device of claim 18, wherein the first magnetic field generating device is configured to be spaced apart from a casing of the first applicator to allow for a cooling fluid to flow between the first magnetic field generating	**Simon teaches the first magnetic field generating device** (*e.g.*, "coil") **is configured to be spaced apart from a casing** (*e.g.*, "housing") **of the first applicator** (*e.g.*, first applicator of "stimulator 30") **to allow for a cooling fluid (***e.g.*, "water," "ferrofluids") **to flow between the first magnetic field generating device and the first applicator.** *See* [18.b]—**Simon** discloses each applicator has "its own housing 37" for a "coil[] 35"; and that the "housing" provides "mechanical support to the coil and core," and "electrical[] insulat[ion]" from a "neighboring coil." Simon, [0098], Fig. 3A-D.

Claim Elements	Simon
device and the first applicator.	**Simon** recognizes that "coils…overheat when used over an extended period" such that cooling was needed. Simon, [0020]. **Simon** discloses that known cooling solutions existed—"cool[ing] the coils with flowing water"/"ferrofluids," which are generally oil-based. Simon, [0020]; Li, 6:13-14 ("oil-based ferrofluid"); Burnett-'870, [0210], Fig. 35 (depicting a path through the "coil power line 365" that directs "fluid cooling" from "logic controller 364" to "coils positioned in the applicator 360"); Ghiron, 5:47-54, 9:1-10 (cited by Simon; discloses "channel 40" to "convey ferrofluid"); *see also* [0010], [0215]; [0235]. It was known that it is necessary to circulate cooling fluid, and conduits were well-known for such purposes. To the extent argued that **Simon** does not explicitly disclose the cooling fluid flows between the coils and the applicators, POSITAs would have been motivated and found it obvious to draw the fluid in between the turns of the conductive surfaces of the coils to cool them and to avoid the coils to be in direct contact with the patient's skin where the applicators are placed as **Simon** teaches the importance of "coil-cooling" to avoid unacceptable heat levels. Simon, [0020]. Bikson, ¶¶200-204, 87-91.
[30] The device of claim 18, wherein the device further comprises a first connecting tube connected to the first applicator and a second connecting tube connected to the second applicator.	**Simon teaches a first connecting tube connected to the first applicator** (*e.g.,* first applicator of "stimulator 30") **and a second connecting tube connected to the second applicator** (*e.g.,* second applicator of "stimulator 30")**.** *See* [29]—**Simon** references Ghiron as a "solution" of "[f]errofluid cooling" to overheating problem. Simon, [0020]. Ghiron teaches using "channel 40" to "convey ferrofluid 30" to a stimulator's coil. Ghiron, 5:47-54, 9:1-10. POSITAs would have been motivated and found it obvious to apply prior art teachings to direct cooling media (*e.g.,* ferrofluid) to the coil of the stimulator as taught in **Simon**.

Claim Elements	Simon
	To the extent argued **Simon** does not disclose a second connecting tube, POSITAs would have been motivated to duplicate the components of one applicator for a two-applicator device, including a second connecting tube such that both applicators are cooled. Bikson ¶¶205-207, 87-100.

B. Ground 2: Claims 18-30 are rendered obvious by Burnett-'870 in view of Magstim

1. Burnett-'870 Overview

Burnett-'870 discloses applying time-varying magnetic fields sufficient to "cause contraction of muscle fibers," and thereby "toning" it. Burnett-'870, *Title, Abstract,* [0003], [0011], [0227]. **Burnett-'870**'s device has multiple applicators comprising coils to generate magnetic fields on target muscles, as shown in Figure 9B where "coils 106" are disposed in an "abdominal garment". Burnett-'870, *Abstract*, [0070], [0114].

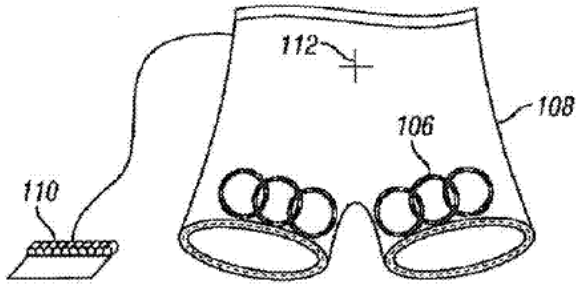


FIG. 9B

Burnett-'870 discloses attaching coils to a body region via a "belt," a "wrap" (Fig. 9A), a "band" (Fig. 9C), or a "strap" (Fig. 9D) that are "adjustable" allowing the coils to be independently positioned. Burnett-'870, [0007], [0114], [0209]. Bikson, ¶¶209-214.

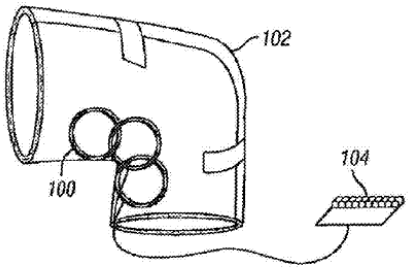


FIG. 9A

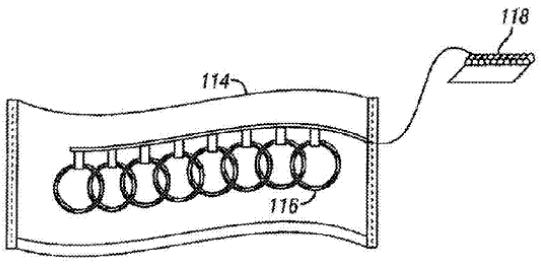


FIG. 9C

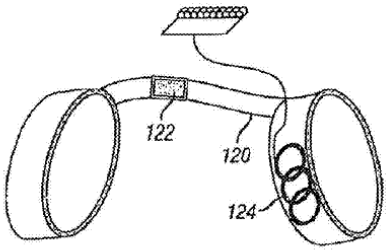


FIG. 9D

Burnett-'870 discloses cooling the coil by direct contact with a liquid coolant. Burnett-'870, [0210], [0215], [0235], Fig. 35. Bikson, ¶215.

Burnett-'870 uses a "logic controller" to adjust the parameters of the magnetic fields based on feedback from a patient via a "display screen". Burnett-'870, *Abstract,* [0196]. **Burnett-'870** discloses it was known to include a "capacitor" in the device, and uses a "switch" to control the connection between the controller and the applicators. Burnett-'870, [0013]–[0014], [0085], [0111].

Burnett-'870 leaves the powering of coils to a POSITA. Burnett-'870, [0130]. Bikson, ¶¶216-218.

Burnett-'870 also discloses that impulses of the magnetic fields may occur "simultaneously or differentially." Burnett-'870, [0087]. The treatment parameters, *e.g.*, "amplitude and/or firing sequence of coils 26," "position of coils 26," and "frequency of stimulation," are adjustable. Burnett-'870, [0070], [0085], [0087], [0117], [0129]. Because **Burnett-'870** explains that the magnetic fields may occur "differentially," this implies that **Burnett-'870** contemplates separate capacitors—one for each coil. Bikson, ¶¶219-221, 78-86.

To the extent argued **Burnett-'870** lacks disclosure of a first applicator including a radio frequency electrode configured to provide treatment, a POSITA would have found it obvious to modify **Burnett-'870**'s device to do so because it was well-known and conventional that RF-and-magnetic treatments provided a complementary effect to increase skin rejuvenation, and may reduce side effects compared to separate treatments. *See,* e.g., Edoute, [0196]-[0197]. **Burnett-'870** discloses lengthy treatments from 30 minutes to many hours daily depending on applications, including muscle stimulation and toning. **Burnett-'870,** [0011], [0195]-[0196]. It was well-known that muscles "contract" while stimulated—but shaping muscles without treating skin might cause skin sagging or other unwanted visual appearances. Burnett-'870, [0006], [0227]. A complementary or

simultaneous RF-and-magnetic treatment would be beneficial to improve the overall visual appearance by tightening skin as muscles are toned/adipose tissue is reduced, as was known in the art. Edoute, [0199]-[0202]; Sokolowski, [0003]-[0005] ("stimulation leads to a breakdown of fatty tissue"). Such modification would predictably work and provide the expected functionality given that **Burnett-'870** already discloses a device using RF operating in the same frequency range. Burnett-'870, [0133], [0117]. Bikson, ¶¶222-225, 101-102.

2. Magstim Overview

Magstim is a "[g]uide" to magnetic stimulation techniques and clinical applications, such as "rehabilitation" and "sports medicine" for "training muscle and… improving its fatigue resistance." Magstim, 1, 3, 39. Bikson, ¶226.

Figure 2 shows a "block diagram of a typical stimulator." Magstim, 3–4.

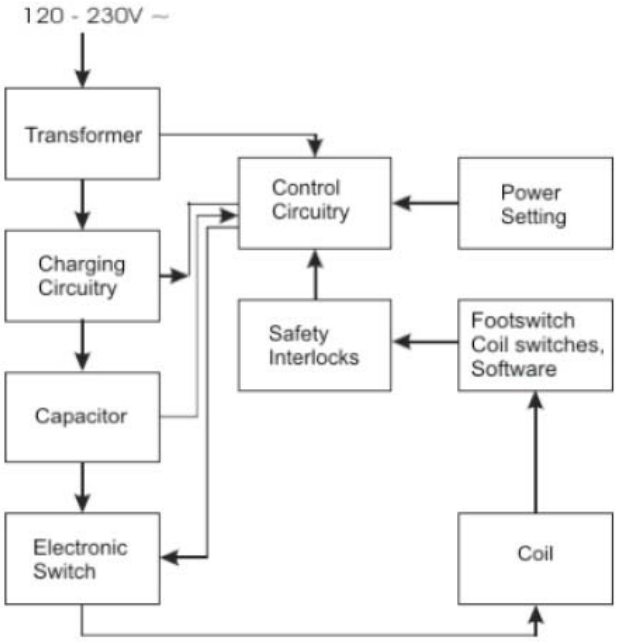


Figure 2: Block diagram of the Magstim 200[2] monophasic stimulator

Figure 2 illustrates "charg[ing] a capacitor under the control of a microprocessor," and connecting the capacitor to "the coil via an electronic switch" to generate a magnetic field, as shown in Figure 3. Magstim, 4. **Magstim** also illustrates the impulses as biphasic and sinusoidal. Magstim, 9, Fig. 14. Bikson, ¶¶227-229.

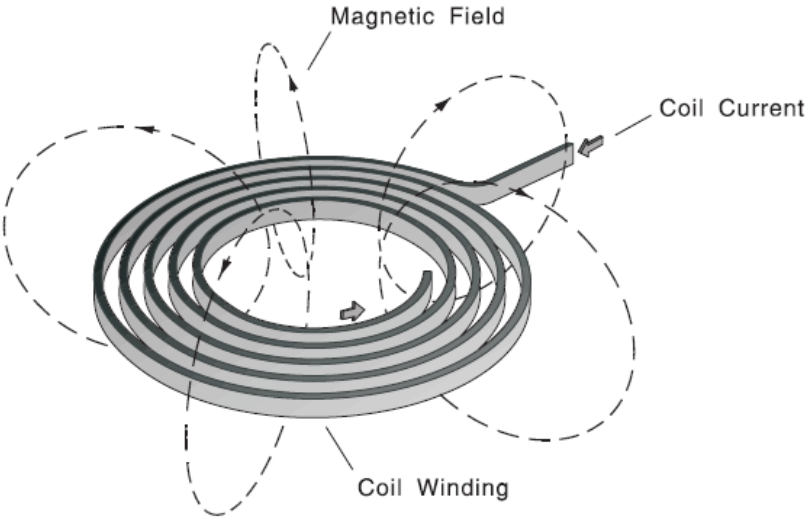


Figure 3: a circular coil showing the lines of force generated when current flows through the winding

Magstim discloses a controller for controlling generation of the magnetic fields using a "touch sensitive" "setup screen" that allows various parameters (*e.g.*, "Start Time, Power, Frequency Duration and Wait Time" over "trains of pulses") to be adjusted, as illustrated in Figure 21. Bikson, ¶¶230-231.

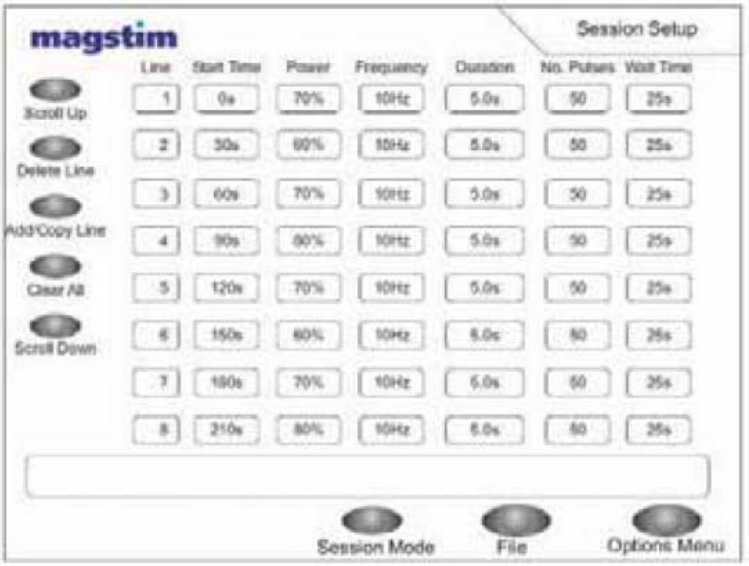


Figure 21: the Session software screen showing the parameters which can be controlled by the program

Magstim was publicly accessible and available to the POSITA as early as 2010. Suarez-Bagnasco, 4833 (reference [11]). **Magstim** was published for "world-wide readership," with copies distributed freely. Magstim, 1, 44. The Wayback Machine shows **Magstim** was disseminated via UC Irvine website by 2012. Magstim, Affidavit. Public documents cited **Magstim** and its URL. Zhi-De-Deng-Electric, 18 (reference [146]); Zhi-De-Deng-Electromagnetic, 276 (reference [161]; Simon-'569, ¶¶0036-0037; Simon-'967, ¶¶0051-0052; Simon-'203, ¶¶0017-0018, 0190; Simon-'432, ¶¶0090, 0094; Simon-'719, 7:48-8:1; Simon-'247, 20:29-43; Simon-'177, 11:19-39; File-history-'568, 10; File-history-'050, 11; File-history-'005, 3; File-history-'727, 4. Bikson, ¶232.

3. Motivation to Combine

Burnett-'870 discloses a device with multiple applicators with coils to generate magnetic fields on target tissues. Burnett-'870, *Abstract*. To the extent argued that **Burnett-'870** does not explicitly disclose details of a typical magnetic stimulation device, **Magstim** describes the details and operations of such device and its applications. Magstim, 1. Bikson, ¶¶233.

Burnett-'870 discloses that incorporating a "capacitor" in a magnetic stimulator was known. Burnett-'870, [0013]–[0014]. **Burnett-'870** also discloses using a "switch" to control the connection between the controller and the applicators. Burnett-'870, [0085], [0111]. **Burnett-'870** leaves the powering of coils to POSITA, **Magstim** teaches a known implementation of incorporating capacitors and switches in circuitry of a "typical stimulator" to control charging (from an energy source, *e.g.,* transformer) and discharging of a capacitor, using an electronic switch, to power a connected stimulation coil. Magstim, 4; Fig. 2. Because **Burnett-'870** discloses using activating two coils "differentially," and in view of known teachings to use a capacitor for storing energy for a coil, a POSITA would have recognized **Burnett-'870** as teaching separate energy source and storage per coil that would allow for independent control of separate coils to provide programmable discharge patterns of pulse channels. It would have been an obvious, "typical," implementation to double the energy source, capacitor and

switch for a two-coiled design such that each coil has its own circuitry. A POSITA would have been motivated and found it obvious to apply **Magstim's** teaching in implementing **Burnett-'870**'s stimulation device to charge and discharge the capacitors using switches such that energy would be stored in the capacitors and that the discharge of the capacitors would be controlled to provide power to the coils to generate the time-varying magnetic fields. Bikson, ¶¶234-237.

Although **Burnett-'870** does not explicitly disclose that the impulses of the magnetic fields are biphasic and sinusoidal, **Magstim** discloses it. Magstim, 9; Fig. 14. A POSITA would have been motivated and found it obvious to look to **Magstim's** teaching of "standard stimulator" biphasic and sinusoidal impulses in implementing **Burnett-'870**'s device. As explained in **Burnett'-870**, these signals had known benefits for therapeutic applications. Bikson, ¶¶238-239.

Both **Burnett-'870** and **Magstim** are in the same field of endeavor—electromagnetic stimulation of the body and are analogous art to '575. **Burnett-'870** discloses using magnetic field to stimulate muscles. Burnett-'870, *Abstract*. **Magstim** discloses using magnetic field to induce electrical current to stimulate muscles. Magstim, 1, 12. Bikson, ¶240.

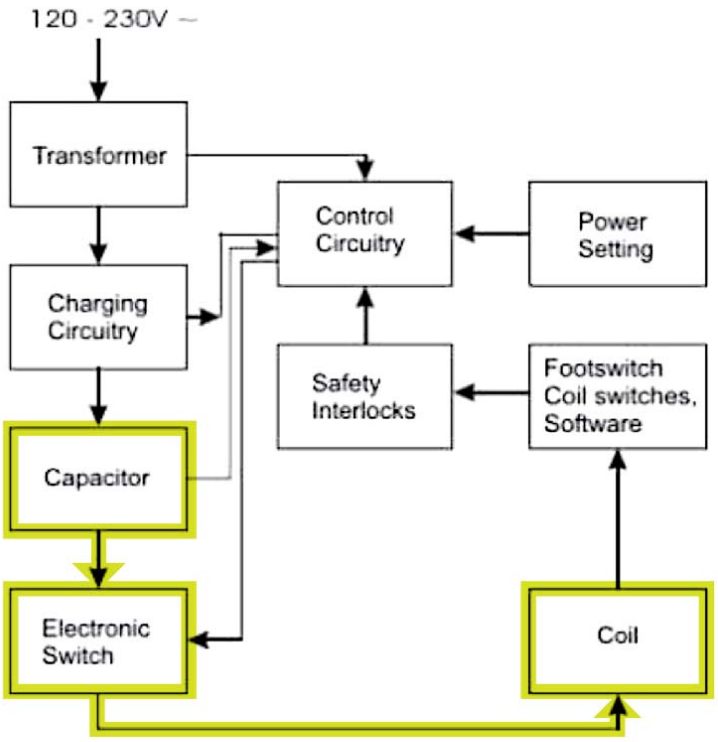
A POSITA would have found it routine, straightforward and advantageous to apply **Magstim's** known teachings of using capacitors to store energy and switches to control their discharge to power stimulation coils to generate magnetic

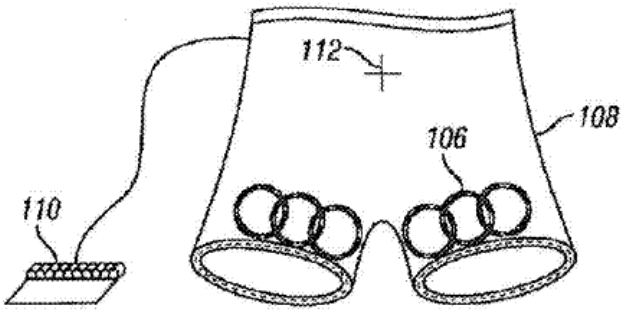
fields, and other known basics of magnetic fields, in implementing **Burnett-'870's** stimulation device, and would have known such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. *See KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007). Bikson, ¶241.

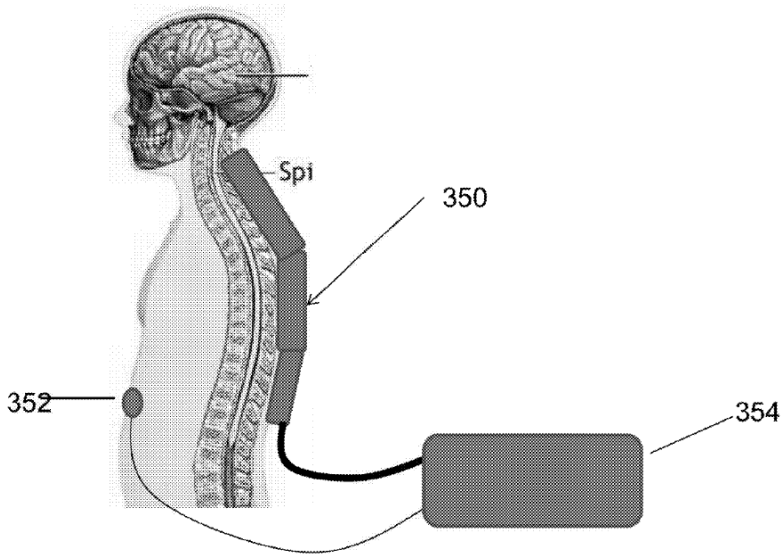
4. Claim Charts

a. Independent Claim 18

Claim Elements	Burnett-'870 in view of Magstim
[18.pre] A device for treating a patient, the device comprising:	**Burnett-'870 discloses a device** (*e.g.*, "system[]…for electromagnetic induction therapy") **for treating** (*e.g.*, "toning") **of a patient.** **Burnett-'870** discloses "systems…for electromagnetic induction therapy" using "body contoured applicators" that include "coils configured to generate an electromagnetic or magnetic field focused on a target nerve, muscle or other body tissues"; and the magnetic fields are "time varying" and "pulsed." Burnett-'870, *Abstract*, [0003]. **Burnett-'870** discloses "toning tissue with focused, coherent EMF [electromagnetic field]." Burnett-'870 [0011], [0225]–[0226]. Bikson, ¶¶242-245, 48-76.
[18.a] a first energy storage device;	**Burnett-'870 in view of Magstim teaches a first energy storage device** (*e.g.*, "capacitor")**.** **Burnett-'870** discloses it was known to use capacitors as energy storage devices in a magnetic stimulator. Burnett-'870, [0013]–[0014]. Indeed, its provisional application discloses using in its invention a LoFIT system described in Burnett-'185. Burnett-Provisional-'720, [0001]–[0002], [0020]. Burnett-'185 discloses incorporating a capacitor in the circuitry of the device, allowing it to be charged, and

Claim Elements	Burnett-'870 in view of Magstim
	using a switch to discharge it to the coil. Burnett-'185, 6:66-7:2, 7:27-8:26. A POSITA would have been motivated and found it obvious to incorporate capacitors in **Burnett-'870's** system based on **Burnett-'870's** reference to the LoFIT system, and **Burnett-'870's** guidance to store energy for the coils, and a POSITA would have understood to charge the capacitors such that they would be discharged to the coils as was known in the art. *See, e.g., id.*; Magstim, 3-4 ("charg[ing] a capacitor under the control of a microprocessor"), Fig. 2. *See* VIII.B.3. Bikson, ¶¶246-251, 83-86.  *Figure 2: Block diagram of the Magstim 200² monophasic stimulator*
[18.b] a first applicator comprising a first magnetic field	**Burnett-'870 discloses a first applicator** (*e.g.*, "applicator") **comprising a first magnetic field generating device** (*e.g.*, "coil") **disposed within the first applicator, wherein the**

Claim Elements	Burnett-'870 in view of Magstim
generating device disposed within the first applicator, wherein the first magnetic field generating device is configured to generate a first time-varying magnetic field,	**first magnetic field generating device is configured to generate a time-varying magnetic field.** *See* [18.pre]. **Burnett-'870** discloses multiple applicators comprising coils to generate magnetic fields on target muscles. Burnett-'870, *Abstract*. Figure 9B illustrates two applicators, each with a set of coils 106, disposed within an "abdominal garment" covering and treating left and right sides of a patient's buttocks/abdomen with time-varying magnetic fields. Burnett-'870, [0114].  FIG. 9B Figure 34 shows multiple "applicators 350" with "multiple coils" for "therapy targeting." Burnett-'870, [0209]. Bikson, ¶¶252-255, 78-80.

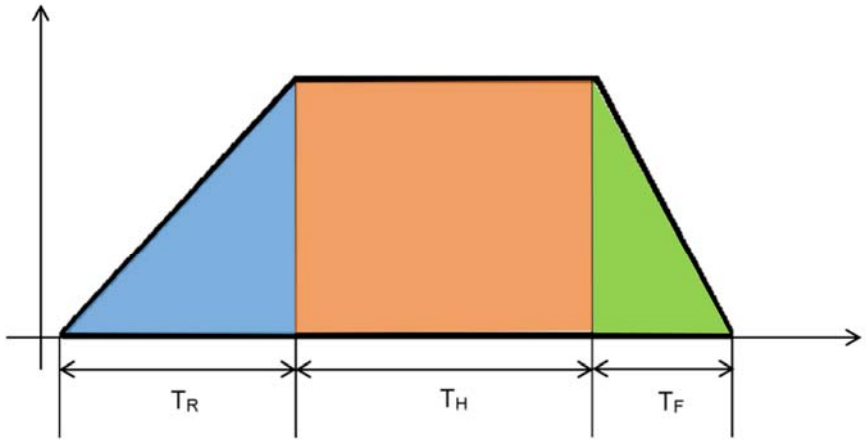
Claim Elements	Burnett-'870 in view of Magstim
	
[18.c] the first time-varying magnetic field comprising: a first plurality of magnetic pulses having a first magnetic flux density; a second plurality of magnetic pulses having a second magnetic flux density; and a third plurality of magnetic pulses having a third magnetic flux density; and	**Burnett-'870 discloses the first time-varying magnetic field comprises: a first plurality of magnetic pulses having a first magnetic flux density; a second plurality of magnetic pulses having a second magnetic flux density; and a third plurality of magnetic pulses having a third magnetic flux density.** *See* [18.pre]–[18.b]. **Burnett-'870** discloses that the magnetic fields are "time varying," "pulsed," and "intermittently applied"; the coils operate at a frequency; and target regions are "exposed to the *impulses*" of the magnetic fields—indicating that the fields generate pluralities of consecutive impulses. Burnett-'870, *Abstract*, [0003], [0195], [0226]. It was known in the art to use consecutive impulses of "fixed frequency" (*i.e.,* each impulse in a train has the same interstimulus interval) because such treatment is "useful" in therapeutic applications, such as rehabilitating muscles. *See, e.g.,* Magstim 3, 6, 11-12. **Burnett-'870** discloses "generating a magnetic field" comprises consecutive impulses having a "magnetic flux" density measured in Tesla. Burnett-'870, [0089], [0195].

Claim Elements	Burnett-'870 in view of Magstim
	Burnett-'870 discloses "the amplitude and/or firing sequence of coils 26 may be ramped up progressively…after which the applied stimulus is adjusted or maintained at its current level," indicating ramp-up and plateau periods. Burnett-'870, [0085]. A POSITA would understand that this "amplitude" refers to "magnetic flux density." **Burnett-'870** further discloses a ramp-down period based on a patient's feedback when the stimulation is "excessive" (*id.*), as was well-known in the art. *See, e.g.*, Belanger, 239 ("smooth downward ramping"). **Burnett-'870** further discloses "adjust[ing] one or more of firing sequence, firing strength or position of coils 26 within coil wrap 20 during the initial setup and also during successive therapy sessions." Burnett-'870, [0087]; *see also id.,* [0023], [0069]–[0070], [0123], [0183], [0188]–[0189], [0193]–[0194], [0196]. Thus, **Burnett-'870** discloses providing multiple pluralities of magnetic pulses having magnetic flux densities that may be "varied according to the efficiency of the treatment" (*e.g.,* based on "sensor input" or adjustment by a patient) to apply "desired" amplitude of magnetic energy on body tissues. Burnett-'870, [0070], [0081], [0083], [0088], [0100]. A POSITA would have been motivated to use first/second/third magnetic flux densities when ramping-up, plateauing, and ramping-down to mimic natural muscle contraction—*see* [20]. Bikson, ¶¶256-268, 48-76, 92-99.
[18.d] a control unit configured to control the generation of the first time-varying magnetic field such that:	**Burnett-'870 discloses a control unit** (*e.g.*, "logic controller") **configured to control the generation of the first time-varying magnetic field:** **Burnett-'870**'s device has a "logic controller…connected to the one or more coils" and "sensors" to provide feedback to the controller. The logic controller adjusts "amplitude, frequency or direction of the magnetic field, or the firing sequence" of the coils to provide efficient tissue treatment. Burnett-'870, [0070]. Bikson, ¶¶269-270, 58.
[18.e] the first plurality of	**Burnett-'870 teaches the first plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular**

Claim Elements	Burnett-'870 in view of Magstim
magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; the second plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; and the third plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope,	**envelope, or a triangular envelope; the second plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; and the third plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope.** *See* [18.c]—**Burnett-'870** teaches generating a trapezoidal envelop by adjusting coils to be "ramped up…maintained at its current level" and ramped down when the stimulation is "excessive" ([0085]). Accordingly, each plurality of magnetic pulses forms a trapezoidal envelope to mimic muscle contraction and relaxation as was known in the art. *See, e.g.*, Belanger, 239 (disclosing to apply a trapezoidal envelope to mimic the "gradual build up and relaxation phases" during a "voluntary muscle contraction" for a "smooth" contraction to increase patient comfort). Bikson, ¶¶271-273, 92-99.
[18.f] wherein the first applicator is configured to be positioned at a body region of the patient, wherein the body region comprises the patient's buttocks or abdomen,	**Burnett-'870 discloses the first applicator** (*e.g.*, "applicator") **is configured to be positioned at a body region of the patient, wherein the body region comprises the patient's buttocks or abdomen.** *See* [18.b]. Bikson, ¶¶274-275.

Claim Elements	Burnett-'870 in view of Magstim
[18.g] wherein each of the first, second, and third pluralities of magnetic pulses has a repetition rate in a range of 1 to 300 Hz,	**Burnett-'870 discloses each of the first, second, and third pluralities of magnetic pulses has a repetition rate in a range of 1 to 300 Hz** (*e.g.,* "10 to 20 hertz")**.** *See* [18.a]–[18.c]—**Burnett-'870** discloses "[o]peration of a conductive coil at about 10 to 20 hertz." Burnett-'870, [0195] (further discloses operating ranges "about 5 to 100 hertz"). It was known in the art to use a repetition rate in the claimed range. *See, e.g.,* Magstim, 13 (disclosing "up to a maximum of 100Hz."). Each pluralities of magnetic pulses would have a repetition rate within the range disclosed in **Burnett-'870.** Bikson, ¶¶276-280, 56, 92-99.
[18.h] wherein the first, second, and third magnetic flux densities are each in a range of 0.5 to 7 Tesla, and	**Burnett-'870 discloses the first, second, and third magnetic flux densities are each in a range of 0.5 to 7 Tesla** (*e.g.*, "0.25 to 1.5 tesla"). *See* [18.a]–[18.c]—**Burnett-'870's** "magnetic field of about 0.25 to 1.5 tesla," as well as a magnetic field of "about 1 to 10 tesla" are within the claimed range. Burnett-'870, [0195]. Bikson, ¶¶281-283, 50-63.
[18.i] wherein the first magnetic field generating device is configured to apply the first time-varying magnetic field to muscle fibers, neuromuscular plates, or nerves innervating muscle fibers in the body region such that muscles of the body region contract.	**Burnett-'870 discloses the first magnetic field generating device** (*e.g.*, "coil") **is configured to apply the first time-varying magnetic field to muscle fibers, neuromuscular plates, or nerves innervating muscle fibers in the body region** (*e.g.*, buttocks/abdomen) **such that muscles of the body region contract.** *See* [18.pre], [18.b], [18.e]–[18.f]. **Burnett-'870**'s device "may stimulate regions of the body to treat conditions requiring [] maximal stimulation (i.e., sufficient to cause contraction of muscle fibers and firing of nerves)." Burnett-'870 [0227]. Thus, **Burnett-'870** applies stimulation from two magnetic fields causing muscles in buttocks or abdomen to contract thereby toning them. Bikson, ¶¶284-287, 48-80.

b. Dependent Claims 19-30

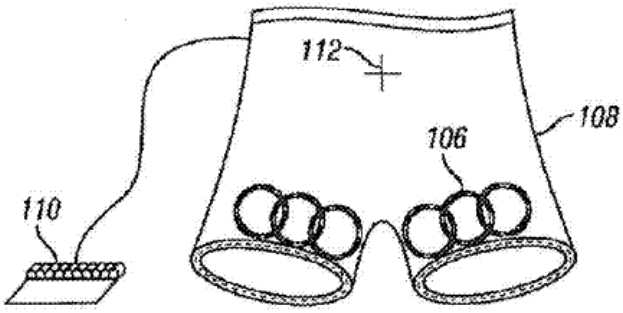
Claim Elements	Burnett-'870 in view of Magstim
[19] The device of claim 18, wherein: the first plurality of magnetic pulses forms a triangular envelope, the second plurality of magnetic pulses forms a rectangular envelope, and the third plurality of magnetic pulses forms a triangular envelope.	**Burnett-'870 teaches the first plurality of magnetic pulses forms a triangular envelope, the second plurality of magnetic pulses forms a rectangular envelope, and the third plurality of magnetic pulses forms a triangular envelope.** *See* [18.pre], [18.d]–[18.e]. **Burnett-'870** teaches a trapezoidal envelope (*see* [18.e]) which consists of a **first triangular envelope (blue)**, **second rectangular envelope (orange)**, and **third triangular envelope (green)** as shown in '894 Fig. 13 (annotated):  Figure 13 *See* '894 Fig. 28b, 30:16-18 (waveform similar to T_R above labeled "triangular shaped envelope 2802), Fig. 29b, 30:42-43 (same). To the extent argued the triangular/rectangular envelopes must be separated, **Burnett-'870** teaches a triangular envelope that "the amplitude and/or firing sequence of coils 26 may be ramped up progressively, so that the magnetic field is increased in strength…after which the applied stimulus is adjusted" to ramp down if the stimulation reaches "an excessive level" ([0085]), as such ramp modulation is known in the art. *See, e.g.*, Johari, *Abstract*,

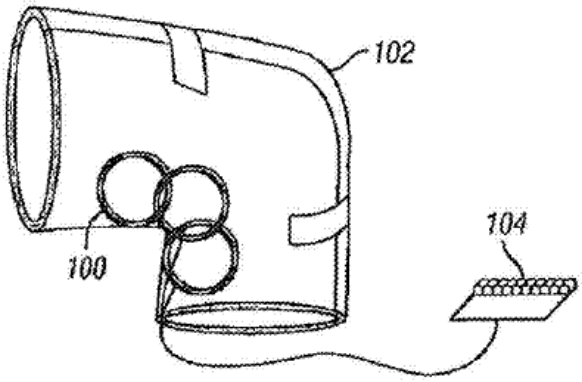
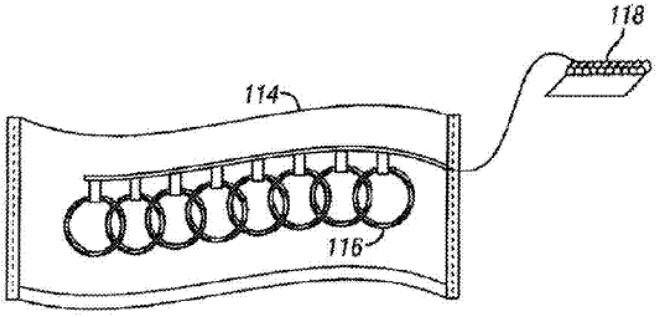
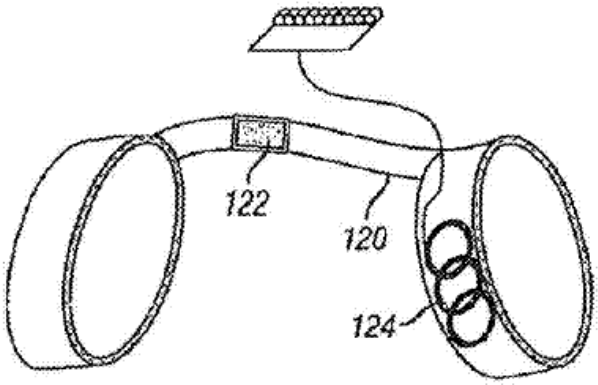
Claim Elements	Burnett-'870 in view of Magstim
	[0038] (disclosing "a ramp up of 4 seconds and a ramp down of four seconds" for muscle stimulation). Rectangular envelope is simply turning the stimulation on and then off without ramping, and POSITAs would have been motivated and found it obvious to do so when an optimal stimulation level is known and at a lower amplitude where ramping up/down is not necessary for patient comfort. For example, Burnett-'870 discloses the amplitude is adjustable and may be set to the optimal level. Burnett-'870, [0070], [0081], [0083], [0085], [0088], [0099]–[0100], [0252]–[0253]. **Burnett-'870** discloses using a treatment plan with various adjustable parameters over time. Burnett-'870, [0012], [0070], [0196], [0251]. POSITAs would have been motivated and found it obvious to use a treatment sequence with a triangular envelope, then a rectangular envelope, followed by another triangular envelope, for a treatment plan requiring a higher stimulation amplitude at the beginning and the end, and a lower stimulation amplitude in the middle, such that ramping is provided for the first and third periods for patient comfort but not needed for the middle portion. POSITAs would have understood that high, then low, then high-amplitude stimulation would be similar to the on-off-on sequence used to "prevent muscle fatigue." Belanger, 244. Bikson, ¶¶288-294, 48-76, 92-99.
[20] The device of claim 19, wherein the control is further configured to control the generation of the time-varying magnetic field such that: an amplitude of the first magnetic flux density increases	**Burnett-'870 teaches the control unit** (*e.g.*, "logic controller") **is further configured to control the generation of the time-varying magnetic field such that: an amplitude of the first magnetic flux density increases over a first time period; an amplitude of the second magnetic flux density remains constant over a second period of time; and an amplitude of the third magnetic flux density decreases over a third time period.** *See* [18.c]–[18.e], [18.h], [19]. Bikson, ¶¶295-296, 92-99.

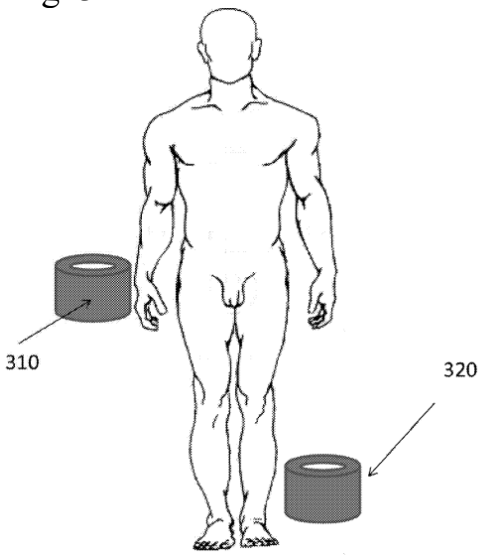
Claim Elements	Burnett-'870 in view of Magstim
over a first time period; an amplitude of the second magnetic flux density remains constant over a second period of time; and an amplitude of the third magnetic flux density decreases over a third time period.	
[21] The device of claim 20 wherein the control unit is further configured to control the generation of the time-varying magnetic field such that no magnetic pulses are generated between the first time period and the second time period and between the second time period and the third time period.	**Burnett-'870 teaches the control unit** (*e.g.*, "logic controller") **is further configured to control the generation of the time-varying magnetic field such that no magnetic pulses are generated between the first time period and the second time period and between the second time period and the third time period.** *See* [18.c]–[18.e], [18.g]–[18.h], [19]. **Burnett-'870** discloses using "intermittent pulsed magnetic fields" to include "periods… not subject to stimulatory signal." Burnett-'870, [0233]–[0234], [0252]–[0253]. It was known in the art that there is a time period between pulses that are called inter-pulse interval to create a time gap which no magnetic field is generated. Magstim, 11 (disclosing "interpulse spacing."). Bikson, ¶¶297-300, 52.
[22] The device of claim 18, wherein the first applicator further comprises an	**Burnett-'870 teaches the first applicator** (*e.g.*, "applicator") **further comprises an electrode configured to provide a radiofrequency treatment having a frequency in a range of 500 kHz to 3 GHz.**

Claim Elements	Burnett-'870 in view of Magstim
electrode configured to provide a radiofrequency treatment having a frequency in a range of 500 kHz to 3 GHz.	**Burnett-'870** discloses "devices and methods…regardless of whether the stimulation source is an electromagnetic field [or] a RF field...." Burnett-'870, [0133]. **Burnett-'870** further discloses its device may deliver "high frequencies…and ultrahigh frequencies." Burnett-'870, [0117]. **Burnett-'870** incorporates by reference ([0002]) Burnett-'325 disclosing that "radio frequency-powered microstimulators that include electrodes" were known. Burnett-'325, [0022]. **Burnett-'870** leaves it to POSITAs to choose a radiofrequency frequency suitable for stimulation treatment, and a frequency in the range of 500 kHz to 3 GHz was known and conventional to be part of the radiofrequency range. *See, e.g.*, Edoute, [0165] (RF refers to "part of the electromagnetic spectrum with frequency range of about 3 Hz to 300 GHz."); Zarsky, cl. 10 (describing the use of "radio frequency electromagnetic waves in the range of 13.553-13.567 or 26.957-27.283 or 40.66-40.70 MHz or 2.4-2.5 GHz from the applicator into the subcutaneous tissue."); [0019], claims 1–9. POSITAs would have been motivated and found it obvious to configure an applicator to apply RF and magnetic treatments together for stimulating tissues, such as toning muscles. *See* VIII.B.1. Bikson, ¶¶301-306, 101-102.
[23] The device of claim 18 wherein the first plurality of magnetic pulses forms a trapezoidal envelope, the second plurality of magnetic pulses forms a trapezoidal envelope, and the third plurality of magnetic pulses forms a	**Burnett-'870 teaches the first plurality of magnetic pulses forms a triangular envelope, the second plurality of magnetic pulses forms a rectangular envelope, and the third plurality of magnetic pulses forms a triangular envelope.** *See* [18.c]–[18.e], [18.h]. Bikson, ¶¶307-308, 92-99.

Claim Elements	Burnett-'870 in view of Magstim
trapezoidal envelope.	
[24] The device of claim 23, wherein the control unit is further configured to control the generation of the time-varying magnetic field such that no magnetic pulses are generated for a first period of time between the first plurality of magnetic pulses and the second plurality and for a second period of time between the second plurality of magnetic pulses and the third plurality of magnetic pulses.	**Burnett-'870 teaches the control unit** (*e.g.*, "logic controller") **is further configured to control the generation of the time-varying magnetic field such that no magnetic pulses are generated for a first period of time between the first plurality of magnetic pulses and the second plurality and for a second period of time between the second plurality of magnetic pulses and the third plurality of magnetic pulses.** *See* [21]. Bikson, ¶¶309-310, 52.
[25] The device of claim 18, further comprising a spacer configured to space the applicator away from the patient's skin during a treatment.	**Burnett-'870 teaches a spacer** (*e.g.*, the portion of the applicator surrounding the "coil") **configured to space the applicator** (*e.g.*, "coil") **from the patient's skin during a treatment.** **Burnett-'870** discloses that coils are "embedded in" and "disposed within" the applicators wrap ([0113]–[0114]) that may be produced by "multiple material layers and may include padding or other filling between the layers" ([0078]). A POSITA would have understood that these layers would provide "a spacer" between the coils and the patient's skin during a treatment. Bikson, ¶¶311-313, 78-84.

Claim Elements	Burnett-'870 in view of Magstim
[26] The device of claim 18, further comprising a belt, wherein the first applicator is configured to be positionable along the belt.	**Burnett-'870 teaches a belt** (*e.g.*, "abdominal garment," "belt")**, wherein the first applicator** (*e.g.*, "coil") **is configured to be positionable along the belt.** **Burnett-'870** explains that "incorporat[ing] an adjustable belt" was known in the art. Burnett-'870, [0007]. Figure 9B discloses a belt (*e.g.*, the portion of the "abdominal garment" which circles the patient's waist) fixing the applicators to the left and rights sides of the patient's buttocks/abdomen, so that the time-varying magnetic field may be applied through the coils. Burnett-'870, [0114].  FIG. 9B Figures 9A-D show fixing the applicators to a body region (*e.g.*, "knee"/"arm"/"head"/"neck"/"lower back") with a belt (*e.g.*, "wrap"/"strap"/"band"/"buckle"). Burnett-'870, [0114]–[0115].

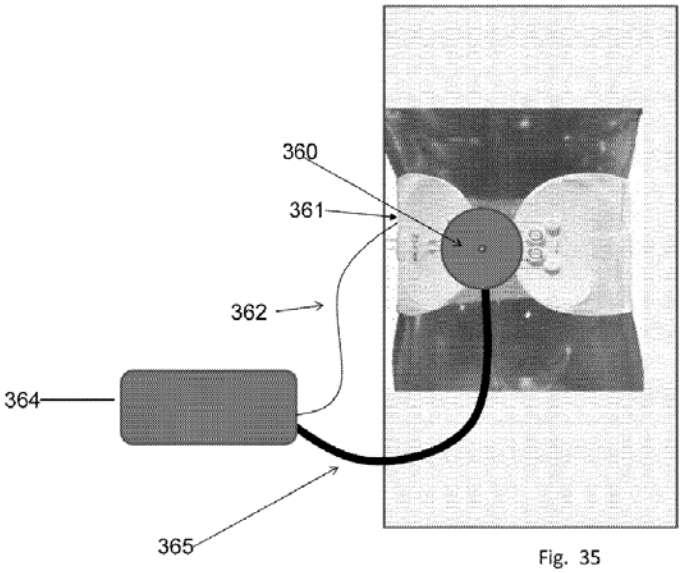
Claim Elements	Burnett-'870 in view of Magstim
	 FIG. 9A  FIG. 9C  FIG. 9D To the extent argued that **Burnett-'870**'s abdominal garment does not explicitly include a belt, a POSITA would have been motivated and found it obvious to modify **Burnett-'870's**

Claim Elements	Burnett-'870 in view of Magstim
	abdominal garment, which fixes both applicators to a body portion, to be a belt because such would allow more flexibility in applications as a belt is adjustable and may be used on different-sized patients, and easier to maintain than an undergarment that may be unsanitary, or require washing after each use. **Burnett-'870's** applicators are not fixed in positioning to each other. **Burnett-'870** discloses, "[t]he direction and location of ***each of coils 26*** may be reversibly or irreversibly adjusted…***customizing the location of the applied stimulation to the anatomy and therapy needs of each patient***." Burnett-'870, [0087]; *see also id.,* [0104]. **Burnett-'870** discloses applicator coils are attached to a belt. The coils are repositioned relative to each other by tilting/stretching/tightening/loosening the belt, such that one applicator's coil moves relative to the other coil. Burnett-'870, [0007] ("adjustable belt"), [0071] ("coils may be… movable"), [0209] ("coils… slidable, adjustable, or moveable"); *see also id.,* [0080], [0087]–[0088], [0090], [0093], [0099], [0102], [0104], [0106], [0110], [0114], [0120]–[0121], [0127], [0180], [0186], [0191], [0204]–[0205], Fig. 31A–B. Fig. 31a  Fig. 31b

Claim Elements	Burnett-'870 in view of Magstim
	To the extent argued that positioning of the applicators along the belt is not explicitly disclosed in Burnett-'870, a POSITA would have been motivated and found it obvious to modify **Burnett-'870's** arrangement to permit applicators to be positioned on the patient, along the belt. Such a modification would account for different sized patients and allow for more precise positioning of the coils. Bikson, ¶¶314-321, 78-84.
[27.a] The device of claim 18, wherein the device further comprises a second applicator comprising a second magnetic field generating device disposed within the second applicator, wherein the second magnetic field generating device is configured to generate a second time-varying magnetic field,	**Burnett-'870 discloses a second applicator** (*e.g.*, "applicator") **comprising a second magnetic field generating device** (*e.g.*, "coil") **disposed within the second applicator, wherein the second magnetic field generating device is configured to generate a second time-varying magnetic field.** *See* [18.pre]–[18.b]. Bikson, ¶¶322-323, 78-80, 100.
[27.b] the second time-varying magnetic field comprising: a fourth plurality of magnetic pulses having a fourth magnetic flux density; a fifth plurality of magnetic pulses	**Burnett-'870 teaches the second time-varying magnetic field comprising: a fourth plurality of magnetic pulses having a fourth magnetic flux density; a fifth plurality of magnetic pulses having a fifth magnetic flux density; and a sixth plurality of magnetic pulses having a sixth magnetic flux density.** *See* [18.c]. Bikson, ¶¶324-325, 48-63, 92-99.

Claim Elements	Burnett-'870 in view of Magstim
having a fifth magnetic flux density; and a sixth plurality of magnetic pulses having a sixth magnetic flux density;	
[27.c] wherein the control unit is further configured to control the generation of the second time-varying magnetic field such that: the fourth plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; the fifth plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; and the sixth plurality of magnetic pulses forms one of a trapezoidal	**Burnett-'870 teaches the control unit** (*e.g.*, "logic controller") **is further configured to control the generation of the second time-varying magnetic field such that: the fourth plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; the fifth plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope; and the sixth plurality of magnetic pulses forms one of a trapezoidal envelope, a rectangular envelope, or a triangular envelope.** *See* [18.c]–[18.e]. Bikson, ¶¶326-327, 92-99.

Claim Elements	Burnett-'870 in view of Magstim
envelope, a rectangular envelope, or a triangular envelope.	
[28] The device of claim 27, wherein the control unit is further configured to control the generation of the second time-varying magnetic field such that the magnetic pulses of the second time-varying magnetic field are generated synchronously with the magnetic pulses of the first time-varying magnetic field.	**Burnett-'870 teaches the control unit** (*e.g.*, "logic controller") **is further configured to control the generation of the second time-varying magnetic field such that the magnetic pulses of the second time-varying magnetic field are generated synchronously with the magnetic pulses of the first time-varying magnetic field.** *See* [18.pre]–[18.d]. **Burnett-'870** discloses "[w]hen multiple coils 26 are present, coils 26 may be activated simultaneously." Burnett-'870, [0086]-[0087]. **Burnett-'870** allows the coils to be adjusted (switched) at the same time. Burnett-'870, [0067], [0083], [0085], [0087]–[0088], [0090], [0093], [0095], [0100], [0110], [0120], [0123], [0127], [0196], [0202], [0220], [0237]–[0241]. Synchronous generation of magnetic fields in a magnetic muscle stimulator was well known. *See, e.g.,* Belanger, 220 ("stimulation modes (synchronous, reciprocal, overlap)"), 242–243, 246. A POSITA would have been motivated and found it obvious to apply this known teaching of synchronous switching and discharge to treat two body regions (that may be mirror image of each other) similarly such that both regions would have the same visual appearance after treatment. *See* VIII.B.3. Bikson, ¶¶328-333, 48-76, 92-100.
[29] The device of claim 18, wherein the first magnetic field generating device is configured to be spaced apart from a casing of the	**Burnett-'870 discloses the first magnetic field generating device** (*e.g.*, "coil") **is configured to be spaced apart from a casing** (*e.g.*, "housing") **of the first applicator** (*e.g.*, "applicator") **to allow for a cooling fluid (***e.g.*, "air," "liquid") **to flow between the first magnetic field generating device and the first applicator.**

Claim Elements	Burnett-'870 in view of Magstim
first applicator to allow for a cooling fluid to flow between the first magnetic field generating device and the first applicator.	**Burnett-'870** discloses "one or more conductive coils disposed in an ergonomic housing," *e.g.*, "wrap"/"cradle"/"garment." Burnett-'870, [0070], [0074]. Bikson, ¶¶334-335, 81-84. **Burnett-'870** discloses it was known to cool the coils by direct contact with a liquid coolant to prevent overheating. Burnett-'870, [0235], [0210], [0215]. **Burnett-'870** discloses in Figure 35 a path through the "coil power line 365" that directs "fluid cooling" from "logic controller 364" to "coils positioned in the applicator 360." Burnett-'870, [0210]; *see also id.*, [0010], [0215]; [0235]. Bikson, ¶¶336-337.  Fig. 35 To the extent argued that **Burnett-'870** does not explicitly disclose the cooling fluid is flow between the coils and the applicators, POSITAs would have been motivated and found it obvious to draw the fluid in between the turns of the conductive surfaces of the coils to cool them and to avoid the coils to be in direct contact with the patient's skin where the applicators are placed. Bikson, ¶¶338, 87-91.
[30] The device of claim 18, wherein	**Burnett-'870 discloses a first connecting tube** (*e.g.*, "coil power line") **connected to the first applicator** (*e.g.*,

Claim Elements	Burnett-'870 in view of Magstim
the device further comprises a first connecting tube connected to the first applicator and a second connecting tube connected to the second applicator.	"applicator") **and a second connecting tube** (*e.g.*, "coil power line") **connected to the second applicator** (*e.g.*, "applicator")**.** *See* [29]. Bikson, ¶¶339-340.

C. Ground 3: Claims 18-21, 23-30 are Rendered Obvious by Simon In View of Burnett-'870

Claims 18-21, 23-30 are rendered obvious by **Simon**—*see* Ground 1. To the extent argued that a trapezoidal/triangular envelope (*e.g.*, [18.e], [19], [23], [27.c]) and connecting tubes for fluid cooling (*e.g.*, [30]) were not well-known or obvious to a POSITA, claims 18-19, 23, 27, 30 (and dependents) are rendered obvious by **Simon** in view of **Burnett-'870**. Bikson, ¶342.

Simon discloses coils may "overheat when used over an extended period of time" such that it was known to use "coil-cooling" mechanisms such as "flowing water or air" or "ferrofluids" (generally oil-based). Simon, [0020]. **Simon** discloses treatments including muscle "[r]ehabilitation" or for "[m]uscle injury," each of which involves an extended treatment period and would be prone to overheating. Simon, [0197]. While **Simon** leaves it to a POSITA to determine the precise cooling mechanism, to the extent argued **Simon** does not disclose flowing

oil from a source through a first/second connecting tube to the first/second applicators, **Burnett-'870** discloses connecting tubes: "coil power line[s]" to direct "fluid cooling" from a "logic controller" to "coils positioned in the applicator." Burnett-'870, [0210]; [0010], [0215]; [0235]; Ground-2-[30]. Bikson, ¶343.

Simon additionally discloses avoiding "discomfort" by increasing current "gradually" until "set to a level" below patient "discomfort." Simon, [0123]. Indeed, **Simon's** signal parameters may be "automatically adjusted…to provide an electrical stimulation signal of whatever type [the user] wishes." Simon, [0063], [0123]. To the extent argued that **Simon** does not disclose a trapezoidal or triangular envelope, *e.g.*, a ramp-down period, **Burnett-'870** expressly discloses a trapezoidal/triangular envelope; it discloses ramp-down based on patient feedback that the stimulation is "excessive," forming a triangular envelope when ramping-down after "amplitude and/or firing sequence of coils 26 may be ramped up progressively" and/or a trapezoidal envelope where "applied stimulus is adjusted or maintained at its current level" between ramp-up and ramp-down. **Burnett-'870**, [0085]; Ground-2-[18.e]-[19]-[23]-[27.c]. Bikson, ¶344-345, 98-99.

A POSITA would also have been motivated to apply **Burnett-'870's** ramp-up and ramp-down teachings in implementing **Simon's** stimulator to increase patient comfort. **Simon** teaches increasing current "gradually" to a level lower than one causing patient "discomfort." Simon, [0123]. **Burnett-'870** similarly discloses

"ramp[] up" times, a "maintained…level," and ramp-down times (*e.g.*, after "excessive" stimulation") during treatment in order to provide an "optimal therapy level" without patient discomfort. Burnett-'870, [0085], [0128] Because **Simon's** device may increase and decrease its parameters including the applied current "to influence the therapeutic result," **Burnett-'870's** ramp-down teachings for trapezoidal/triangular envelopes would be introduced to **Simon's** system by simply adjusting **Simon's** device parameters, and a POSITA would have been motivated to do so in order to advantageously avoid "pain or discomfort." Simon, [0016], [0062]-[0064], [0123]. Likewise, a POSITA would have had a reasonable expectation of success in implementing **Simon's** system as taught with **Burnett-'870's** ramp-down to avoid patient discomfort, *e.g.*, from "excessive stimulation." Simon, [0123]; Burnett-'870, [0085]. Bikson, ¶¶347-348, 98-99.

A POSITA would also have been motivated to apply **Burnett-'870's** cooling connecting tube teachings in implementing **Simon's** stimulator to prevent overheating during treatment. **Simon** teaches avoiding patient "discomfort," and further teaches that coil-cooling mechanisms may be used. Simon, [0020], [0123]. **Burnett-'870** similarly discloses "cooling features" in its applicators, e.g., using "liquid cooling" to "cool the coils or applicator." Burnett-'870, [0210], [0215]. **Simon's** device contains a housing that holds electronics and conducting gel (Simon, [0094]), so **Burnett-'870's** connecting tubes would be introduced to

Simon's device by simply including them within the housing. A POSITA would have been motivated to do so, and had a reasonable expectation of success in implementing **Simon's** system as taught with **Burnett-'870's** liquid-cooling connecting tubes to avoid patient discomfort from overheating, especially for prolonged muscle treatments like "rehabilitation." Simon, [0020], [0197]; Bikson, ¶346, 87-91.

D. Ground 4: Claim 22 is rendered obvious by Simon in view of Edoute

Simon in view of Edoute teaches the first applicator (*e.g.*, applicator of "stimulator 30") **further comprises an electrode** (*e.g.*, "electrode") **configured to provide a radiofrequency treatment** (*e.g.*, "RF…pulses") **having a frequency in a range of 500 kHz to 3 GHz** (*e.g.*, "3 Hz to 300 GHz")**.** Bikson, ¶349.

Edoute is directed to a device for "simultaneously emit[ting] RF and magnetic pulses" to target body regions for *e.g.*, "superficial muscle contractions." Edoute, Abstract, [0328], [0243]. **Edoute** discloses applying a pulsed "magnetic field" and recognizes that pulsed electromagnetic fields are known for "musculoskeletal" applications." Edoute, [0008], [0107], [0241]. **Edoute's** device contains electrodes 41, each containing a "coil" serving as a "pulsed electromagnetic frequency generator (2);" electrodes are adapted both to "provid[e] electromagnetic pulses…[and] apply[] heat" via "RF radiation" to a "region of a

patient's skin." Edoute, [0098]-[0099], [0197]-[0198]; [0129]-[0130] (various pulse frequencies and durations, *e.g.*, 16 or 25Hz; 5ms duration.)

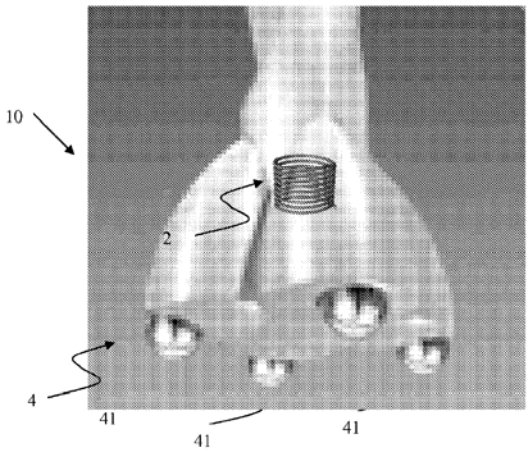


FIG. 1B

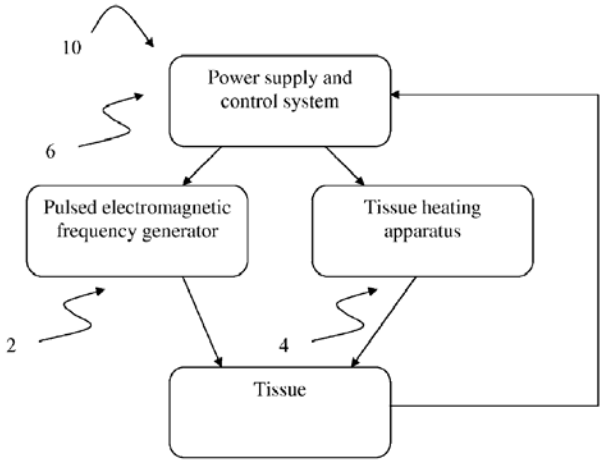


FIG. 2

Edoute, Figs. 1B, 2. Bikson, ¶350.

Edoute recognizes RF frequency refers to a "frequency range of about 3 Hz to 300 GHz," falling within the claimed range. Edoute, [0165]. While **Edoute's** device applies "heat" to patient's skin, it is also compatible with "a mechanism for skin cooling." Edoute, [0117]. **Edoute** discloses a complementary effect on tissue improvement resulting from simultaneous heat (RF) and electromagnetic stimulation. Edoute, [0200]. Moreover, **Edoute** describes heating tissue through radiofrequency stimulation causes "tissue injury" promoting collagen fibers and resulting in "overall tightened and rejuvenated appearance of the skin." Edoute, [0201]-[0207]. Bikson, ¶¶350-352, 101-102.

A POSITA would have been motivated to apply **Edoute's** simultaneous RF-

and-magnetic stimulation to **Simon's** device to increase skin tightness when toning muscles. **Simon** discloses "repeated," lengthy treatments, *e.g.*, "1 to 200 minutes" per session (Simon, [0022], [0111], [0123], [0141]), including muscle "rehabilitation" (Simon, [0197]). Such treatments cause muscle toning/shaping; it was well-known that muscles "contract" while stimulated—but shaping muscles without treating skin might cause skin sagging or other unwanted visual appearances. Simon, [0158] ("signal causes the smooth muscle…to contract"), [0194], [0195]; Bikson, ¶353. **Edoute** teaches application of radiofrequency energy heats the dermis, stimulates collagen production and leads to an "overall tightened and rejuvenated appearance of the skin." Edoute, [0201]. A POSITA would have understood and found it obvious to apply radiofrequency treatment alongside magnetic treatment to improve the overall visual appearance by tightening skin as muscles are toned/adipose tissue is reduced, *e.g.*, to provide additional skin tightness alongside muscle toning, and to prevent skin sagging or stretch marks during muscle treatment. Edoute, [0199]-[0202]; Sokolowski, [0003]-[0005] ("stimulation leads to a breakdown of fatty tissue"). Bikson, ¶¶353-354. Moreover, **Edoute** discloses that simultaneous RF-and-magnetic treatment may provide a complementary effect of increasing skin rejuvenation and may reduce side effects compared to separate treatments. Edoute, [0196]-[0197], [0199]-[0200]. Herbst, incorporated into **Simon**, additionally discloses setting

repetition rates for multiple output channels such that **Simon**'s device would support simultaneous RF-and-magnetic stimulation with different frequencies. Herbst, [0031], [0037]. Bikson, ¶355.

Both **Simon** and **Edoute** are in the same field of endeavor—electromagnetic stimulation of the body—also analogous art to the '894. **Simon** is directed to a "magnetic stimulation device" for muscles; **Edoute** is also directed to a device for tissue "rejuvenation," *e.g.* for applying "dynamic magnetic field" to "injured tissue" to promote "rapid and improved healing." Simon, title, [0029]-[0030]; Edoute, Abstract, [0010], [0015]-[0017], [0234], [0284]. A POSITA would have recognized applying **Edoute's** teachings of simultaneous RF-and-magnetic stimulation would provide a benefit of tightening skin during lengthy treatments using **Simon's** device, resulting in improved visual appearance, and would have been straightforward and predictably worked. Simon, [0123], [0141], [0147]; Edoute, [0192]-[0207]; Bikson, ¶356.

In light of the above, a POSITA would have found it routine, straightforward, and advantageous to apply **Edoute's** known teachings of combined RF-and-magnetic stimulation to **Simon's** device, and would have known such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Bikson, ¶357; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401-02 (2007).

IX. SECONDARY CONSIDERATIONS

'894 Claims are overwhelmingly demonstrated as obvious by the grounds presented herein that cannot be overcome by any alleged objective indicia. Petitioner is aware that Patent Owner presented purported evidence of secondary considerations of non-obviousness in the ITC Case. Because the purported evidence was presented in confidential expert reports, Petitioner does not have access to such evidence. Petitioner reserves the right to respond to any secondary considerations Patent Owner may assert in this proceeding. Bikson, ¶358.

X. CONCLUSION

Petitioner respectfully requests IPR of Claims 18-30 of the '894. Bikson, ¶359-361.

Dated: August 13, 2021

Respectfully submitted,

By: */Scott A. McKeown/*
Scott A. McKeown
Registration No. 42,866
ROPES & GRAY LLP

Lead Counsel for Petitioner

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. §42.24(a) and (d), the undersigned hereby certify that the Petition For *Inter Partes* Review complies with the type-volume limitation of 37 C.F.R. §42.24(a)(i) because, exclusive of the exempted portions, it contains 12,508 words as counted by the word processing program used to prepare the paper.

Dated: August 13, 2021

/Keyna Chow/
Keyna Chow
ROPES & GRAY LLP

CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§42.6(e) and 42.105(b) on the Patent Owner by FedEx of a copy of this Petition for Inter Partes Review and supporting materials at the correspondence address of record for the '894 patent:

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON DC 20005

J.C. Rozendaal
JCROZENDAAL@sternekessler.com
Cc: BTL_Emsculpt_Litigation@sternekessler.com

Dated: August 13, 2021

Respectfully submitted,

By: */Scott A. McKeown/*
Scott A. McKeown
Registration No. 42,866
ROPES & GRAY LLP

Lead Counsel for Petitioner