UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUMENIS BE LTD.,
Petitioner,

v.

BTL HEALTHCARE TECHNOLOGIES A.S.,
Patent Owner.

Case IPR2021-01403
Patent No. 10,821,295

PETITION FOR *INTER PARTES* REVIEW

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LIST OF EXHIBITS

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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	*Reserved*
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	*Reserved*
1059	*Reserved*
1060	*Reserved*
1061	U.S. Patent Application Publication No. 2015/0025299 ("Edoute")
1062	*Reserved*
1063	U.S. Patent Application Publication No. 2011/0172735 ("Johari")
1064	U.S. Patent Application Publication No. 2013/0123765 ("Zarsky")
1065	*Reserved*
1066	U.S. Patent Application Publication No. 2020/0155221 ("Marchitto-'221")
1067	*Reserved*
1068	*Reserved*
1069	U.S. Patent Application Publication No. 2016/0129274 ("Park")
1070	U.S. Patent Application Publication No. 2001/0031906 ("Ishikawa")
1071	U.S. Patent No. 5,766,124 ("Polson")
1072	*Reserved*

Exhibit (Ex-)	Description
1073	U.S. Patent Application Publication No. 2009/0284339 ("Choi")
1074	Javier Ruiz-Esparza & Julio Barba Gomez, *The Medical Face Lift: A Noninvasive, Nonsurgical Approach to Tissue Tightening in Facial Skin Using Nonablative Radiofrequency*, Dermatol Surg 29:325-332 (2003) ("Ruiz-Esparza")
1075	Nils Krueger et al., *Safety and Efficacy of a New Device Combining Radiofrequency and Low-Frequency Pulsed Electromagnetic Fields for the Treatment of Facial Rhytides*, J Drugs Dematol. 11(11):1306-1309 (2012) ("Krueger")
1076	U.S. Patent No. 10,195,454 ("Yamashiro")
1077	Venus Concept Ltd., Venus Freeze MP^2 User Manual International (2012) ("Venus Freeze")
1078	European Patent EP 2069014 B1 ("Hancock")
1079	U.S. Patent No. 8,204,446 ("Scheer")
1080	Agilent 33500 Series 30 MHz Function / Arbitrary Waveform Generator User's Guide ("Agilent")
1081	Jim Turley, *Agilent Technologies Announces 30 MHz Function/Arbitrary Waveform Generators with Unparalleled Signal Accuracy*, Elec. Eng'g J. (Aug. 4, 2010), https://www.eejournal.com/article/20100804-03/ ("Turley")
1082	*Agilent Announces 30 MHz Function/Arbitrary Waveform Generators*, Microwave J. (Aug. 3, 2010), https://www.microwavejournal.com/articles/9851-agilent-announces-30-mhz-function-arbitrary-waveform-generators ("Microwave")
1083	Declaration of Jonathan Bradford

I. INTRODUCTION

Lumenis Be Ltd. ("Petitioner") respectfully requests IPR of Claims 8-22 ("Claims") of U.S. 10,821,295 ("'295") pursuant to §§311-319 and §42.100.

'295 is directed to treating a patient using a combination of a time-varying magnetic field and radiofrequency waves, to provide "improved treatment." '295, *Abstract*, 2:1–7, 4:12–15, 6:42–49. Its exemplary device includes two applicators placed on a patient's body, which apply radiofrequency waves to heat muscles and apply magnetic fields to cause the muscles to contract, thereby "ton[ing] the muscle[, and] providing a more attractive appearance." '295, 3:53–67, 6:50–52, 28:60–62, *see also id.*, 6:66–7:1; 19:13–14.

Figure 11a shows a treatment device (44) including **a magnetic field generating device (45)** and **a radiofrequency (RF) means (46)**. '295, 98:23–26. Bikson, ¶¶102-105.

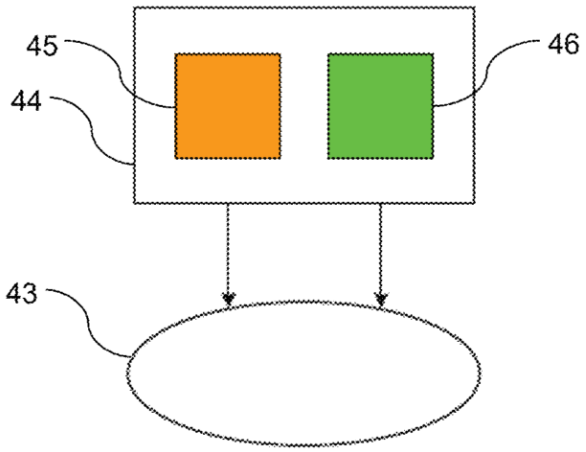


Figure 11a

’295 explains that both “magnetic methods” a well as “radiofrequency treatment” were already in use, but that these “treatment methods…[were] used separately.” ’295, 2:17–27, 2:45–47. Thus, ’295’s purported novelty is to combine technologies of “magnetic field with radiofrequency.” ’295, 2:4–7. Indeed, ’295 Claims require both a magnetic field and radiofrequency waves. ’295, cls. 1–30. Bikson, ¶¶41-42, 102-105.

But the combination of magnetic stimulation and heat treatment using radiofrequency waves was well-known and the claimed features were merely conventional. Bikson, ¶¶43-101. **Edoute** discloses a device for applying RF and magnetic field simultaneously to target body region for complementary effect resulting from simultaneous heat (RF) and electromagnetic stimulation on muscles. Edoute, *Abstract*, [0200]. Bikson, ¶¶122-124, 211. **Park** discloses treating a patient with a combination of pulsed electromagnetic field and heat energy such as RF for “firming muscles.” Park, [0004], [0036]. Bikson, ¶¶221-223. **Zarsky** discloses circuit components to generate RF for treating tissues. Zarsky, *Abstract*, Fig. 1. Bikson, ¶¶212-213, 329.

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

A. Real Party-in-Interest

Lumenis Be 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 (IPR2021-01402) challenging claims 1-7, 23-30 of the '295 patent. Due to word-count constraints and the large number of claims, requiring 12,449 words in IPR2021-01402 and 12,404 words in IPR2021-01403, claims 8-22 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 '295 patent is not the subject of any other litigation.

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. 116610-0004-651. 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 ’295 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)
Edoute	1061	9/18/2014	1/22/2015	§102(a)(1)-(2)
Burnett-'870	1005	11/20/2013	5/29/2014	§102(a)(1)-(2)
Zarsky	1064	11/16/2011	5/16/2013	§102(a)(1)-(2)
Park	1069	11/10/2014	5/12/2016	§102(a)(2)

2. Statutory Grounds on Which the Challenge is based

Ground	Statute	Claim(s)	Prior Art
1	§103	8, 11-17, 20-22	Simon in view of Edoute
2	§103	9-10, 18-19	Simon in view of Edoute and Zarsky
3	§103	8, 11-17, 20-22	Simon in view of Edoute and Park
4	§103	9-10, 18-19	Simon in view of Edoute, Park, and Zarsky

[2] The art predates '295's earliest priority date; Petitioner takes no position as to the priority claims.

5	§103	8-22	Burnett-'870 in view of Park and Zarsky

See §VIII.

V. BACKGROUND

A. '295 Patent

'295 is directed to combining application of a time-varying magnetic field with radiofrequency waves, to remodel or improve muscles and adjacent body regions. '295, *Abstract*, 2:1–7, 4:12–15, 6:42–49. '295 recognizes that "radiofrequency treatment" was one of the "most common methods used for non-invasive aesthetic applications" and its effect is known to be "based specifically on heat production in the biological structure." '295, 2:17-27.

Both the magnetic field generating device and the radiofrequency electrode are in the same device. '295, 98:21-29. As shown in Fig. 11a, device 44 includes **magnetic field generating device 45** and **RF means 46** applied to a patient's body region 43. *Id.;* Bikson, ¶102.

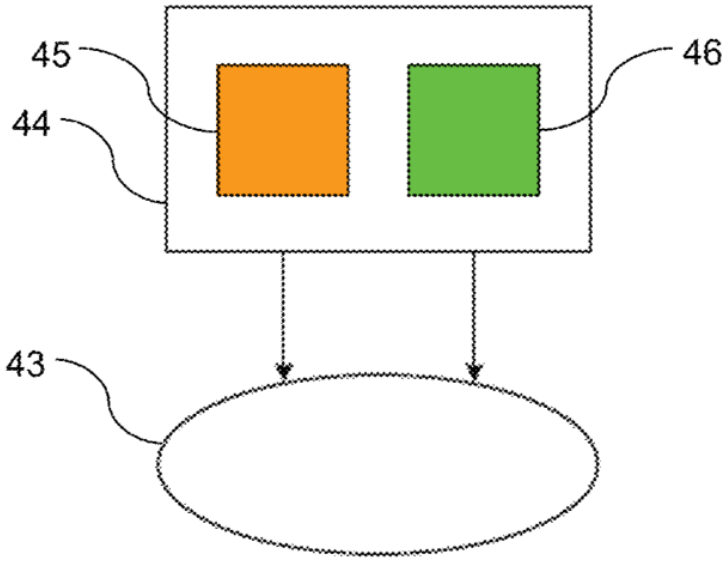


Figure 11a

’295 uses an RF (radiofrequency) source providing radiofrequency waves to an electrode, to heat a target body region. ’295, 25:51–54, 26:13–46, 98:23–26. The RF means may be a radiofrequency electrode. ’295, 26:24-29. The radiofrequency electrode is powered by a high frequency (HF) generator. The HF signal may be transferred via transmatch. ’295, 25:48-55. A balun transformer may also be used to transform unbalanced signal to balanced signal. ’295, 25:49-50. Bikson, ¶103.

’295’s device may include two circuits generating two magnetic fields. ’295, 5:28-30. The circuits include energy storage devices (*i.e.*, capacitors) discharging energy to **two magnetic field generating coils**. ’295, 3:31–33, 19:56-64, 20:23–26.

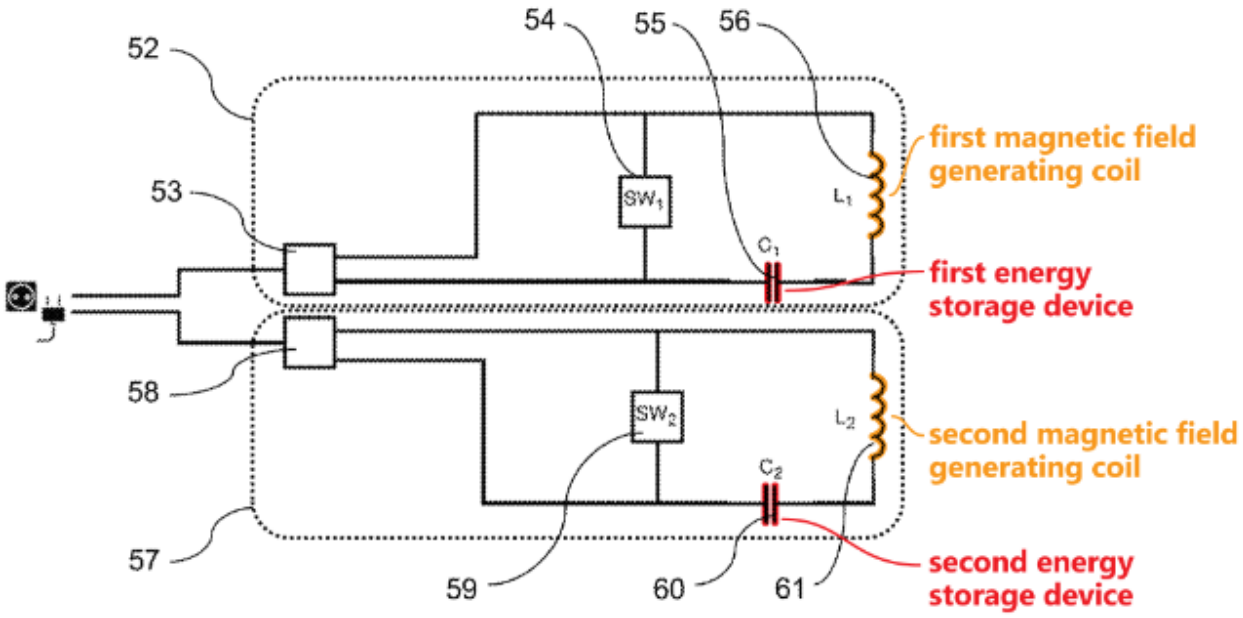


Figure 12

The coils generate "impulses" (*i.e.*, "magnetic stimulus") to cause muscle contractions. '295, 6:66–7:2. Figure 8 shows that these impulses are biphasic and sinusoidal. Bikson, ¶103.

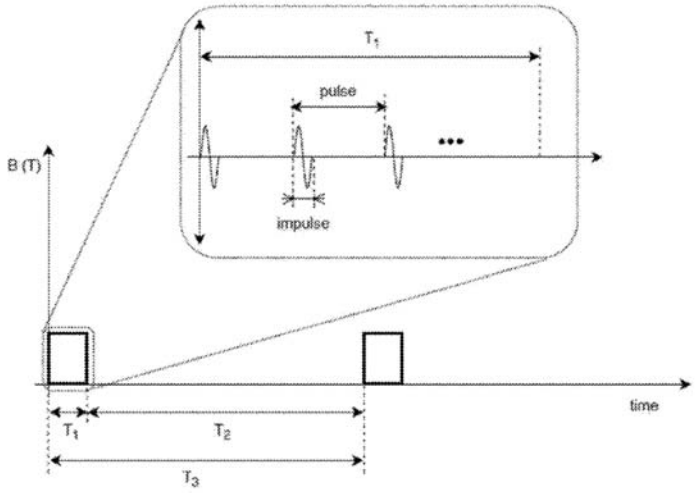


Figure 8

'295, Fig. 8, 6:66–7:2, 105:26–29. A "pulse" is defined by the period of treatment

between the beginning of a first impulse and the beginning of a second impulse. ’295, 7:3–6. The magnetic field is applied by the magnetic field device including the coil. ’295, 3:31–33, 8:4–6. Bikson, ¶103.

The device includes a “control unit” to regulate the magnetic field and radiofrequency generations, and uses a “casing” with a “cooling media” for the applicators. ’295, 10:21–25, 15:1–6, 20:23–26, 25:51–54. Figure 2 shows a cross-section of a magnetic applicator using a “blower 4” that allows better air flow (as indicated by arrows 6) on the lower and upper sides of magnetic field generative device and thus more efficient heat dissipation. ’295, 9:57-60, 10:36-47. Bikson, ¶104.

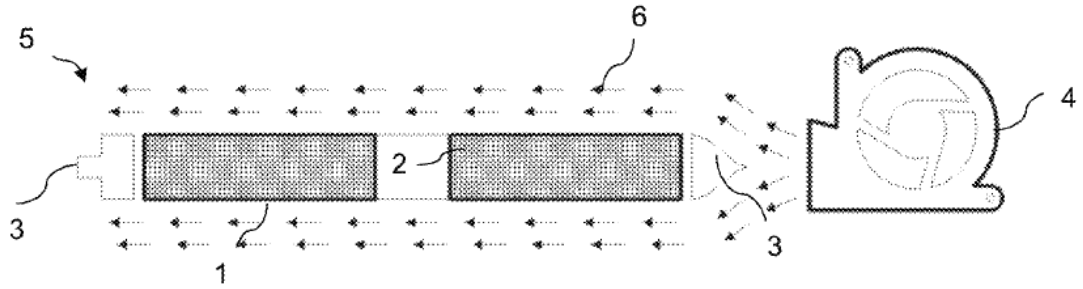


Figure 2

The ’295 patent further discloses positioning applicators on target body regions using a “length adjustable belt.” ’295, 11:16–21, Figs. 15–16. Bikson, ¶105.

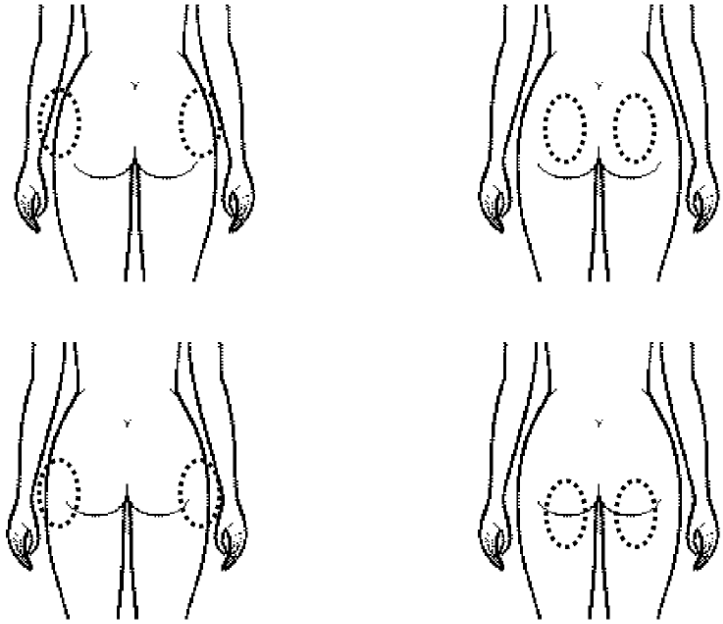


Figure 15

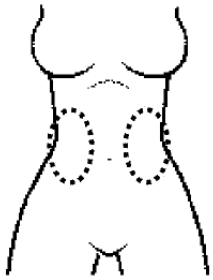


Figure 16

B. Prosecution History

'295 issued from U.S. Application No. 16/266,570, filed 2/4/2019. Ex-1003, 1-126. Applicant filed a Preliminary Amendment 2/25/2019, amending claim 1 and adding 29 other claims. Ex-1003, 127–136. Track 1, prioritized status was granted 2/27/2019. Ex-1003, 141–142.

Examiner issued an Office Action on 4/18/2019, rejecting pending claims as anticipated by Edoute (US2011/0130618) ("Edoute-'618") and obvious over Edoute-'618 in view of Hallgren (US3,841,306). Ex-1003, 152-161. The Examiner indicated that Edoute-'618 taught every limitation of independent claim 1, except for "an energy storage device," and found that it would have been

obvious to combine Edoute-'618 with Hallgren's signal generator including a capacitor—*i.e.*, "an energy storage device." Ex-1003, 158. Bikson, ¶¶106-107.

On 7/18/2019, in response to the Examiner's rejection, Applicant argued that the Examiner failed to provide any rationale to modify Edoute-'618 in view of Hallgren to "include such an energy storage device." Ex-1003, 185. Applicant amended independent claim 1 to further recite values for the magnetic field's repetition rate and magnetic flux density, and applying magnetic field to cause a muscle to contract, and argued that these features were not disclosed in Edoute-'618. Ex-1003, 175, 186-188. The Examiner allowed the claims 11/20/2019. Ex-1003, 210–216. Subsequently, Applicant amended the claims, specification, and figures on 2/20/2020 and 8/21/2020. Ex-1003, 252–262, 373–389. Bikson, ¶108.

The table below summarizes, for each issued independent claim, the features Applicant argued as not taught in the prior art during an amendment, and the features Examiner found to be missing in the prior art in allowing the claims. *See* Ex-1003, 160, 185-188. Bikson, ¶109.

Independent Claims	Applicant Arguments in an Amendment: Prior Art does not teach	Reasons for Allowance: Prior Art does not teach
1	Specific repetition rate, specific magnetic field density, causing muscles to contract	--
8	--	Specific magnetic flux density derivative
15	--	Specific magnetic flux density derivative
23	Specific coil inductance	--

C. § 325(d) is inapplicable

All grounds contain at least one of these references—**Simon** and **Park** were not before the Examiner. **Burnett-'870** and **Zarsky** were cited in an IDS, but not otherwise identified or applied to reject claims during prosecution. Ex-1003, 226; *see Digital Check Corp. v. E-Imagedata Corp.*, IPR2017-00178, Pap. 6, 12-13 (Apr. 25, 2017) (instituting IPR where references were cited in an IDS but "there is no indication in the record that the Examiner rejected any claims based on either reference or that the Examiner or applicant substantively discussed either reference during prosecution").

Edoute was cited in an IDS. A related patent (Edoute-'618) was applied as

the primary reference[3] in an obviousness combination with another reference, which Applicant argued Edoute-'618 as lacking disclosure for a capacitor and there was no motivation to combine with another reference that discloses a capacitor. The Applicant further distinguished Edoute-'618 on the basis that it does not teach various magnetic field parameters and applying magnetic field causing muscles to contract. *See* §V.B. The Examiner never considered the testimony of Dr. Bikson (Ex-1002) regarding these references. Ex-1003.

Importantly, the Examiner failed to consider and apply the references and/or combinations presented herein that teach the recited features and rationale Applicant argued, or Examiner found, to be missing in the prior art. Both **Simon** and **Burnett-'870**, applied here as primary references in separate grounds, disclose a capacitor (*i.e.,* the recited "energy storage device"), which Applicant argued to be missing in Edoute-'618. *See* §V.B. Referring to the table in §V.B above, **Simon** and **Burnett-'870** disclose the various magnetic field parameters and applying magnetic field to cause muscles to contract, which Applicant argued to be missing in Edoute-'618. *Id.* The Examiner erred by (1) applying Edoute-'618 as the primary reference, and (2) never combining **Simon** in view of Edoute-'618. The Examine further erred by failing to consider that the recited very broad range of

[3] Here, **Edoute** is applied as a secondary reference to **Simon** that was not before the Examiner.

coil inductance was known and conventional and within a POSITA knowledge. *See* §VIII. **Simon** and **Burnett-'870** further disclose the recited magnetic flux density derivative, which the Examiner found to be missing in prior art. *Id*. Moreover, **Zarsky** discloses a balun transformer and a transmatch recited in dependent claims. *Id*. **Park** provides the rationale not before the Examiner on why a POSITA would modify a magnetic device to incorporate the teachings of radiofrequency electrode and application in a combined treatment. *Id.*

Accordingly, the "same or substantially the same art or arguments" were not previously presented to the Office during prosecution. *Thorne Research v. Trustees of Dartmouth College*, IPR2021-00491, Pap. 18, *8-9 (PTAB Aug. 12, 2021) (granting institution; finding first prong of *Advanced Bionics* not satisfied when prior art reference considered by Examiner was combined with references not cited during prosecution); *Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GMBH*, IPR2019-01469, Pap. 6, *8-9.

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, ¶¶1-40.

VII. CLAIM CONSTRUCTION

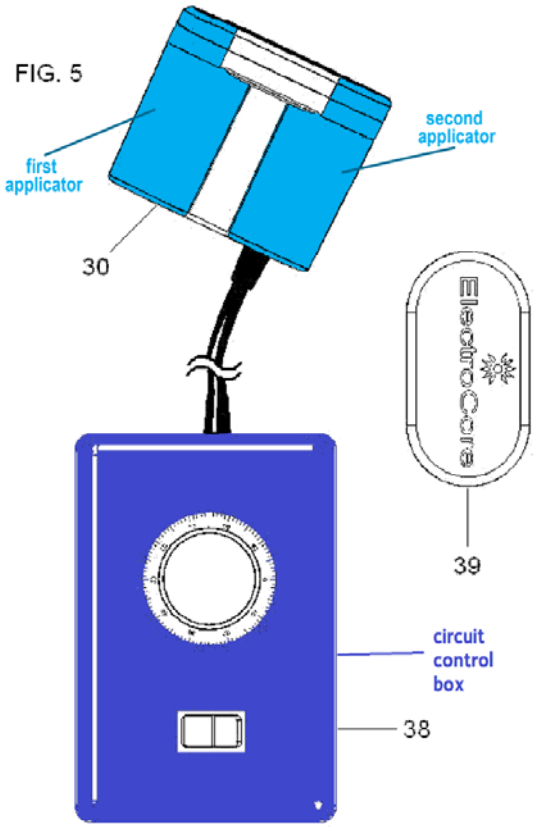
Claim terms subject to IPR are to be construed according to the *Phillips* standard applied in district court. §42.100(b). Petitioner applies the plain and ordinary meanings of terms. Only terms necessary to resolve the controversy must be construed. *Nidec Motor v. Zhongshan Broad Ocean Motor*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). Bikson, ¶¶110-111.

VIII. GROUNDS OF UNPATENTABILITY

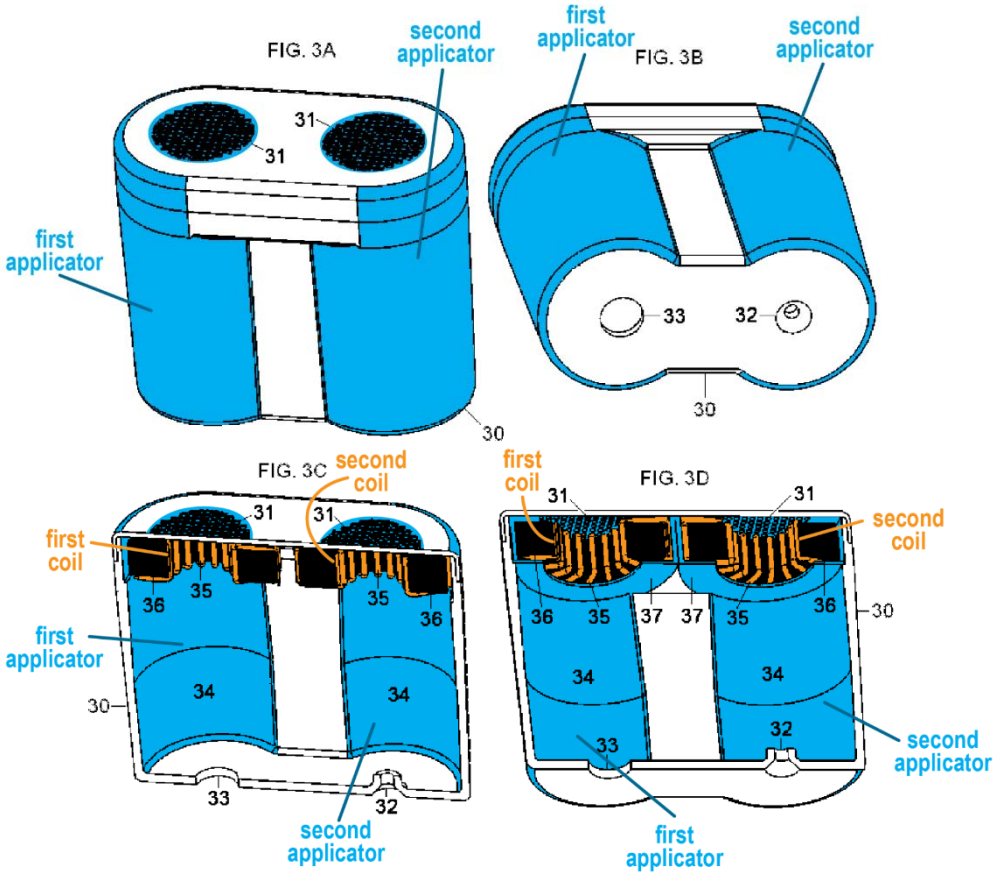
A. Ground 1: Claims 8, 11-17, 20-22 are rendered obvious by Simon in view of Edoute

1. Simon Overview

Simon discloses a magnetic stimulator used to deliver "energy" to "target tissue," *e.g.*, for muscle "[r]ehabilitation." Simon, *Title*, *Abstract*, [0002], [0197].



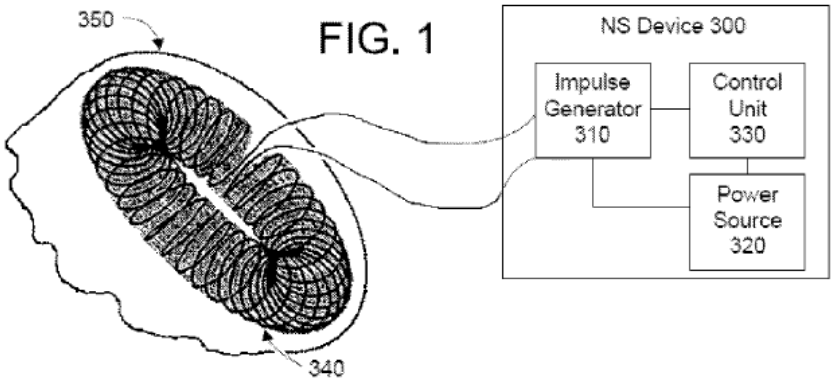
Simon, Fig. 5, [0103]. Figures 3A-3D (annotated) show **Simon's** stimulator with two **applicators** situated within a "housing," each **applicator** containing a "**coil**" that generates a time-varying magnetic field when a capacitor is "discharged." Simon, [0012], [0045], [0047], [0098]. Bikson, ¶¶112-113.



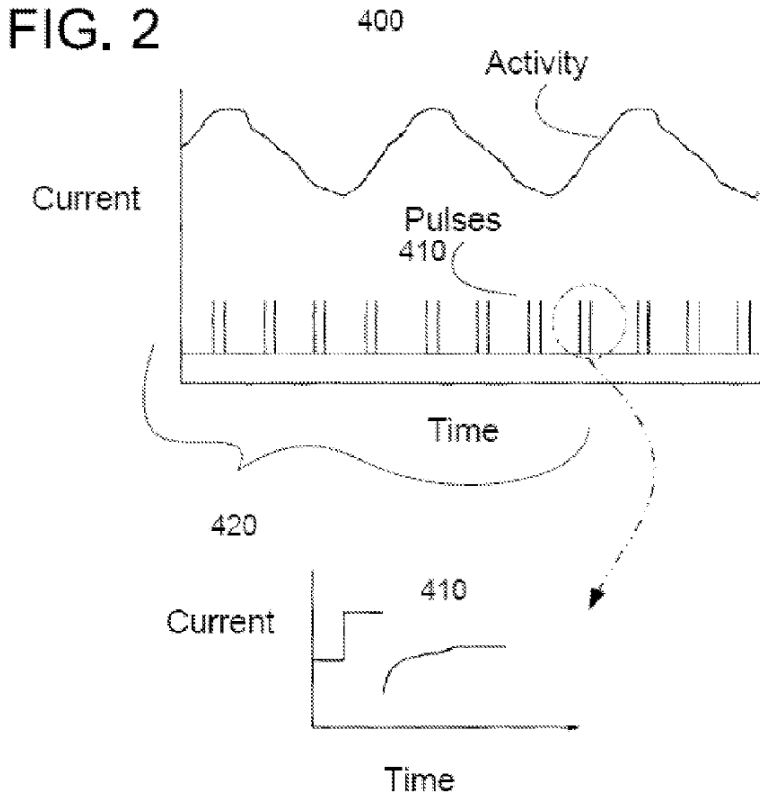
Each **coil** "induces an electromagnetic field" to apply "electrical impulses" to muscles within target body regions (*e.g.*, abdomen). Simon, [0024], [0027]-[0028], [0035], [0053]. Simon's stimulator may contain more than two **applicators**, with varying shapes and configurations for different applications based on the "anatomical location of the stimulation and determining the appropriate pulse configuration." Simon, [0031], [0100]-[0102], Fig. 4C-4D. Bikson, ¶¶114-115

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, ¶116.



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 power level, frequency, pulse amplitude, and repetition rate. Simon, [0059], [0063]-[0064], [0104]. Bikson, ¶117. Moreover, **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, ¶¶118-120.

Simon discusses the "Agilent 33522A Function/Arbitrary Waveform Generator," which is a HF (30MHz) generator—see Simon [0057], Bikson ¶121—but to the extent argued **Simon** lacks a detailed disclosure of a high-frequency generator and radiofrequency electrode configured to apply radiofrequency waves

to a patient, heating tissue, a POSITA would have found it obvious to modify **Simon**'s device to do so for the reasons discussed below in §VIII.A.3; VIII.D—*e.g.*, as the '295 patent concedes, RF stimulation was known. '295, 2:17-27. Indeed, it was also 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]; Park, [0029]-[0030], [0034]-[0036] (describing benefits when combining radiofrequency-and-magnetic treatment). Such modification would predictably work and provide the expected functionality given that **Simon** already discloses a device with applicators to provide tissue treatment, and radiofrequency electrodes may be utilized within the applicators. Simon, [0012], [0045], [0047], [0098]. Bikson, ¶121.

2. Edoute Overview

Edoute is directed to a device for "simultaneously emit[ting] RF and magnetic pulses" to target body regions for *e.g.*, "muscle contractions." Edoute, *Abstract*, [0328], [0243]. **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":

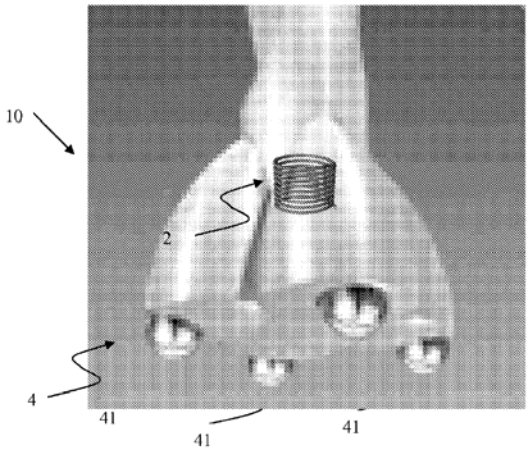


FIG. 1B

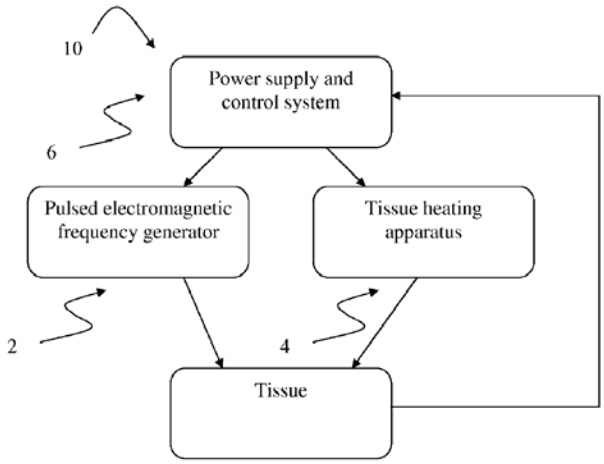


FIG. 2

Edoute, Figs. 1B, 2, [0015]-[0017], [0098]-[0099], [0197]-[0198]; [0129]-[0130] (various pulse frequencies and durations, *e.g.*, 16 or 25Hz; 5ms duration.) Bikson, ¶122. RF/heat is applied via the "**electrodes**"—"Radio Frequency" is defined as frequencies of 3Hz-30GHz. Edoute, [0021]-[0023], [0165].

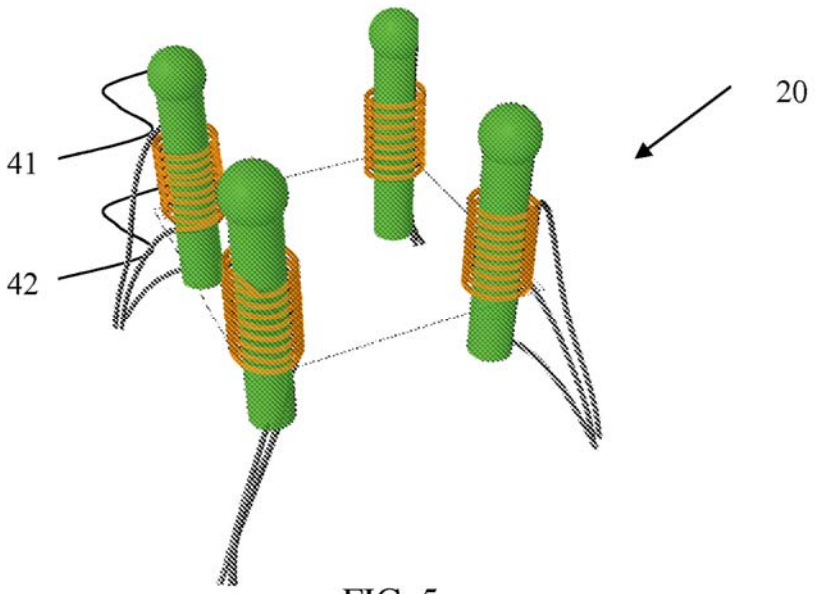


FIG. 5

Edoute, Fig. 5 (color-annotated).

Edoute describes that RF/heating of tissue via electrodes causes "tissue injury" promoting collagen fibers and resulting in "overall tightened and rejuvenated appearance of the skin." Edoute, [0201]-[0207]. Simultaneously, **Edoute's** coil generates pulsed magnetic fields that provide "non-thermal" effects on tissue, *e.g.*, there may be "muscle contractions" during treatment. Edoute, [0006]-[0008], [0041]. **Edoute** discloses a complementary effect on tissue improvement resulting from simultaneous heat (RF) and electromagnetic stimulation. Edoute, [0200] (by exposing "tissue" to "combination of regulated heat and a pulsed electromagnetic [field], a synergic effect of improving skin rejuvenation is obtained"). While **Edoute's** device applies "heat" to patient's skin, it recognizes compatibility with "a mechanism for skin cooling." Edoute, [0117].

Bikson, ¶¶123-124.

3. Motivation to Combine

Simon discusses the "Agilent 33522A Function/Arbitrary Waveform Generator," which is a HF (30MHz) generator—*see* Simon [0057], Bikson ¶125—but lacks a detailed disclosure of radiofrequency treatment generated by a HF generator and applied simultaneously to a body region with **Simon's** magnetic treatment. A POSITA would have been motivated and found it obvious to apply radiofrequency treatment to provide "skin tightening and rejuvenation," improving the overall visual appearance of a patient undergoing muscle toning treatment. *See* Edoute [0196]-[0197]. **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]. **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"). 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]. Such modification would predictably work and provide the expected functionality given that **Simon** already discloses a device with applicators to apply treatment to the body, suggests RF treatment capability, and **Edoute** discloses utilizing a coil and an RF electrode in an applicator to apply simultaneous RF-and-magnetic treatment. 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, ¶¶125-127.

Both **Simon** and **Edoute** are in the same field of endeavor—treatment devices using electromagnetic stimulation of tissue—also analogous art to the '295. **Simon** is directed to a "magnetic stimulation device" for "target tissue" including muscles; **Edoute** is 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*, *Abstract*, [0029]-[0030]; Edoute, *Abstract*, [0010], [0015]-[0017], [0234], [0284]. A POSITA would have recognized **Edoute** provides teachings of radiofrequency waves applied to a patient via a radiofrequency electrode such that a complementary effect is provided (Edoute, [0196]-[0197], [0199]-[0200]); such teachings could be used in **Simon's** treatment device, and applying those teachings would have been straightforward and predictably worked. Bikson, ¶128.

In light of the above, a POSITA would have found it routine, straightforward, and advantageous to apply **Edoute's** known details of radiofrequency treatment teachings to **Simon's** magnetic stimulation device, and would have known such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Bikson, ¶129; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401-02 (2007).

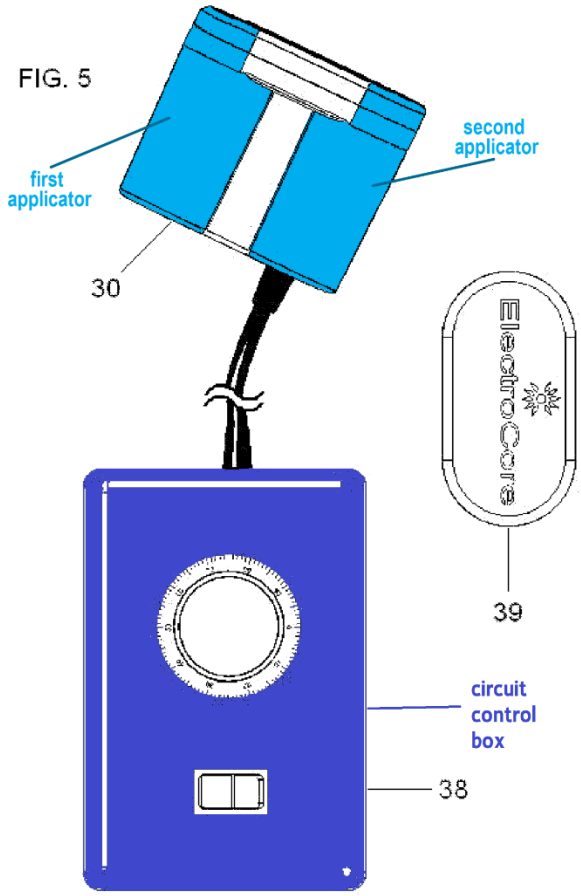
4. Claim Charts

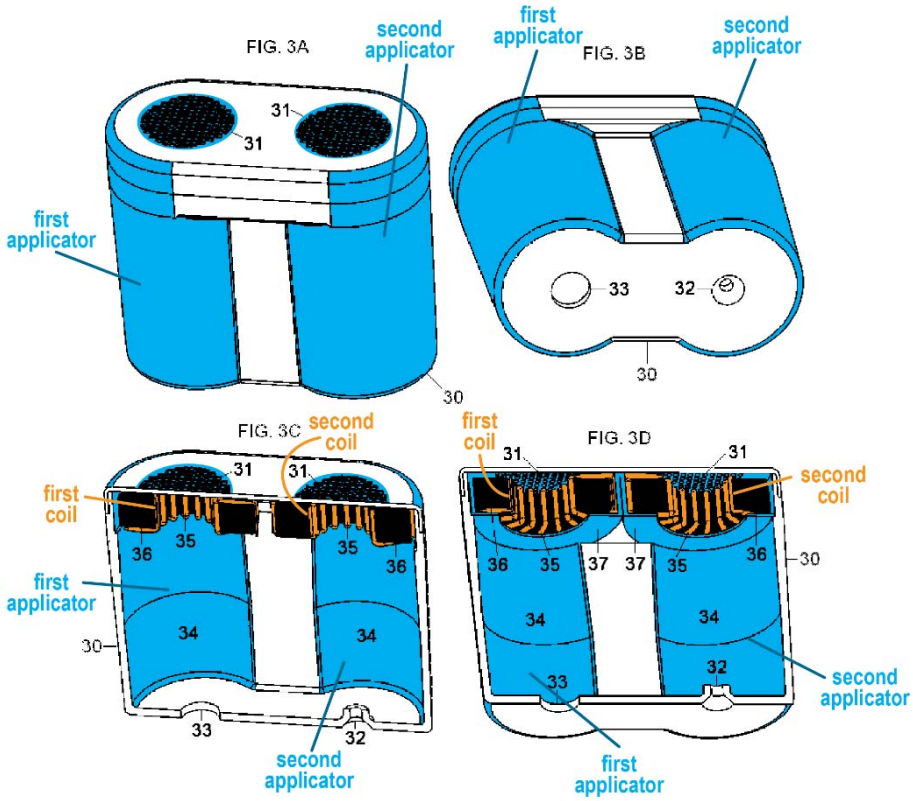
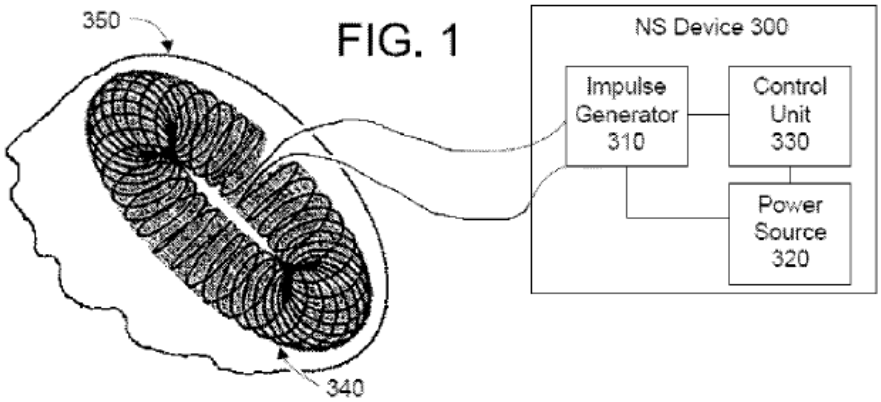
a. Independent Claims 8, 15

Claim Elements	Simon in view of Edoute
[8.pre] A method of patient treatment comprising:	**Simon discloses a method of patient treatment.** **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 ¶¶130-131.
[8.a] providing energy from an	**Simon discloses providing energy from an energy storage device** (*e.g.*, "capacitor in the impulse generator") **to a**

Claim Elements	Simon in view of Edoute
energy storage device to a magnetic field generating device to generate a time-varying magnetic field with a magnetic flux density in a range of 0.1 T to 7 T, a repetition rate in a range of 1 Hz to 300 Hz, with an impulse duration in a range of 3 µs to 1 ms, and a maximal value of a magnetic flux density derivative in a range of 0.3 kT/s to 800 kT/s;[4]	**magnetic field generating device** (*e.g.*, "coil") **to generate a time-varying magnetic field with a magnetic flux density in a range of 0.1 T to 7 T** (*e.g.*, "0.1 to 2 Tesla")**, a repetition rate in a range of 1 Hz to 300 Hz** (*e.g.*, "15 Hz to 50 Hz")**, with an impulse duration in a range of 3 µs to 1 ms** (*e.g.*, "about 50…to about 1000 microseconds")**, and a maximal value of a magnetic flux density derivative in a range of 0.3 kT/s to 800 kT/s** (*e.g.*, 0.63-251 kT/s)**.** **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]. **Simon's** apparatus/device includes a "stimulator 30" containing **applicators** and connected to "**circuit control box** 38":

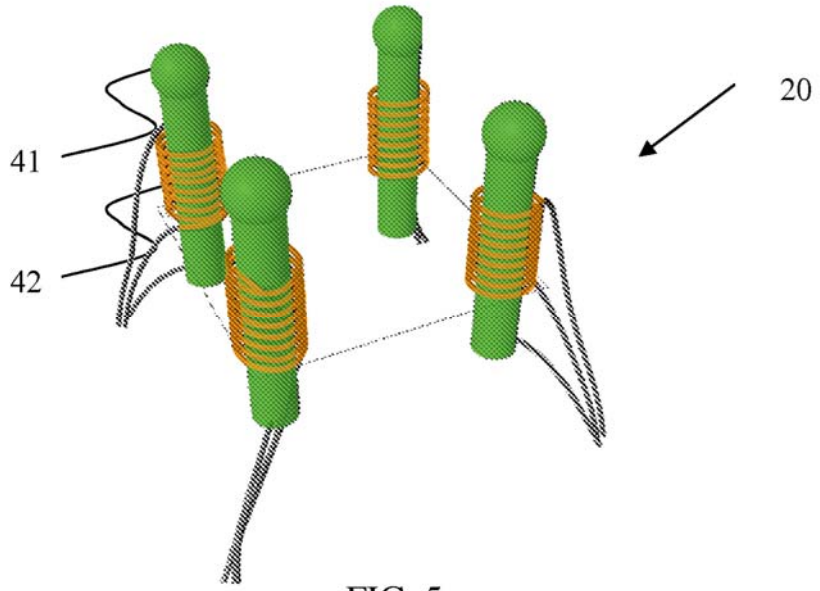
[4] For claim limitations [8.a], [8.c], [11]-[13], [15.b], [15.d], [21] reciting a specific range, the claimed range is obvious in view of prior art's teachings that "overlap or lie inside" the range or even do not overlap but are merely close, absent an explicit showing that the claimed range is critical in achieving unexpected results relative to the prior art's range. MPEP § 2144.05; *see also In re Wertheim,* 541 F.2d 257 (CCPA 1976); *In re Brandt*, 886 F.3d 1171, 1177, (Fed. Cir. 2018). The prior art teaches the claimed range and the '295 specification describes no such unexpected results.

Claim Elements	Simon in view of Edoute
	 Simon, Fig. 5 (annotated); [0103]. The stimulator may have two **applicators** "that lie side-by-side," each containing a "**coil[]**" disposed in "its own housing":

Claim Elements	Simon in view of Edoute
	 Simon, Fig. 3A-D (annotated), [0031], [0098]. **Simon** is not limited to two **applicators**; the shapes and configurations vary based on "anatomical location of the stimulation." Simon, [0031], [0100]-[0102], Fig. 4C-4D. **Simon's** device is charged via "an impulse generator" coupled to a "power source" and "control unit":  Simon, Fig. 1, [0054].

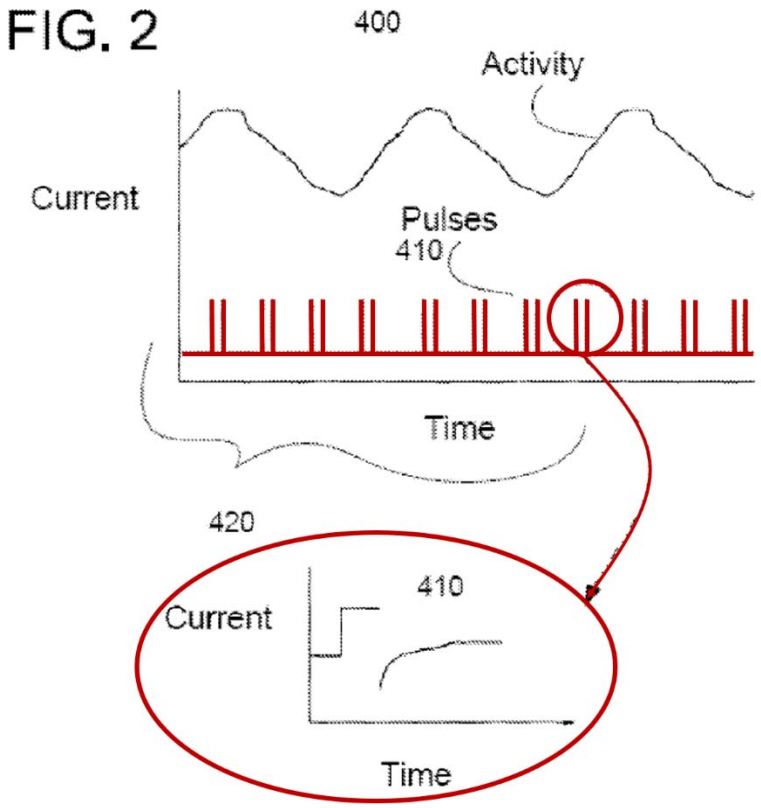
Claim Elements	Simon in view of Edoute
	The "impulse generator" contains "a capacitor," which stores energy when "[charged]…under the control of a control unit." Simon, [0019]. A capacitor is "discharged" through each coil when a user wishes to "apply [a] stimulus." Simon, [0019], [0025]. **Simon** discloses "amplitude, duration, repetition rate" are "adjustable." Simon, [0020], [0063]. **Simon** discloses a "pulse duration"/"impulse[]…duration" of each electrical impulse, *e.g.*, "about 50…to about 1000 microseconds" or "50…to about 400 microseconds." Simon, cls. 9-10; [0030], [0033], [0104]. **Simon** discloses "modulating impulse signal" at a "frequency" (i.e., repetition rate) "about 1 Hz or greater, such as between about 15 Hz to 50 Hz". Simon, [0064]; *see also id.*, [0030], [0033], cl. 8. Herbst, incorporated into **Simon**, additionally discloses setting repetition rates for multiple output channels. Herbst, [0037]. Bikson, ¶¶94-95. **Simon** discloses that "current passing through the coil produces a magnetic field within the core of about 0.1 to 2 Tesla." Simon, [0030], [0104]. 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. Because magnetic field flux density derivative is calculated using flux density and impulse duration, **Simon's** device yields a range of 0.63-251 kT/s, falling within the claimed range as was well-known in the art. *See, e.g.*, Magstim 3-4

Claim Elements	Simon in view of Edoute
	(4T; 100µs-1ms ranges yield flux derivative range of 25.12-251.2 kT/s). Bikson, ¶¶132-150.
[8.b] applying the time-varying magnetic field to muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within a body region of a patient such that a muscle of the patient is caused to contract;	**Simon discloses applying the time-varying magnetic field to muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within a body region of a patient** (*e.g.*, "abdomen") **such that a muscle of the patient is caused to contract.** *See* [8.a]—**Simon** discloses placing applicators on abdomen (Simon, [0035]), which comprises multiple muscles. The resulting consecutive "electrical impulses" stimulate muscles/tissues. Simon, *Abstract*, [0012], [0053], [0060]-[0061], [0083], [0105], Fig. 2. Bikson, ¶¶151-152, 43-71.
[8.c] generating radiofrequency waves with a frequency in a range of 500 kHz to 3 GHz; and	**Simon in view of Edoute teaches generating radiofrequency waves with a frequency in a range of 500 kHz to 3 GHz** (*e.g.*, Edoute's "3 Hz to 300 GHz")**.** **Simon** discusses the "Agilent 33522A Function/Arbitrary Waveform Generator," which is a HF generator used to generate radiofrequency waves (*e.g.*, 30MHz frequency). Simon, [0057], Bikson 121. It was known that high-frequency encompasses radiofrequency. *See, e.g.,* '295, 26:13-19 ("HF…generator" provides "energy for radiofrequency treatment"). **Simon** discloses a two-applicator embodiment where one applicator may be used for RF and the second coil may be used for magnetic treatment. Simon, Fig. 5, [0031], [0055], [0078]-[0079]. The '295 concedes that a "coil [may] be the electrode for radiofrequency treatment," and Simon discloses each applicator contains a "coil," such that one coil may be used for RF. Simon, [0031] ("two…coils"), [0098]; '295, 26:42-44; Bikson, ¶¶77-79.

Claim Elements	Simon in view of Edoute
	Simon additionally discloses electrodes which may be used for radiofrequency treatment when connected to the HF generator. **Simon** recognizes using "electrodes" on the "surface of the skin…without breaking the skin" for treatment. Simon, [0014]. To the extent argued that Simon does not disclose this limitation, **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]. As shown in Fig. 5, **Edoute's** device contains a high-frequency generator, *i.e.* "electrical output device" to "generate RF…energy" as well as "**electrodes**" placed on a region of a patient to "apply said RF energy." Edoute, [0021]-[0023]. **Edoute's** "electrical output device" is the claimed "HF…generator" which, in the '295, "provid[es] energy for radiofrequency treatment." '295, 26:13-19. Indeed, **Edoute's** electrical output device may operate in high-frequency ranges; **Edoute** defines "Radio Frequency (RF)" as being between 3Hz-30GHz. Edoute. [0165].  FIG. 5

Claim Elements	Simon in view of Edoute
	POSITAs would have been motivated and found it obvious to apply **Edoute's** simultaneous RF-and-magnetic stimulation teaching to **Simon's** device to increase skin tightness when toning muscles in order to improve 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] (application of RF/heat leads to "overall tightened and rejuvenated appearance of the skin"); Sokolowski, [0003]-[0005] ("stimulation leads to a breakdown of fatty tissue"). Bikson, ¶¶72-75. 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]. *See* §VIII.A.3. Bikson, ¶¶153-159.
[8.d] applying the radiofrequency waves to the patient to cause heating of a biological structure of the patient.	**Simon in view of Edoute teaches applying the radiofrequency waves to the patient to cause heating of a biological structure of the patient.** *See* [8.c]—**Simon** discloses applying treatment to a "patient," *e.g.*, on the "abdomen." Simon, *Abstract*, [0015], [0023]-[0024], [0035]-[0036], [0053]. Moreover, **Edoute** discloses applying "RF radiation," *e.g.*, via "electrodes," *e.g.*, to a patient's "dermis" causing heating. Edoute, [0013], [0015]-[0017], [0020], [0236]-[0238]. **Edoute** discloses that heat application using RF waves may "cause[] contraction and tightening of collagen fibers" or collagen production, "result[ing] in an overall tightened and rejuvenated appearance of the skin." Edoute, [0201]. POSITAs would have been motivated and found it obvious to apply **Edoute's** RF-and-magnetic stimulation teaching in

Claim Elements	Simon in view of Edoute
	implementing **Simon's** device for the benefit of a combined treatment for the reasons listed in [1.c]. *See also* §VIII.A.3. **Edoute** indicates that pulsed radiofrequency treatments were approved for use on patients by the FDA "two decades" prior to **Edoute's** priority date. Edoute, [0008]. Bikson, ¶¶160-163.
[15.pre] A method of patient treatment comprising:	**Simon discloses a method of patient treatment.** *See* [8.pre]. Bikson, ¶¶164-165.
[15.a] providing energy from an energy storage device to a magnetic field generating device;	**Simon discloses providing energy from an energy storage device** (*e.g.*, "capacitor in the impulse generator") **to a magnetic field generating device** (*e.g.*, "coil")**.** *See* [8.a]. Bikson, ¶¶166-167.
[15.b] generating, by the magnetic field generating device, a time-varying magnetic field having a plurality of magnetic pulses with a magnetic flux density in a range of 0.1 Tesla to 7 Tesla, a maximal value of a magnetic flux density derivative in a range of 300 T/s to 800 kT/s, and a repetition	**Simon discloses generating, by the magnetic field generating device** (*e.g.*, "coil")**, a time-varying magnetic field having a plurality of magnetic pulses with a magnetic flux density in a range of 0.1 Tesla to 7 Tesla** (*e.g.*, "0.1 to 2 Tesla")**, a maximal value of a magnetic flux density derivative in a range of 300 T/s to 800 kT/s, and a repetition rate in a range of 1 Hz to 300 Hz** (*e.g.*, "15 Hz to 50 Hz")**.** *See* [8.pre]—**Simon** discloses using "a bank of capacitors," *i.e.*, charging multiple energy storage devices for "[g]reater flexibility" such that they are discharged "at different times" or "sequentially" to generate multiple, and serial pulses as demanded for varying treatment options. Simon, [0019], [0063]. Moreover, as illustrated in Fig. 2, **Simon** discloses a plurality of "pulses"/"impulse[s]" 410:

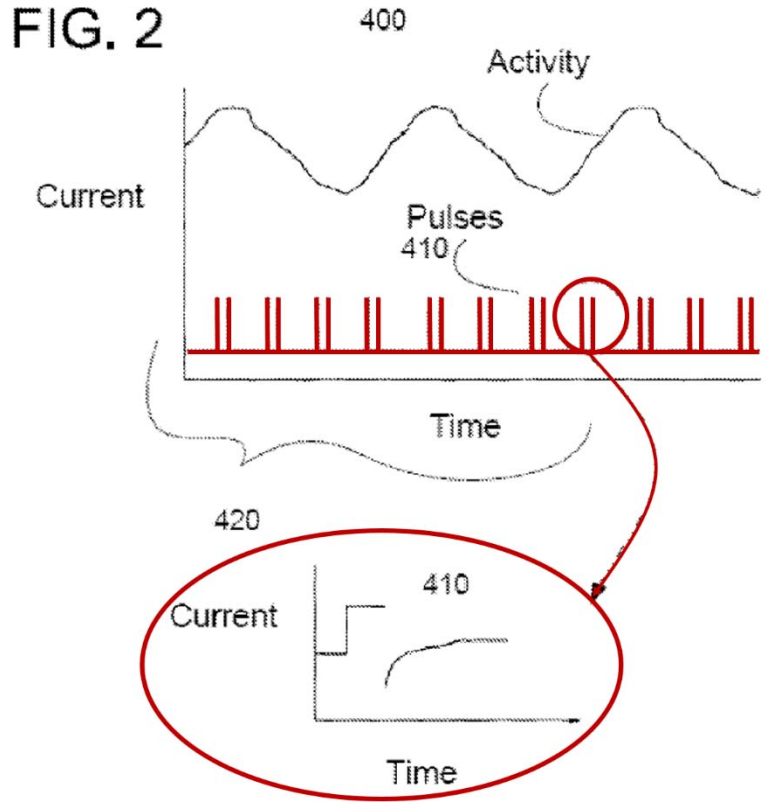
Claim Elements	Simon in view of Edoute
rate in a range of 1 Hz to 300 Hz;	 Simon, Fig. 2, [0060]-[0061] **Simon** discloses "impulse rates," a "selected frequency range," and a "modulating impulse," each of which POSITAs would have understood to require a plurality of consecutive impulses. Simon, [0019], [0063]-[0064], [0060]-[0061], [0156]. Bikson, ¶¶168-171, 84-96.
[15.c] applying the plurality of magnetic pulses of the time-varying magnetic field to muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers	**Simon discloses applying the plurality of magnetic pulses of the time-varying magnetic field to muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within a body region of a patient** (*e.g.*, "abdomen") **such that a muscle is caused to contract.** *See* [8.b]. Bikson, ¶¶172-173.

Claim Elements	Simon in view of Edoute
within a body region of a patient such that a muscle is caused to contract;	
[15.d] generating radiofrequency waves by an HF generator and providing the radiofrequency waves in a range of 500 kHz to 3 GHz to a radiofrequency electrode; and	**Simon in view of Edoute teaches generating radiofrequency waves by an HF generator** (*e.g.*, Edoute's "electrical output device") **and providing the radiofrequency waves in a range of 500 kHz to 3 GHz** (*e.g.*, Edoute's "3 Hz to 300 GHz") **to a radiofrequency electrode** (*e.g.*, Edoute's "electrode[]")**.** *See* [8.c]. Bikson, ¶¶174-175.
[15.e] applying the radiofrequency waves to the patient,	**Simon in view of Edoute teaches applying the radiofrequency waves to the patient.** *See* [8.d]. Bikson, ¶¶176-177.
[15.f] heating a target biological structure of the patient by the radiofrequency waves.	**Simon in view of Edoute teaches applying the radiofrequency waves to the patient.** *See* [8.d]. Bikson, ¶¶178-179.

b. Dependent Claims 11-14, 16-17, 20-22

Claim Elements	Simon in view of Edoute
[11] The method of treatment of claim 8, wherein the energy storage device has a capacitance in a	**Simon teaches the energy storage device** (*e.g.,* "capacitor") **has a capacitance in a range of 5 nF to 100 mF; and wherein the magnetic field generating device** (*e.g.*, "coil") **has an inductance in a range of 1 nH to 50 mH.**

Claim Elements	Simon in view of Edoute
range of 5 nF to 100 mF; and wherein the magnetic field generating device has an inductance in a range of 1 nH to 50 mH.	*See* [8.a]—**Simon** leaves it to a POSITA to choose a specific coil inductance, and it was well-known to use coils with inductance in the claimed range. *E.g.*, Ishikawa, [0008] (coil inductance "10~50 μH"); Magstim, 4 (exemplary coil inductances of 13.5, 16, 23.5 μH). Furthermore, **Simon** leaves it to POSITAs to choose a capacitor, and using a capacitor with the broad claimed range of capacitance in a stimulator was known in the art. For example, **Simon** cites Epstein as an exemplary "magnetic stimulator[] circuit," including capacitors with capacitance of "at least 50 uF," (0.05mF). Epstein, 8:19-22; Burnett-'585, [0071] (capacitance of "at least 5,000 microfarads": 5mF). Bikson, ¶¶180-182.
[12] The method of treatment of claim 8, wherein the step of applying the radiofrequency waves heats the biological structure of the patient to a temperature in a range of 37° C. to 60° C.	**Simon in view of Edoute teaches the step of applying the radiofrequency waves heats the biological structure of the patient to a temperature in a range of 37° C. to 60° C** (*e.g.*, Edoute's "30 to about 80 degrees")**.** *See* [8.b]-[8.d]—**Edoute** discloses selecting a temperature "from a region about 30 to about 80 degrees," further indicating that these temperatures in Celsius fall within the "safe" treatment range. Edoute, [0084], [0241] (listing "safe treatment parameters" in Celsius). [0261]. **Edoute** describes "temperature T" as the temperature to which tissue is heated. Edoute, [0035]; §VIII.A.3. Bikson, ¶¶183-184.
[13.a] The method of treatment of claim 8, further comprising: assembling magnetic pulses of the time-varying magnetic field into a train lasting in a range of 1 second to 30 seconds; and	**Simon discloses assembling magnetic pulses of the time-varying magnetic field into a train lasting in a range of 1 second to 30 seconds** (*e.g.*, "10 seconds on")**.** *See* [8.a]-[8.b]—**Simon** discloses a plurality of consecutive "impulse[s] 410" to produce a "pulse train 420 to the stimulator coil(s)" to deliver a "stimulating, blocking and/or modulating impulse," resulting in biological activity such as tissue stimulation in a patient:

Claim Elements	Simon in view of Edoute
	 Simon, Fig. 2, [0060]-[0061]. **Simon** discloses an adjustable "duty cycle," *i.e.* stimulation on/off ratio indicating trains are followed by relaxation periods, and acknowledges a "10 seconds on, 10 seconds off" treatment cycle wherein a 10-second train is followed by a 10-second relaxation period. Simon, [0062], [0064], [0111]. Bikson, ¶¶185-188, 91-96.
[13.b] generating no magnetic pulses of the time-varying magnetic field for a time period in a range of 1 second to 7 seconds after a last magnetic pulse of the train	**Simon discloses generating no magnetic pulses of the time-varying magnetic field for a time period in a range of 1 second to 7 seconds** (*e.g.*, "10 seconds off") **after a last magnetic pulse of the train to establish a burst.** *See* [8.a], [13.a]—**Simon** acknowledges a "10 seconds on, 10 seconds off" treatment cycle wherein a 10-second train is followed by a 10-second relaxation period. Simon, [0062], [0064], [0111]. Bikson, ¶¶189-190, 94-95.

Claim Elements	Simon in view of Edoute
to establish a burst; and	
[13.c] applying the train to the muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within the body region of the patient such that the muscle is caused to contract.	**Simon discloses applying the train to the muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within the body region of the patient such that the muscle is caused to contract.** *See* [8.a]-[8.b]. Bikson, ¶¶191-192, 59-71.
[14] The method of treatment of claim 8, wherein the step of applying the time-varying magnetic field causes a repetitive contraction of at least one muscle selected from a group comprising: a) rectus abdominis muscle, external oblique muscle, internal oblique muscle and/or transversus abdominis; or b) gluteus maximus muscle, gluteus medius muscle and/or gluteus	**Simon discloses the step of applying the time-varying magnetic field causes a repetitive contraction of at least one muscle selected from a group comprising: a) rectus abdominis muscle, external oblique muscle, internal oblique muscle and/or transversus abdominis.** *See* [8.a]-[8.b]—consecutive impulses cause repetitive muscle contractions. Moreover, "abdomen" comprises "rectus abdominis," abdominal internal/external obliques, transverse abdominal, and pyramidalis. Simon, [0175]. Bikson, ¶¶193-194, 59-71.

Claim Elements	Simon in view of Edoute
minimus muscle; or c) m. biceps femoris, m. semimembranosus, m. semitendinosus, tensor fascia latae muscle, vastus lateralis muscle, iliotibial muscle and/or m. triceps surae.	
[16.a] The method of treatment of claim 15, further comprising: assembling the plurality of magnetic pulses of the time-varying magnetic field into a train; and	**Simon discloses assembling the plurality of magnetic pulses of the time-varying magnetic field into a train** (*e.g.*, "pulse train")**.** *See* [13.a]. Bikson, ¶¶195-196, 91-93.
[16.b] applying the train to the muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within the body region of the patient such that a muscle is caused to contract.	**Simon discloses applying the train to the muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within the body region of the patient such that the muscle is caused to contract.** *See* [8.a]-[8.b], [13.c]. Bikson, ¶¶197-198.
[17] The method of treatment of	**Simon discloses cooling the magnetic field generating device.**

Claim Elements	Simon in view of Edoute
claim 15, further comprising cooling the magnetic field generating device.	Simon discloses that "coils . . . overheat . . . over an extended period of time" and recognizes that as a result, magnetic stimulation devices and coils often need cooling. Simon, [0020]. Simon then discloses that cooling solutions already existed, and were well-known in the art – *e.g.*, it was known to "cool the coils with flowing water or air" or with "ferrofluids," -- known to be oil-based – and oil itself was also well known as a coolant for magnetic stimulation devices. Simon, [0020] (citing Ghiron). Bikson, ¶¶199-201, 86-90.
[20] The method of treatment of claim 15, wherein the step of applying the time-varying magnetic field causes a repetitive contraction of at least one muscle selected from a group consisting of: a) rectus abdominis muscle, external oblique muscle, internal oblique muscle and/or transversus abdominis; or b) gluteus maximus muscle, gluteus medius muscle and/or gluteus minimus muscle; or c) m. biceps femoris, m. semimembrano	**Simon discloses the step of applying the time-varying magnetic field causes a repetitive contraction of at least one muscle selected from a group consisting of: a) rectus abdominis muscle, external oblique muscle, internal oblique muscle and/or transversus abdominis.** *See* [8.a]-[8.b], [14]—"abdomen" comprises "rectus abdominis," abdominal internal/external obliques, transverse abdominal, and pyramidalis. Simon, [0175]. Bikson, ¶¶202-203.

Claim Elements	Simon in view of Edoute
sus, m. semitendinosus, tensor fascia latae muscle, vastus lateralis muscle, iliotibial muscle and/or m. triceps surae.	
[21] The method of treatment of claim 15, wherein the energy storage device has a capacitance in a range of 5 nF to 100 mF; and wherein the magnetic field generating device has an inductance in a range of 1 nH to 50 mH.	**Simon teaches the energy storage device has a capacitance in a range of 5 nF to 100 mF; and wherein the magnetic field generating device has an inductance in a range of 1 nH to 50 mH.** *See* [11]. Bikson, ¶¶204-205.
[22.a] The method of treatment of claim 15, further comprising: generating, by a second magnetic field generating device, a second time-varying magnetic field;	**Simon discloses generating, by a second magnetic field generating device, a second time-varying magnetic field** (*e.g.*, "second time-varying magnetic field")**.** *See* [8.a]—Simon discloses "first and second time-varying magnetic fields" are generated by "first and second coils." Simon, [0025]. Bikson, ¶¶206-207.
[22.b] applying the second time-varying magnetic field to a second group of muscle fibers,	**Simon discloses applying the second time-varying magnetic field to a second group of muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within the body region of the patient such that a second muscle is caused to contract.**

Claim Elements	Simon in view of Edoute
neuromuscular plates, or peripheral nerves innervating muscle fibers within the body region of the patient such that a second muscle is caused to contract.	*See* [8.a], [14]—the "abdomen" comprises multiple muscles. **Simon** recognizes that it was known in the art to position applicators on different muscles like "ulnar edge of the forearm" for one electrode and "abdomen" for another electrode. Simon, [0175]. It was known in the art to treat multiple muscles (abdomen). Simon, [0035]; *See, e.g.,* Belanger, Fig. 13-16 (depicting multiple pairs of applicators "positioned over the quadriceps contractile area"), 246 (position applicators on "two different muscle groups); Burnett-'870, Fig. 9B, [0114] ("abdominal garment" worn over both buttocks). Bikson, ¶¶208-209.

B. Ground 2: Claims 9-10, 18-19 are rendered obvious by Simon in view of Edoute and Zarsky

1. Zarsky Overview

Zarsky is directed to applying electromagnetic energy, specifically radiofrequency, to heat subcutaneous tissues and tightening skin. Zarsky, *Abstract*, [0019]. Figure 1 shows the schematic diagram of a "system 16" with "electrodes 6" for applying radiofrequency to a target body region. Zarsky, [0019], [0024]. Bikson, ¶212.

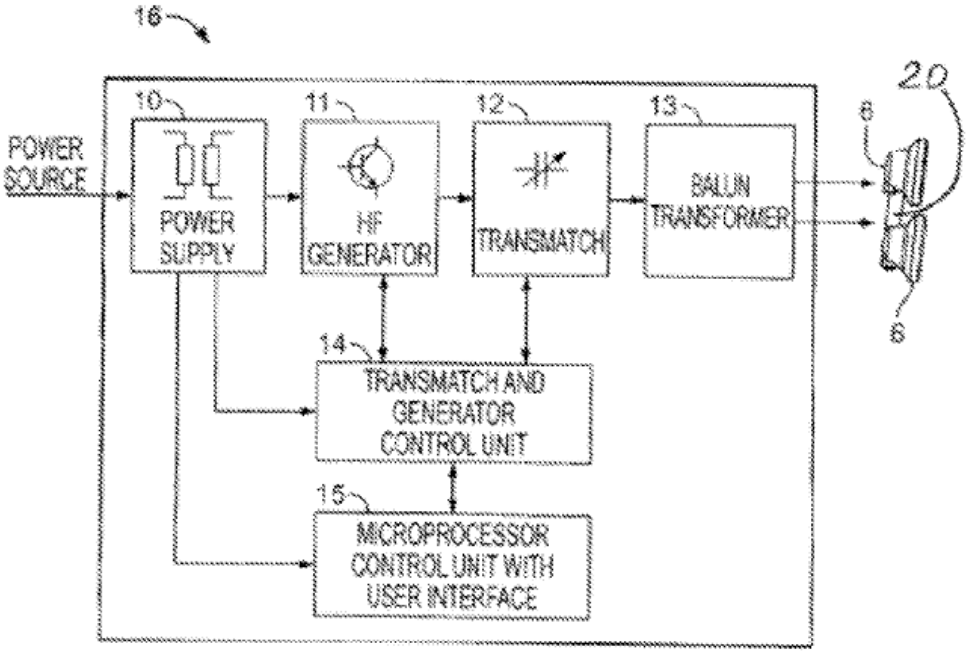


FIG. 1

Figure 1 illustrates high frequency (HF) generator 11 is connected to a power supply 10 receiving energy from a power source, a transmatch 12, and a balun transformer 13, and microprocessor control unit controls generation of the RF waves. Zarsky, [0019]–[0021]; Bikson, ¶213.

2. Discussion

Claims 8 (from which claims 9-10 depend) and 15 (from which 18-19 depend) are rendered obvious by **Simon** in view of **Edoute**—*see* Ground 1; and Claims 9-10, 18-19 is rendered obvious in further view of **Zarsky**. Bikson, ¶214; *see* Ground-5-[30] (describing Zarsky). POSITAs would have been motivated and found it obvious to modify **Simon** in view of **Zarsky's** teachings of an RF circuit in view of **Edoute's** teachings that combined treatment is beneficial. Bikson,

¶214. **Zarsky discloses providing a radiofrequency signal to a balun transformer** (*e.g.*, "Balun Transformer 13") **to convert an unbalanced radiofrequency signal to a balanced radiofrequency signal; and providing a radiofrequency signal to a transmatch** (*e.g.*, "Transmatch 12") **to adjust an impedance of at least one radiofrequency electrode** (*e.g.*, Edoute's "electrode")**.**

Simon discloses its device may "measure impedance" such that the "power of the stimulating coil may be modulated" when impedance changes are detected. Simon, [0185]-[0186], [0195]. As discussed in §VIII.A.3, a POSITA would have been motivated to apply **Edoute's** radiofrequency teachings to **Simon,** utilizing **Zarsky's** teachings of an RF circuit. A POSITA would have understood that a transmatch would be used to conduct "impedance" matching, and a balun transformer would be used to convert unbalanced impedance to balanced impedance, such that treatment parameters based on "tissue impedance" may be modified. Bikson, ¶215, 100-101. **Zarsky** discloses providing energy from "HF [high-frequency] generator" to a "Transmatch 12" for impedance matching to a target body structure, such as skin, and a "Balun Transformer 13," which "converts unbalanced impedance to balanced impedance," as depicted below in Fig. 1:

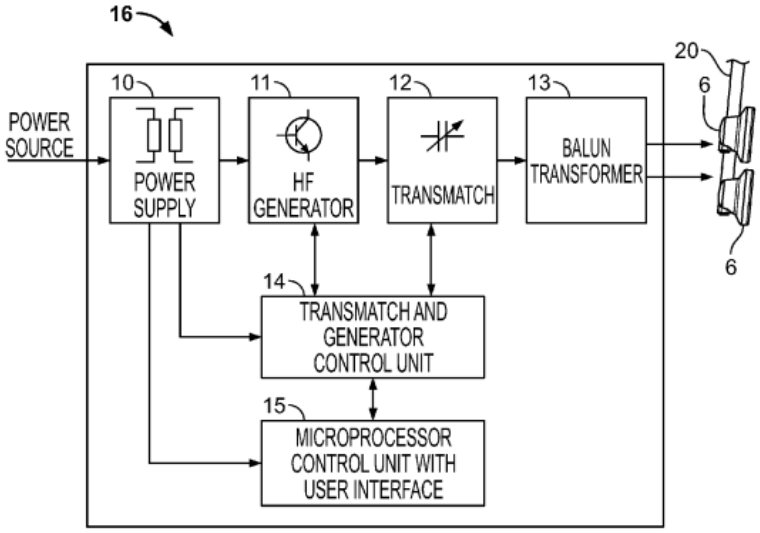


FIG. 1

Zarsky, [0019]-[0021], Fig. 1. Bikson, ¶¶215, 100-101.

Because **Edoute** leaves the implementation details of a radiofrequency circuit to a POSITA, a POSITA would have been motivated to modify **Simon's** treatment device with the teachings of **Zarsky's** known transmatch in a radiofrequency circuit. It was well-known to use a transmatch for impedance matching (*e.g.*, Zarsky, Fig. 6, [0019]-[0021]) and a POSITA would have been motivated to provide the radiofrequency signal of **Simon's** device modified using **Edoute's** teachings to a transmatch in order to adjust an impedance of a radiofrequency electrode to correspond with an impedance of the biological structure of the patient as **Simon** discloses measuring "impedance," *e.g.*, when determining whether to adjust power. Simon, [0195]. A POSITA would have had a reasonable expectation of success in applying **Zarsky's** teachings of a transmatch

to **Simon's** system, allowing **Simon's** device to match impedance of the radiofrequency electrode to the patient's biological structure/skin as **Simon** already discloses measuring impedance. *Id.* Bikson, ¶¶215-217

Moreover, because **Edoute** leaves the implementation details of a radiofrequency circuit to a POSITA, a POSITA would have been motivated to modify **Simon's** device with the teachings of **Zarsky's** balun transformer in a radiofrequency circuit. It was well-known to use a balun transformer to convert an unbalanced radiofrequency signal to a balanced signal. *E.g.*, Choi, [0072] ("[a] variety of types of baluns are well-known in the art…"); [0094] ("balun may be required" to convert "balanced" to "unbalanced" signals in "RF" device). For example, figure 1 of **Zarsky** shows that the "HF Generator 11," which provides energy at "13.56 or 40.68 or 27.12 MHz, or 2.45 GHz," is connected to "Balun Transformer 13," which "converts unbalanced impedance to balanced impedance." Zarsky, [0019], [0021]. A POSITA would have been motivated to provide energy in **Simon's** system to a balun transformer in order to convert an unbalanced to a balanced radiofrequency signal such that it may be supplied to a transmatch for impedance matching purposes, and would have had a reasonable expectation of success in doing so. Choi, [0072], [0094], [0099], Bikson, ¶218, 100-101.

Zarsky is in the same field of endeavor as **Simon, Edoute,** and the '295 (*see* §VIII.A.3): electromagnetic stimulation of a patient's body. Zarsky, *Abstract*,

[0019]. Thus, **Zarsky** is also analogous art to the ’295. **Zarsky** discloses applying radiofrequency via electrodes to a target body region, and discloses a schematic diagram for generating RF energy, including power source, power supply, high frequency generator, transmatch, and balun transformer to provide RF energy to the electrodes. Zarsky, [0019]–[0021], [0024]. A POSITA would have recognized **Zarsky** provides additional circuitry details for radiofrequency stimulation, so utilizing those teachings in **Simon’s** muscle/tissue stimulation device modified by **Edoute’s** RF teachings would have been straightforward and predictably worked. Bikson, ¶219.

POSITAs would have found it routine, straightforward and advantageous to modify **Simon’s** device to apply **Edoute’s** RF teachings (*see* §VIII.A.3) and **Zarsky**’**s** RF-circuit teachings of a transmatch and balun transformer in its design in view of **Simon’s** disclosure of measuring impedance, 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, ¶220.

C. Grounds 3-4: Claims 8, 11-17, 20-22 are rendered obvious by Simon in view of Edoute and Park; Claims 9-10, 18-19 are rendered obvious in further view of Zarsky

1. Park Overview

Park discloses a "wearable energy delivery system" that applies a combination of pulsed electromagnetic field and heat energy for "firming and toning of skin and muscles, and enhanced athletic performance" as shown in Figure 8. Park, *Abstract*, [0004], [0007], [0022], [0027]. Bikson, ¶221.

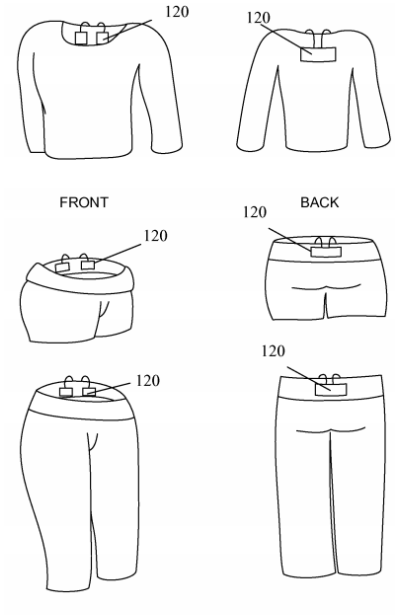


Fig. 8

Park discloses its device that is integrated with an article of clothing delivers a combination of energy such as pulsed electromagnetic field and radio frequency. Park, [0029]. The combination of different energies are beneficial in many ways, including "firming and tightening of skin and muscles, especially in the gluteal, abdominal, and pectoral muscles," and "energizing muscles." Park,

[0030]. For example, pulsed electromagnetic field provides "long-term" and "deeper therapeutic effects" for muscle stimulation; and heat energy, such as radiofrequency, provides "soothing effect to skin and short-term relief." Park, [0034]–[0036]. Bikson, ¶222.

Figures 5A–D (color-annotated) illustrates different configurations of **Park**'s combination device 110 applying magnetic fields through **coils 112** and a heat energy source (*e.g.*, RF) via **electrodes 114**. Park, [0061]–[0065]. Bikson, ¶223.

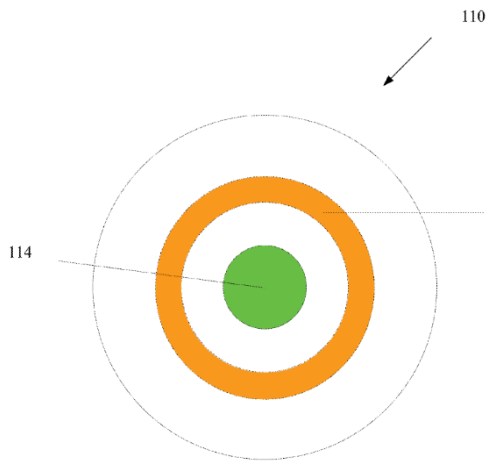


Fig. 5A

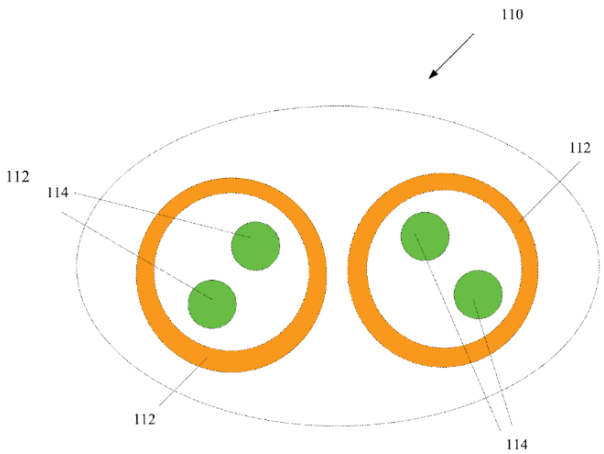


Fig. 5B

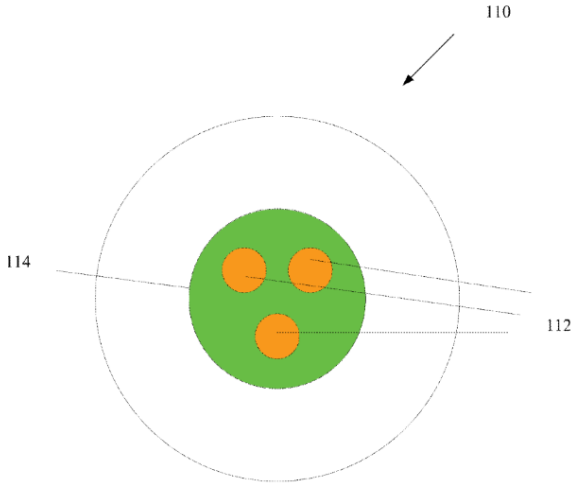


Fig. 5C

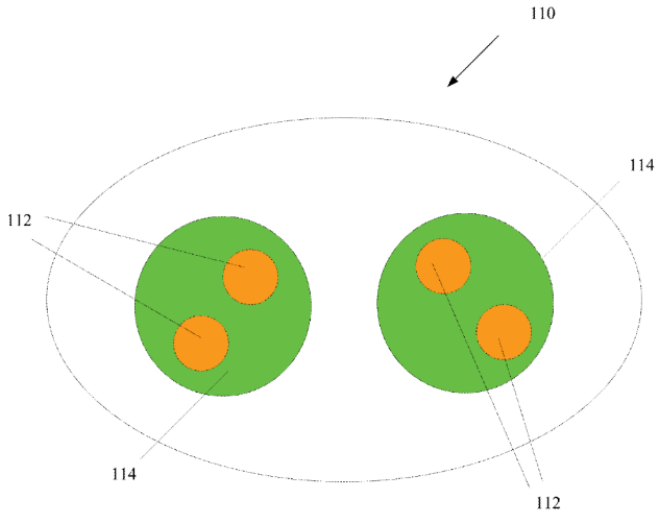


Fig. 5D

2. Discussion

Claims 8, 11-17, 20-22 are rendered obvious by **Simon** in view of **Edoute** for the reasons discussed above—*see* §VIII.A. Claims 9-10, 18-19 are rendered obvious in further view of Zarsky—*see* §VIII.B. POSITAs would further have been motivated and found it obvious to modify **Simon** in view of **Edoute's** radiofrequency teachings in view of **Park's** teachings that the combined RF-and-magnetic treatment is beneficial. Bikson, ¶224.

Park discloses that the combined treatment of pulsed electromagnetic field and heat energy (including RF) provides a complementary effect when firming/toning skin and muscle; magnetic field provides long-term and deeper therapeutic effects on muscle stimulation, and heat energy (such as RF) providing short-term relief on muscle and a soothing effect on skin. Park, *Abstract*, [0027],

[0030], [0034]-[0036]. In light of these known benefits of POSITAs would have been motivated and found it obvious to apply **Park**'s teaching of a combination treatment with RF to improve the therapeutic and soothing effect of **Simon's** device on tissue/muscle. Bikson, ¶225.

Park is in the same field of endeavor, as **Simon** and **Edoute** (*see* §VIII.A.3)—electromagnetic stimulation of a patient's body—and are analogous art to '295. **Park** discloses applying electromagnetic stimulation to tissues. Park, [0036]. Bikson, ¶226.

In light of the above, a POSITA would have found it routine, straightforward, and advantageous to modify **Simon's** magnetic stimulation device to apply **Edoute's** teachings of applying radiofrequency treatment, and additionally, for claims 9-10, 18-19, using **Zarsky's** RF circuit, in view of the complementary effects of the combined magnetic field and RF treatment explained by **Park**, and would have known such a combination (yielding the claimed limitations) would predictably work and provide the expected functionality. Bikson, ¶227; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401-02 (2007).

D. Ground 5: Claims 8-22 are rendered obvious by Burnett-'870 in view of Park and Zarsky

1. Burnett-'870 Overview

Burnett-'870 discloses applying time-varying magnetic fields sufficient to "cause contraction of muscle fibers," thereby "toning" muscles. Burnett-'870,

Title, Abstract, [0003], [0011], [0227]. **Burnett-'870**'s device has multiple applicators comprising coils to generate magnetic fields on a patient's target muscles, as shown in Figure 9B where "coils 106" are disposed in an "abdominal garment" covering the patient's abdomen/buttocks. Burnett-'870, *Abstract*, [0070], [0114]. Bikson, ¶¶228-229.

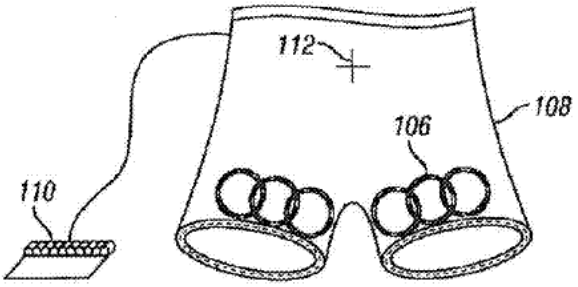


FIG. 9B

Burnett-'870 discloses cooling the coil by direct contact with liquid coolant. Burnett-'870, [0210], [0215], [0235], Fig. 35. Bikson, ¶230.

Burnett-'870 uses a "logic controller" to power the coils and to adjust the parameters of the magnetic fields, based on feedback from a sensor or the patient. Burnett-'870, *Abstract,* [0070], [0018]–[0082], [0134], [0196]. The parameters include, *e.g.*, the magnetic field's "amplitude" and "frequency of stimulation." Burnett-'870, [0070], [0085], [0087], [0117], [0129]. **Burnett-'870** discloses it was known to include a "capacitor" in the device, and uses a "switch" to control energy charging/discharging among components including 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, ¶231.

Burnett-'870 discloses that its device may deliver "high frequencies" and "ultrahigh frequencies" which would encompass radiofrequency. Burnett-'870, [0117]. It explicitly states that its device may apply stimulations such as a "RF field" Burnett-'870, [0133]. Burnett-'870 further discloses an embodiment of its device comprising **conductive coils 212** and "microneedle patch **228… having one or more electrodes** 232" as illustrated in Fig. 12. Burnett-'870, [0135]; *id.*,[0075], [0116] ("a transcutaneous stimulator, such as an electrode 126"), [0139]-[0140], [0150], [0157]-[0160], Figs. 22-23; *see also id.*, [0002] (incorporating by reference **Burnett-'325** disclosing "radio frequency-powered microstimulators that include electrodes" were known (Burnett-'325, [0022])).

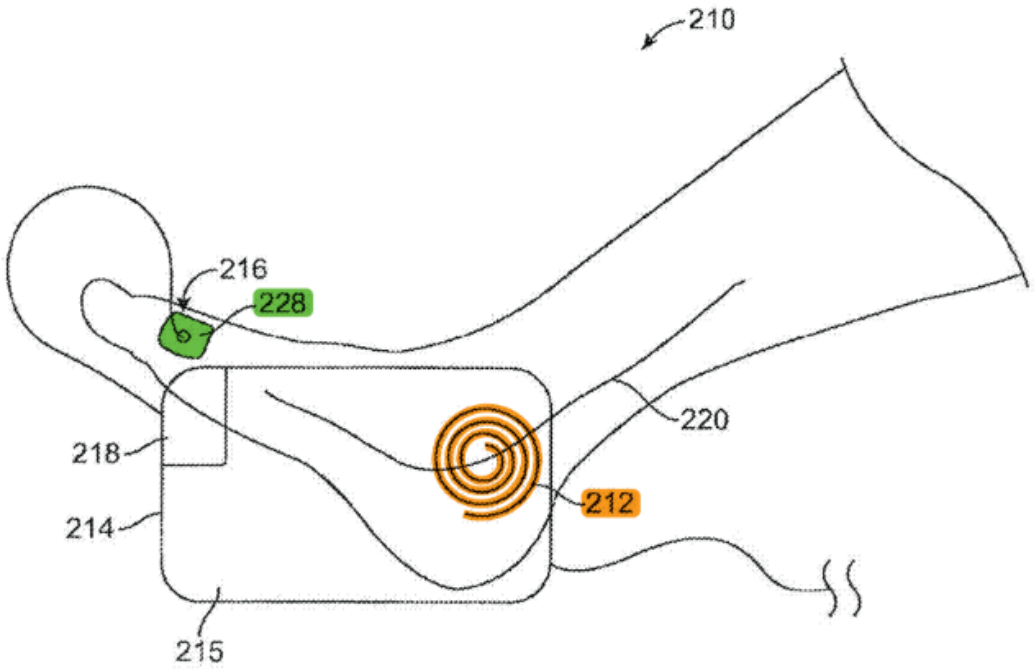


FIG. 12

To the extent argued **Burnett-'870** lacks particular disclosure of a radiofrequency electrode and circuit configured to apply radiofrequency waves for heating tissues, a POSITA would have found it obvious to modify **Burnett-'870**'s device to do so for the reasons discussed below in §VIII.D.2—*e.g.*, it was well-known and conventional that RF-and-magnetic treatments provided a complementary effect for firming and toning skin and muscle. Park, [0029]-[0030], [0034]-[0036]. Such modification would predictably work and provide the expected functionality given that **Burnett-'870** already discloses a device with coils and electrodes to provide tissue treatment, and applying stimulation using radiofrequency. Bikson, ¶¶232-233.

2. Motivation to Combine

Burnett-'870 discloses a device applying magnetic field to stimulate muscles. Burnett-'870, *Abstract*. **Burnett-'870** further discloses applying radiofrequency treatment to tissues and using a device with coils and electrodes for simultaneous application. Burnett-'870, [0117], [0133], [0135]. To the extent argued that **Burnett-'870** does not explicitly disclose a combination device that applies magnetic field and radiofrequency to a target body region, POSITAs would have been motivated and found it obvious to modify **Burnett-'870**'s in view of **Zarsky**'s teachings of an RF circuit and electrodes in view of **Park**'s teachings that the combined treatment is beneficial. Bikson, ¶234

Park discloses that the combined treatment of pulsed electromagnetic field and heat energy (which includes RF) is advantageous for firming and toning skin and muscle especially in buttocks and abdomen. Park, *Abstract*, [0027], [0030]. The two energies are complimentary with magnetic field providing long-term and deeper therapeutic effects on muscle stimulation, and heat energy (such as RF) providing short-term relief on muscle and a soothing effect on skin. Park, [0034]–[0036]. Because **Burnett-'870** shares the same objective for muscle toning and skin treatment (*e.g., Abstract*, [0011], [0133], [0148]) and its device is also integrated in an article of clothing (such as "abdominal garment") similar to **Park's** wearable, POSITAs would have been motivated and found it obvious to

apply **Park**'s teaching of a combination treatment with RF to improve the therapeutic and soothing effect of **Burnett-'870**'s device on skin and muscle, and further look to **Zarsky** for implementation details of an RF circuit and electrodes. Furthermore, such improvement would merely be combining known techniques for known benefits as the '295 recognizes that "radiofrequency treatment" is one of "the most common methods used for non-invasive aesthetic applications" and its effect was known to be "based specifically on heat production in the biological structure." '295, 2:17–27. Bikson, ¶235.

Similar to **Burnett-'870** and **Park, Zarsky** is also directed to applying electromagnetic energy for tightening skin and tissue. Zarsky, *Abstract*, [0019]. **Zarsky** discloses applying radiofrequency via electrodes to a target body region, and discloses a schematic diagram for generating RF energy, including power, source, power supply, high frequency generator, transmatch, and a balun transformer to provide RF energy to the electrodes. Zarsky, [0019]–[0021], [0024]. POSITAs would have found it routine, straightforward and advantageous to modify **Burnett-'870**'s device to apply **Zarsky**'s teachings of an RF circuit and electrodes in its design in view of the complimentary effects of the combined magnetic field and RF treatment explained by **Park**, and would have known such a combination (yielding the claimed limitations) would predictably work and provide

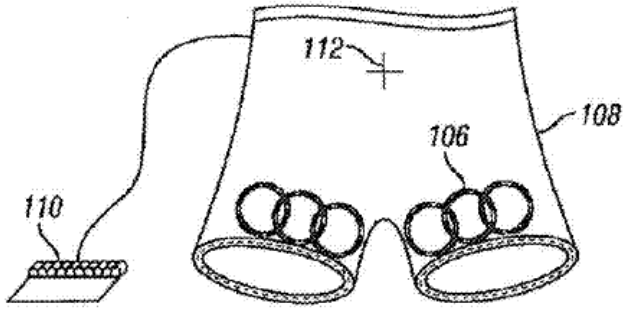
the expected functionality. *See KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007). Bikson, ¶236.

Burnett-'870, **Park**, and **Zarsky** are in the same field of endeavor—electromagnetic stimulation of a patient's body—and are analogous art to '295. **Burnett-'870** and **Park** disclose applying magnetic field and RF waves to stimulate tissues. Burnett-'870, *Abstract*; Park, [0036]. **Zarsky** discloses applying electromagnetic energy such as RF to tighten skin and heat targeted body area. Zarsky, *Abstract*, [0019]. Bikson, ¶237.

3. Claim Charts

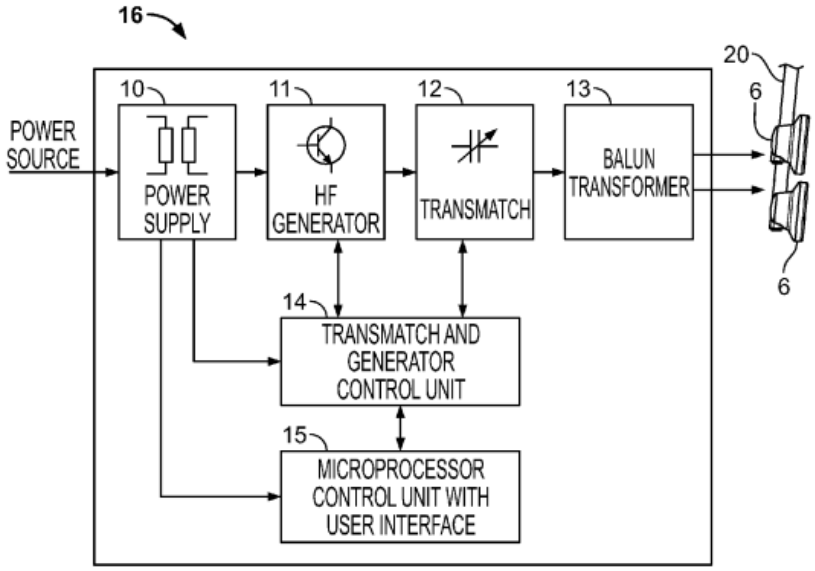
a. Independent Claims 8, 15

Claim Elements	Burnett-'870 in view of Park and Zarsky
[8.pre] A method of patient treatment comprising:	**Burnett-'870 discloses a method of patient treatment.** **Burnett-'870** discloses "systems and[] methods 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]. 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. Burnett-'870, [0114].

Claim Elements	Burnett-'870 in view of Park and Zarsky
	 FIG. 9B **Burnett-'870** discloses "toning tissue with focused, coherent EMF [electromagnetic field]." Burnett-'870 [0011], [0225]–[0226]. Bikson, ¶¶238-240.
[8.a] providing energy from an energy storage device to a magnetic field generating device to generate a time-varying magnetic field with a magnetic flux density in a range of 0.1 T to 7 T, a repetition rate in a range of 1 Hz to 300 Hz, with an impulse duration in a range of 3 µs to 1 ms, and a maximal value of a magnetic flux density derivative in a range of 0.3 kT/s to 800 kT/s;	**Burnett-'870 teaches providing energy from an energy storage device** (*e.g.*, "capacitor") **to a magnetic field generating device** (*e.g.*, "applicator" comprising "coils") **to generate a time-varying magnetic field with a magnetic flux density in a range of 0.1 T to 7 T** (*e.g.*, "0.25 to 1.5 tesla")**, a repetition rate in a range of 1 Hz to 300 Hz** (*e.g.*, "10 to 20 hertz")**, with an impulse duration in a range of 3 µs to 1 ms** (*e.g.*, "50 µs")**, and a maximal value of a magnetic flux density derivative in a range of 0.3 kT/s to 800 kT/s** (*e.g.*, 31.4 to 188 kT/s). *See* [8.pre]. **Burnett-'870** discloses it was known to use capacitors in a magnetic stimulator. Burnett-'870, [0013]-[0014]. Indeed, its provisional application discloses using a LoFIT system described in Burnett-'185 in its invention. Burnett-Provisional-'720, [0001]–[0002], [0020]. Burnett-'185 discloses incorporating a capacitor in the circuitry of the device, allowing it to be charged, and using a switch to discharge it to the coil. Burnett-'185, 6:66-7:2, 7:27–8:26. POSITAs would have been motivated and found it obvious to incorporate capacitors in **Burnett-'870's** device based on its

Claim Elements	Burnett-'870 in view of Park and Zarsky
	reference to the LoFIT system, and its guidance to store energy for the coils, and POSITAs would have understood to charge the capacitors such that they would be discharged to the coils to generate a time-varying magnetic field 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. **Burnett-'870** discloses "[o]peration of a conductive coil at about 10 to 20 hertz generating a magnetic field of about 0.25 to 1.5 tesla," and operating at "about 5 to 100 hertz" to generate a magnetic field of "about 1 to 10 tesla." Burnett-'870, [0195]. **Burnett-'870** incorporates by reference Burnett-'325. Burnett-'870, [0002]. Burnett-'325 discloses that it was known to use a magnetic field having an impulse of "a 50 μs duration." Burnett-'325, [0010]. **Burnett-'870** leaves it to POSITAs to choose an impulse duration, the range of 3 μs to 1 ms was known and conventional. *E.g.,* Magstim, 3 ("a pulse duration from 100–1000μs, dependent on stimulator type"). Because magnetic flux density derivative is calculated based on flux density (0.25–1.5T) and impulse duration (50μs), this yields a range of 31.4 to 188 kT/s, falling within the claimed range as was well known in the art. *See, e.g.,* Magstim 3–4 (disclosing 4 Tesla and 100μs to 1ms, which yields a flux derivative range of 25.12 to 251.2 kT/s). Bikson, ¶¶241-256, 45-53, 84-85.
[8.b] applying the time-varying magnetic field to muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers	**Burnett-'870 teaches applying the time-varying magnetic field to muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within a body region** (*e.g.,* buttocks/abdomen) **of a patient such that a muscle of the patient is caused to contract.** *See* [8.pre]–[8.a].

Claim Elements	Burnett-'870 in view of Park and Zarsky
within a body region of a patient such that a muscle of the patient is caused to contract;	**Burnett-'870**'s device provides "maximal stimulation (i.e., sufficient to cause contraction of muscle fibers and firing of nerves)." Burnett-'870 [0227]. Thus, **Burnett-'870** applies stimulation from a magnetic field causing muscles of buttocks/abdomen to contract. Bikson, ¶¶257-259.
[8.c] generating radiofrequency waves with a frequency in a range of 500 kHz to 3 GHz; and	**Burnett-'870 teaches generating radiofrequency waves.** **Burnett-'870** discloses an "energy generator to produce, generate or deliver energy, *e.g.,* a magnetic or electromagnetic field." Burnett-'870, [0175], [0069]. **Burnett-'870** discloses that its device may deliver "high frequencies" and "ultrahigh frequencies." Burnett-'870, [0117]. A POSITA would have understood that such energy generator is high frequency because **Burnett-'870** discloses applying stimulation such as "a RF field," which is known to be high/ultrahigh frequency. Burnett-'870, [0133]; '295, 26:13–15 (describing how "HF…generator" provides "energy for radiofrequency treatment"). **Burnett-'870** further discloses an embodiment of its device comprising conductive coils 212 and "microneedle patch… having one or more electrodes 232" in Fig. 12. Burnett-'870, [0135]; *id.,* [0075], [0116], [0139]–[0140], [0150], [0157]–[0160], Figs. 22–23. **Burnett-'870** incorporates by reference ([0002]) Burnett-'325 disclosing that "radio frequency-powered microstimulators that include electrodes" were known. Burnett-'325, [0022]. To the extent argued **Burnett-'870** does not explicitly discloses a radiofrequency waves with a frequency within the claimed range, **Zarsky discloses generating radiofrequency waves** (*e.g.*, "radiofrequency") **with a frequency in a range of 500 kHz to 3 GHz** (*e.g.,* "13.56 or 40.68 or 27.12 MHz, or 2.45 GHz")**.** **Zarsky** discloses a "HF Generator (high frequency generator) 11" that generates and provides radiofrequency waves to "electrodes 6" at "13.56 or 40.68 or 27.12 MHz, or 2.45 GHz." Zarsky, Fig. 1, [0019], [0024], [0026], [0014], cls. 1–10. In view of the teachings from **Park** ([0005],

Claim Elements	Burnett-'870 in view of Park and Zarsky
	[0029], [0036]) for the benefits of combination treatment**,** POSITAs would have been motivated and found it obvious to modify **Burnett-'870**'s device to apply **Zarsky**'s teaching of a "high-frequency generator" and a "radiofrequency electrode" such that both magnetic field and RF are applied simultaneously, which would reduce the total treatment time, and provide synergistic effects compared to separate treatments. *See* §VIII.D.2. Bikson, ¶260-263, 72-75.  FIG. 1
[8.d] applying the radiofrequency waves to the patient to cause heating of a biological structure of the patient.	**Burnett-'870 in view of Park and Zarsky teaches applying the radiofrequency waves to the patient to cause heating of a biological structure of the patient.** *See* [8.c]—**Zarsky** discloses RF waves are applied to the patient by positioning "electrodes 6" on or above the patient's skin. Zarsky, [0024], [0026], cls. 1, 8–9. **Zarsky** discloses using RF for "controlled heating of the targeted areas on the human body." Zarsky, [0001], [0007], [0018], cl. 1 ("heating of the subcutaneous tissue"). Bikson, ¶¶264-266.
[15.pre] A method of patient treatment comprising:	*See* [8.pre]. Bikson, ¶¶267-268.

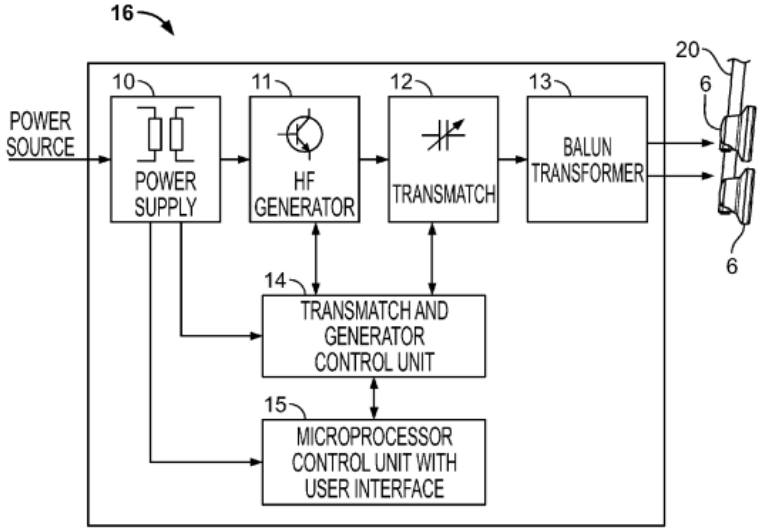
Claim Elements	Burnett-'870 in view of Park and Zarsky
[15.a] providing energy from an energy storage device to a magnetic field generating device;	*See* [8.a]. Bikson, ¶¶269-270.
[15.b] generating, by the magnetic field generating device, a time-varying magnetic field having a plurality of magnetic pulses with a magnetic flux density in a range of 0.1 Tesla to 7 Tesla, a maximal value of a magnetic flux density derivative in a range of 300 T/s to 800 kT/s, and a repetition rate in a range of 1 Hz to 300 Hz;	**Burnett-'870 teaches generating, by the magnetic field generating device** (*e.g.*, "applicator" comprising "coils"), **a time-varying magnetic field having a plurality of magnetic pulses with a magnetic flux density in a range of 0.1 T to 7 T** (*e.g.*, "0.25 to 1.5 tesla")**, a maximal value of a magnetic flux density derivative in a range of 300 T/s to 800 kT/s** (*e.g.*, 31.4 to 188 kT/s)**, and a repetition rate in a range of 1 Hz to 300 Hz** (*e.g.*, "10 to 20 hertz")**.** *See* [8.a]. **Burnett-'870** discloses that the magnetic fields are "time varying," "pulsed," and "intermittently applied"; the coils operate at a frequency; and that target regions are "exposed to the *impulses*" of the magnetic fields—indicating that the time-varying magnetic field generate a plurality of consecutive impulses. Burnett-'870, *Abstract*, [0003], [0195], [0226]. It was also 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**'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 a magnetic field causing muscles of buttocks or abdomen to contract. **Burnett-'870** further discloses using "intermittent pulsed magnetic fields" to include a relaxation period "during which the nerve is not subject to stimulatory signal." Burnett-'870, [0233]–[0234], [0252]–[0253].

Claim Elements	Burnett-'870 in view of Park and Zarsky
	Burnett-'870 thus teaches a plurality of magnetic pulses that cause muscle contraction, followed by a period of no stimulation allowing muscle relaxation, as was known in the art. *See, e.g.,* Belanger, 239 (disclosing to a train to mimic the "gradual build up and relaxation phases" during a "voluntary muscle contraction" for a "smooth" contraction). Bikson, ¶¶271-275, 91-96.
[15.c] applying the plurality of magnetic pulses of the time-varying magnetic field to muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within a body region of a patient such that a muscle is caused to contract;	**Burnett-'870 teaches applying the plurality of magnetic pulses of the time-varying magnetic field to muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within a body region** (*e.g.,* buttocks/abdomen) **of a patient such that a muscle of the patient is caused to contract.** *See* [8.a]–[8.b], [15.b]. Bikson, ¶¶276-277.
[15.d] generating radiofrequency waves by an HF generator and providing the radiofrequency waves in a range of 500 kHz to 3 GHz to a radiofrequency electrode; and	**Burnett-'870 in view of Park and Zarsky teaches generating radiofrequency waves by an HF generator** (*e.g.*, "HF Generator 11" of Zarsky) **and providing the radiofrequency waves in a range of 500 kHz to 3 GHz** (*e.g.,* "13.56 or 40.68 or 27.12 MHz, or 2.45 GHz" of Zarsky) **to a radiofrequency electrode** (*e.g.*, "electrodes 6" of Zarsky). *See* [8.c]. Bikson, ¶¶278-279.
[15.e] applying the radiofrequency	*See* [8.d]. Bikson, ¶¶280-281.

Claim Elements	Burnett-'870 in view of Park and Zarsky
waves to the patient,	
[15.f] heating a target biological structure of the patient by the radiofrequency waves.	*See* [8.d]. Bikson, ¶¶282-283.

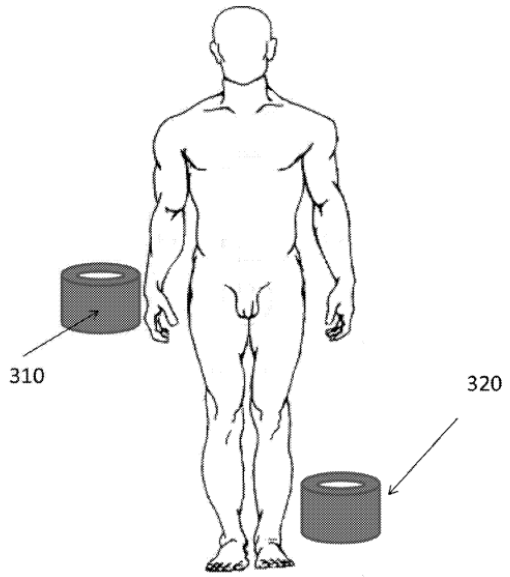
b. Dependent Claims 9-14, 16-22

Claim Elements	Burnett-'870 in view of Park and Zarsky
[9] The method of treatment of claim 8, further comprising: providing a radiofrequency signal to a balun transformer to convert an unbalanced radiofrequency signal to a balanced radiofrequency signal.	**Burnett-'870 teaches providing a radiofrequency signal** (*e.g.*, "radiofrequency")**.** *See* [8.c]. **Burnett-'870** leaves it to POSITAs to determine the components for generating and receiving RF waves. To the extent argued **Burnett-'870** does not disclose a balun transformer, **Zarsky discloses providing a radiofrequency signal to a balun transformer** (*e.g.*, "Balun Transformer 13") **to convert an unbalanced radiofrequency signal to a balanced radiofrequency signal.** Figure 1 of **Zarsky** shows that the "HF Generator 11," which provides energy at "13.56 or 40.68 or 27.12 MHz, or 2.45 GHz," is connected to "Balun Transformer 13," which "converts unbalanced impedance to balanced impedance." Zarsky, [0019], [0021]. Figure 1 further shows that the "Transmatch 12" is connected to the "Balun Transformer 13" and "generator control unit 14" for impedance matching to a target body structure, such as skin. Zarsky, [0019]–[0021]. Bikson, ¶¶284-287, 100-101.

Claim Elements	Burnett-'870 in view of Park and Zarsky
	 FIG. 1
[10] The method of treatment of claim 8, further comprising: providing a radiofrequency signal to a transmatch to adjust an impedance of at least one radiofrequency electrode.	**Burnett-'870 in view of Park and Zarsky teaches providing a radiofrequency signal** (*e.g.*, "radiofrequency" of Zarsky) **to a transmatch** (*e.g.*, "Transmatch 12" of Zarsky) **to adjust an impedance of at least one radiofrequency electrode** (*e.g.*, "electrodes 6" of Zarsky)**.** *See* [8.c], [9]. Bikson, ¶¶288-289, 100-101.
[11] The method of treatment of claim 8, wherein the energy storage device has a capacitance in a range of 5 nF to 100 mF; and wherein the magnetic field	**Burnett-'870 teaches the energy storage device** (*e.g.*, "capacitor") **has a capacitance in a range of 5 nF to 100 mF; and wherein the magnetic field generating device has an inductance in a range of 1 nH to 50 mH.** *See* [8.a]. **Burnett-'870** leaves it to POSITAs to choose a capacitor, and using a capacitor with the very broad claimed range of capacitance in a stimulator device was known in the art. *See,*

Claim Elements	Burnett-'870 in view of Park and Zarsky
generating device has an inductance in a range of 1 nH to 50 mH.	*e.g.,* Burnett-'585, [0071] (using capacitors having a capacitance of "at least 5,000 microfarads," which is 5mF); Epstein, 8:19–22 ("at least 50 uF," which is 0.05mF). **Burnett-'870** also leaves it to POSITAs to choose the coils, and using coils with the very broad claimed range of inductance in a stimulator device was known in the art. *See, e.g.,* Magstim, 4, Table 1 (all coils have an inductance between 2,550nH and 0.0235mH). Bikson, ¶¶290-293, 84-85.
[12] The method of treatment of claim 8, wherein the step of applying the radiofrequency waves heats the biological structure of the patient to a temperature in a range of 37° C. to 60° C.	**Burnett-'870 in view of Park and Zarsky teaches the radiofrequency waves** (*e.g.*, "radiofrequency") **heat the biological structure of the patient** (*e.g.*, buttocks/abdomen) **to a temperature in a range of 37° C. to 60° C.** *See* [8.c]–[8.d]—**Zarsky** discloses applying radiofrequency waves to heat tissue "to about 40° C." Zarsky, [0005], cl. 31 ("heating the subcutaneous tissue via radio frequency electromagnetic waves, with the temperature of skin over the subcutaneous tissue increased to about 32–45° C"). Bikson, ¶¶294-296.
[13.a] The method of treatment of claim 8, further comprising: assembling magnetic pulses of the time-varying magnetic field into a train lasting in a range of 1 second to 30 seconds; and	**Burnett-'870 teaches assembling magnetic pulses of the time-varying magnetic field into a train lasting in a range of 1 second to 30 seconds.** *See* [8.a], [15.b]—**Burnett-'870** discloses generating a train of pulses, but leaves it to POSITAs to choose the duration of train, and a train duration of 1-30 seconds was known and conventional in the art. *See, e.g.,* Magstim, Fig. 21 (showing "5.0s" for "Duration…for each train."). POSITAs would have been motivated and found it obvious to choose this train duration for patient comfort and to mimic muscle contraction and relaxation—muscle contractions of "3 to 6 seconds" were known to mimic natural muscle contraction, leading to a "smooth" and comfortable evoked contraction. Belanger, 236. Bikson, ¶¶297-299, 91-96.

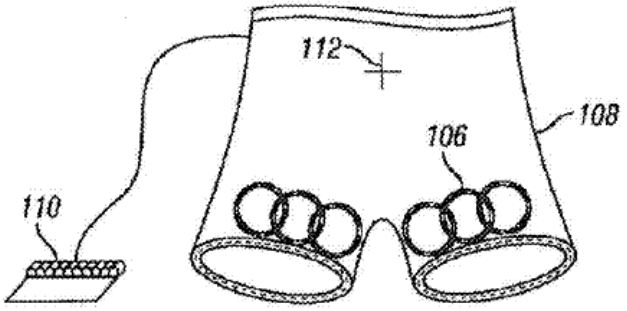
Claim Elements	Burnett-'870 in view of Park and Zarsky
[13.b] generating no magnetic pulses of the time-varying magnetic field for a time period in a range of 1 second to 7 seconds after a last magnetic pulse of the train to establish a burst; and	**Burnett-'870 teaches generating no magnetic pulses of the time-varying magnetic field for a time period in a range of 1 second to 7 seconds after a last magnetic pulse of the train to establish a burst.** *See* [8.a], [13.a], [15.b]—**Burnett-'870** teaches a plurality of magnetic pulses to establish a burst. **Burnett-'870** further discloses a period of no stimulation to allow for relaxation (*e.g.,* [0234]) and leaves it to POSITAs to determine the duration of no stimulation period. Relaxation period between 1 to 7 seconds was well-known and conventional. *See, e.g.,* Johari, [0038], [0043] (disclosing a 4 to 5 seconds muscle relaxation period). It was also known that muscles relax during the wait time following the pulses. For example, Magstim's Figure 21 shows configurable wait times. POSITAs would have been motivated and found it obvious to configure relaxation period in this range, in view of this disclosure, to allow time for the muscle to relax between pulse trains to reduce muscle fatigue. Bikson, ¶¶300-302.
[13.c] applying the train to the muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within the body region of the patient such that the muscle is caused to contract.	**Burnett-'870 teaches applying the train to the muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within the body region** (*e.g.,* buttocks/abdomen) **of a patient such that the muscle is caused to contract.** *See* [8.a]–[8.b], [13.a]–[13.b], [15.b]. Bikson, ¶¶303-304.
[14] The method of treatment of claim 8, wherein the step of applying the time-varying magnetic	**Burnett-'870 teaches applying the time-varying magnetic field causes a repetitive contraction of at least one muscle selected from a group consisting of: a) rectus abdominis muscle, external oblique muscle, internal oblique muscle and/or transversus abdominis; or b) gluteus maximus muscle, gluteus medius muscle and/or gluteus minimus**

Claim Elements	Burnett-'870 in view of Park and Zarsky
field causes a repetitive contraction of at least one muscle selected from a group comprising: a) rectus abdominis muscle, external oblique muscle, internal oblique muscle and/or transversus abdominis; or b) gluteus maximus muscle, gluteus medius muscle and/or gluteus minimus muscle; or c) m. biceps femoris, m. semimembranosus, m. semitendinosus, tensor fascia latae muscle, vastus lateralis muscle, iliotibial muscle and/or m. triceps surae.	**muscle; or c) m. biceps femoris, m. semimembranosus, m. semitendinosus, tensor fascia latae muscle, vastus lateralis muscle , iliotibial muscle and/or m. triceps surae.** *See* [8.a]–[8.b], [13.a]–[13.b], [15.b]—**Burnett-'870** discloses applying consecutive impulses would cause repetitive contractions on target muscles in abdomen and buttocks; POSITAs would have understand that the muscles in group (a) are part of the abdomen, and muscles in group (b) are part of the buttocks. **Burnett-'870**'s "body-contoured applicators" include embodiments for the legs, as shown in Figure 9, 30-31. Burnett-'870, [0012] ("coils to be placed around…a leg"), [0088], [0109], [0118], [0157], [0163], [0174], [0176], [0179], [0205] ("leg applicator 320"), [0218]; and POSITAs would have understand that the muscles in group (c) are part of the legs. Bikson, ¶¶305-307. Fig. 31a  Fig. 31b
[16.a] The method of treatment of claim 15, further comprising: assembling the plurality of magnetic pulses of	**Burnett-'870 teaches assembling the plurality of magnetic pulses of the time-varying magnetic field into a train** *See* [8.a], [13.a]–[13.b], [15.b]. Bikson, ¶308-309.

Claim Elements	Burnett-'870 in view of Park and Zarsky
the time-varying magnetic field into a train; and	
[16.b] applying the train to the muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within the body region of the patient such that a muscle is caused to contract.	**Burnett-'870 teaches applying the train to the muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within the body region** (*e.g.*, buttocks/abdomen) **of the patient such that a muscle is caused to contract.** *See* [8.b], [13.c], [15.b]–[15.c]. Bikson, ¶¶310-311.
[17] The method of treatment of claim 15, further comprising cooling the magnetic field generating device.	**Burnett-'870 discloses cooling the magnetic field generating device** (*e.g.*, "applicator" comprising "coils")**.** *See* [8.pre]–[8.a] **Burnett-'870** discloses cooling the coils by direct contact with a liquid coolant to prevent overheating. Burnett-'870, [0235], [0210], [0215]. Bikson, ¶¶312-314, 86-90.
[18] The method of treatment of claim 15, further comprising: providing a radiofrequency signal to a balun transformer to convert an unbalanced radiofrequency signal to a balanced	*See* [9], [8.c]. Bikson, ¶¶315-316, 100-101.

Claim Elements	Burnett-'870 in view of Park and Zarsky
radiofrequency signal.	
[19] The method of treatment of claim 18, further comprising: providing the radiofrequency signal to a transmatch to adjust an impedance of at least one radiofrequency electrode.	*See* [10], [8.c], [9]. Bikson, ¶¶317-318.
[20] The method of treatment of claim 15, wherein the step of applying the time-varying magnetic field causes a repetitive contraction of at least one muscle selected from a group consisting of: a) rectus abdominis muscle, external oblique muscle, internal oblique muscle and/or transversus abdominis; or b) gluteus maximus muscle, gluteus medius muscle and/or gluteus	*See* [14]. Bikson, ¶¶319-320.

Claim Elements	Burnett-'870 in view of Park and Zarsky
minimus muscle; or c) m. biceps femoris, m. semimembranosus, m. semitendinosus, tensor fascia latae muscle, vastus lateralis muscle, iliotibial muscle and/or m. triceps surae.	
[21] The method of treatment of claim 15, wherein the energy storage device has a capacitance in a range of 5 nF to 100 mF; and wherein the magnetic field generating device has an inductance in a range of 1 nH to 50 mH.	*See* [11], [8.a]. Bikson, ¶¶321-322.
[22.a] The method of treatment of claim 15, further comprising: generating, by a second magnetic field generating device, a second time-varying magnetic field;	**Burnett-'870 teaches generating, by a second magnetic field generating device** (*e.g.*, "applicator" comprising "coils") **a second time-varying magnetic field.** *See* [8.pre]–[8.b]—**Burnett-'870** discloses multiple applicators comprising coils to generate multiple 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." Burnett-'870, [0114].

Claim Elements	Burnett-'870 in view of Park and Zarsky
	 FIG. 9B Figure 34 shows multiple "applicators 350" with "multiple coils" for "therapy targeting." Burnett-'870, [0209]. Bikson, ¶¶323-325, 77-83.
[22.b] applying the second time-varying magnetic field to a second group of muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within the body region of the patient such that a second muscle is caused to contract.	**Burnett-'870 teaches applying second time-varying magnetic field to a second group of muscle fibers, neuromuscular plates, or peripheral nerves innervating muscle fibers within the body region** (*e.g.*, buttocks/abdomen) **of the patient such that a second muscle is caused to contract.** *See* [8.a]–[8.b], [13.b]–[13.c], [15.b]–[15.c], [22.a]—**Burnett-'870** applies stimulation from two magnetic fields causing left and right muscles of buttocks/abdomen to contract. Bikson, ¶¶326-328, 96.

IX. SECONDARY CONSIDERATIONS

Petitioner is unaware of evidence of secondary considerations relevant to the Challenged Claims at the date of this filing. Bikson, ¶330.

X. CONCLUSION

Petitioner respectfully requests IPR of Claims 8-22 of the ’295. Bikson, ¶¶331-333.

Dated: September 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 12,404 words as counted by the word processing program used to prepare the paper.

Dated: September 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 '295 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: September 13, 2021

Respectfully submitted,

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

Lead Counsel for Petitioner