PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	21 DEC 2018
Applicant's or agent's file reference HER08FP100WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB2018/056649	30 August 2018	01 September 2017

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61N 1/18; A61N 1/36 (2018.01)
CPC - A61N 1/18; A61N 1/328; A61N 1/36 (2018.08)

Applicant HER TECHNOLOGIES, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	07 December 2018	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	4, 7, 8, 12, 15-20	YES
	Claims	1-3, 5, 6, 9-11, 13, 14, 21-32	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-32	NO
Industrial applicability (IA)	Claims	1-32	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-3, 5, 6, 9-11, 13, 14, and 21-32 lack novelty under PCT Article 33(2) as being anticipated by Avrahami et al. (hereinafter Avrahami).

Regarding Claim 1, Avrahami discloses a skin rejuvenation device (abstract, treating skin), the device comprising: a power supply adapted to generate a voltage (power supply 172 with voltage, paragraph 179, see figure 8a); an applicator (figure 8a, paragraph 179, abstract) comprising a first node and a second node (174, 176 as nodes, see figure 8a, paragraph 179), wherein the first node is adapted to be configurable between a positive electrode electrically coupled to the power supply or electrically isolated from the power supply (see figure 8a, anode node 174 connected to the positive side of the power supply and electrode 120, paragraph 179), and wherein the second node is adapted to be configurable between a negative electrode electrically coupled to the power supply or electrically isolated from the power supply (176, connected to the negative part of the power supply via skin 22, see figure 8a); and wherein the power supply delivers a current through the first node when the first node is configured as the positive electrode (see figure 8a, as 174 connected to the positive side of the voltage 172, 174 as the positive electrode for 178) and current returns to the power supply through the second node when the second node is configured to be the negative electrode (second node 176 connected to the negative side of the voltage 172, via skin 22, the node 176 will then be the negative node and the current returns to the power supply 172 via the skin 22 through the second node 176).

Regarding Claim 2, Avrahami discloses the device of claim 1, further comprising a voltage control adapted to modulate a frequency of the voltage (paragraph 174, the driving frequency is cyclically modulated between two endpoints (e.g., 2 kHz and 15 kHz) during application of the electric field; therefore modulating the frequency of the voltage).

Regarding Claim 3, Avrahami discloses the device of claim 2, wherein the voltage control is further adapted to modulate the frequency of the voltage between 1,000 Hz and 350,000 Hz (paragraph 174, the driving frequency is cyclically modulated between two endpoints (e.g., 2 kHz and 15 kHz) [2,000 Hz and 15,000 Hz] during application of the electric field; therefore modulating the frequency of the voltage).

Regarding Claim 5, Avrahami discloses the device of claim 1, wherein the applicator further comprises a convex surface (ablation head 402 is convex, see figure 12), wherein the first node and the second node are disposed on the convex surface (see figure 12, nodes as electrodes 320 attached to the surface).

Regarding Claim 6, Avrahami discloses the device of claim 1, wherein the power supply is adapted to deliver a periodic voltage comprising of a first period of positive voltage through the first node followed by a second period of no voltage through the first node (paragraph 184, During the positive phase, a diode 224 in electrolyte cell 230 passes current to cause alternating node 226 to act as an anode and common node 240 to act as a cathode [first period of positive voltage]... during the negative phase, diode 224 blocks conduction through alternating node 226 [second period of no voltage]).

Regarding Claim 9, Avrahami discloses a skin rejuvenation device (abstract, treating skin), the device comprising: a power supply adapted to generate a voltage (power supply 172 with voltage, paragraph 179); an applicator (figure 8a, paragraph 179, abstract) comprising a plurality of nodes (174, 176 as nodes, see figure 8a, paragraph 179), wherein each node is adapted to be configurable between a positive electrode electrically coupled to the power supply, a negative electrode electrically coupled to the power supply, or electrically isolated from the power supply (see figure 8a, each node is in between the positive and negative sides of the power supply); and wherein the power supply delivers a current through each node configured as a positive electrode (see figure 8a, each positive node, 174, connects to the positive side of the power supply therefore the node is configured as a positive electrode) and current returns to the power supply through each node configured as a negative electrode (see figure 8a, the current returns to the power supply through 176, which is then the node that is configured as a negative electrode, as the node is attached to the negative side of the power supply via the skin 22; see figure 8b, multiple sets of electrodes).

Regarding Claim 10, Avrahami discloses the device of claim 9, further comprising a voltage control adapted to modulate a frequency of the voltage (paragraph 174, the driving frequency is cyclically modulated between two endpoints (e.g., 2 kHz and 15 kHz) during application of the electric field; therefore modulating the frequency of the voltage).

Regarding Claim 11, Avrahami discloses the device of claim 10, wherein the voltage control is adapted to modulate the frequency of the voltage between 1,000 Hz and 350,000 Hz (paragraph 174, the driving frequency is cyclically modulated between two endpoints (e.g., 2 kHz and 15 kHz) [2,000 Hz and 15,000 Hz] during application of the electric field; therefore modulating the frequency of the voltage).

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Regarding Claim 13, Avrahami discloses the device claim 9, wherein the applicator further comprises a convex surface (ablation head 402 is convex, see figure 12), wherein the first node and the second node are disposed on the convex surface (see figure 12, nodes as electrodes 320 attached to the surface).

Regarding Claim 14, Avrahami discloses the device of claim 9, wherein the power supply is adapted to deliver a periodic voltage comprising of a first period of positive voltage through at least one of the electrodes followed by a second period of no voltage through any of the electrodes (paragraph 184, During the positive phase, a diode 224 in electrolyte cell 230 passes current to cause alternating node 226 to act as an anode and common node 240 to act as a cathode [first period of positive voltage]... during the negative phase, diode 224 blocks conduction through alternating node 226 [electrode] [second period of no voltage through any of the electrodes 226]).

Regarding Claim 21, Avrahami discloses a skin rejuvenation device (abstract, treating skin), the device comprising: a power supply adapted to generate a voltage (power supply 222 with voltage, paragraph 183, see figure 10) and having at least one output terminal (see figure, output to 224, paragraph 184, during the positive phase), said power supply providing a particular polarity between said output terminal and ground (see paragraph 184, during the positive phase, therefore a positive polarity between the output and the ground at 22, see figure 10); an applicator comprising a plurality of spaced apart electrically conductive nodes (see figure 10, common node 240 for electrode, paragraph 183; paragraph 184, multiple electrodes therefore multiple common nodes spaced apart); and a control adapted to selectively connect each of said nodes with said at least one output terminal of said power supply (paragraph 164 switching unit 50 monitors current flow to electrodes... and selectively terminates the flow to one or more electrodes; therefore a controller adapted to selectively connected each of the electrodes to the power supply, therefore each of the nodes to the power supply), and selectively to allow each of said nodes to float with respect to said at least one output (see paragraph 184, the common nodes float, that is, is either a cathode or an electrode depending upon the output of the voltage, as either a positive or negative phase, therefore selecting the float).

Regarding Claim 22, Avrahami discloses the device as claimed in claim 21, wherein said control applies said output to at least one of said nodes to activate that node and not to at least one other node (see figure 10, the voltage output is to 226 and not attached to 240) to allow that other node to float (240 floats as it floats between positive and negative, see paragraphs 183-184).

Regarding Claim 23, Avrahami discloses the device as claimed in claim 21, wherein said control applies said output to at least one of said nodes to activate that node (paragraph 184, During the positive phase, a diode 224 in electrolyte cell 230 passes current to cause alternating node 226 to act as an anode) and allows that node to float to discharge that node (discharging as an anode, floating between on and off, paragraph 184, during the negative phase, diode 224 blocks conduction through alternating node 226).

Regarding Claim 24, Avrahami discloses the device as claimed in claim 21 or claim 22, wherein said at least one output terminal comprises at least two output terminals (see figure 10, two outputs via the diodes 224 and 234), said power supply providing said particular polarity between one of said output terminals and ground (paragraph 184, AC source 222 produces a voltage difference across electrodes 120 (only one electrode is shown), which cycles between positive and negative phases [polarity] at a predetermined frequency, in order to provide the energy to ablate stratum corneum 100 in skin 22 [ground]. During the positive phase, a diode 224 in electrolyte cell 230 passes current to cause alternating node 226 to act as an anode; therefore a positive polarity between 226 and the ground of skin 22); and an opposite polarity between other of said output terminals and ground (paragraph 184, during the negative phase, a second diode 234 passes current which allows alternating node 236 to act as a cathode; therefore a negative polarity between the second output at 234 and ground, skin).

Regarding Claim 25, Avrahami discloses the device as claimed in claim 24, wherein said control is adapted to selectively connect each of said nodes with one of said output terminals, the other of said output terminals or to float (one of the output terminals, due to the different phases, see paragraph 184).

Regarding Claim 26, Avrahami discloses the device as claimed in claim 25, wherein said plurality of said nodes comprise a plurality of first nodes (226, figure 10, paragraph 184, multiple electrodes 120, therefore multiple nodes), a plurality of second nodes (236, figure 10), and a plurality of third nodes (240, see figure 10), wherein at least some of said third nodes are between one of said first nodes and said one of said second nodes (see figure 10, 240 is between and below 226 and 236), said wherein said control is adapted to selectively connect said first nodes with said one output terminal (paragraph 184, during the positive phase), said second nodes with said other of said output terminals (paragraph 184, during the negative phase) and said third nodes to float (paragraph 184, between positive and negative), in order to defined a first pattern wherein only said first and second nodes are activated (paragraph 184, the pattern is the switching between the positive and negative phases, alternatingly activating only the first and second nodes only as the third node is not directly connected to the output).

Regarding Claim 27, Avrahami discloses the device as claimed in claim 26, wherein said control is adapted to connect alternating ones of said electrodes with said one output terminal and said second output terminal to define a second pattern wherein all of said nodes are activated (see figure 10, activating the third node 240 by the first and second nodes 226, 236 via 230 by alternating the phases, paragraph 184).

Regarding Claim 28, Avrahami discloses the device of claim 21, further comprising a voltage control adapted to modulate a frequency of the voltage (paragraph 174, the driving frequency is cyclically modulated between two endpoints (e.g., 2 kHz and 15 kHz) [2,000 Hz and 15,000 Hz] during application of the electric field; therefore modulating the frequency of the voltage).

Regarding Claim 29, Avrahami discloses the device of claim 28, wherein the voltage control is adapted to modulate the frequency of the voltage between 1,000 Hz and 350,000 Hz (paragraph 174, the driving frequency is cyclically modulated between two endpoints (e.g., 2 kHz and 15 kHz) [2,000 Hz and 15,000 Hz] during application of the electric field; therefore modulating the frequency of the voltage).

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Regarding Claim 30, Avrahami discloses the device of claim 21, wherein the power supply is adapted to deliver a periodic voltage comprising of a first period positive voltage through at least one output terminal followed by a second period of no voltage through any of the output terminals (paragraph 184, During the positive phase, a diode 224 in electrolyte cell 230 passes current to cause alternating node 226 to act as an anode and common node 240 to act as a cathode [first period of positive voltage, and positive output terminal of the voltage]... during the negative phase, diode 224 blocks conduction through alternating node 226 [second period of no voltage through any of the positive output terminals 226]).

Regarding Claim 31, Avrahami discloses a method for stimulating skin with a device (abstract, treating skin), the device having a power supply adapted to generate a voltage (power supply 172 with voltage, paragraph 179, see figure 8a) and an applicator (figure 8a, paragraph 179, abstract) comprising a first node and a second node (174, 176 as nodes, see figure 8a, paragraph 179), the method comprising: configuring the first node as a positive electrode electrically coupled to the power supply or electrically isolated from the power supply (see figure 8a, the first node connected to the positive side of the power supply, therefore a positive electrode), and configuring the second node as a negative electrode coupled to the power supply or electrically isolated from the power supply (see figure 8a, the second node connected to the negative side of the power supply, via the skin, therefore a negative electrode); and wherein the power supply delivers a current through the first node when the first node is configured as the positive electrode (see figure 8a, power from the positive side of the power supply for the first node) and current returns to the power supply through the second node when the second node is configured to be the negative electrode (see figure 8a, via the skin, the second node as a negative electrode as it is attached to the negative side of the power supply).

Regarding Claim 32, Avrahami discloses a method for stimulating skin with a device (abstract, treating skin), the device having a power supply adapted to generate a voltage and having at least one output terminal (power supply 222 with voltage, paragraph 183, see figure 10, outlet), said power supply providing a particular polarity between said output terminal and ground (see paragraph 184, during the positive phase, therefore a positive polarity between the output and the ground at 22, see figure 10) and an applicator comprising a plurality of spaced apart electrically conductive nodes (see figure 10, common node 240 for electrode, paragraph 183; paragraph 184, multiple electrodes therefore multiple common nodes spaced apart), the method comprising: selectively connect each of said nodes with said at least one output terminal of said power supply (paragraph 164 switching unit 50 monitors current flow to electrodes... and selectively terminates the flow to one or more electrodes; therefore a controller adapted to selectively connected each of the electrodes to the power supply, therefore each of the nodes to the power supply) and selectively allowing each of said nodes to float with respect to said at least one output terminal (see paragraph 184, the common nodes float, that is, is either a cathode or an electrode depending upon the output of the voltage, as either a positive or negative phase, therefore selecting the float).

Claims 4, 7, 8, 12, and 15-20 lack an inventive step under PCT Article 33(3) as being obvious over Avrahami et al. (hereinafter Avrahami) in view of Sigma Instruments Holdings, Llc (hereinafter Sigma).

Regarding Claims 4, 7-8, 12, 18, Avrahami fails to explicitly disclose wherein the voltage control is further adapted to modulate at least one of an amplitude, pulse rate, pulse sweep, and duty cycle of the voltage (claims 4, 12, 18); the device further comprises a network interface (claim 7); the device further comprises a wireless interface (claim 8).
In the same field of endeavor, Sigma teaches a skin treatment device (abstract) wherein the voltage control is further adapted to modulate at least one of an amplitude, pulse rate, pulse sweep, and duty cycle of the voltage (paragraphs 209-213, Control signals received from the computing device 102 by the facial stimulator instrument 106 via an electrical cable 2236 or other signal communication method control one or more characteristics of the force impulses. Non-limiting examples of characteristics of the force impulses include the frequency of production of the force impulses, the peak force of each force impulses, the duration of the series of force impulses; therefore pulse rate modulation); the device further comprises a network interface (paragraph 261, connect via the data link 420... the data link may comprise a network connection); the device further comprises a wireless interface (paragraph 261, wi-fi).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Avrahami with the teaching of Sigma for the purpose of increasing the efficiency of the treatment (Sigma, paragraph 8).

Regarding Claim 15, Avrahami discloses a skin rejuvenation device (abstract, treating skin), the device comprising: a power supply adapted to generate a voltage (power supply 172 with voltage, paragraph 179; see figure 8); an applicator (302, see figure 16, paragraph 202) comprising an applicator head (head, 510, see figure 16), wherein the applicator head comprises a plurality of nodes (174, 176 as nodes, see figure 8a, paragraph 179), wherein each node is adapted to be a positive electrode electrically coupled to the power supply or a negative electrode electrically coupled to the power supply (see figure 8a, 174 as a positive electrode node as it is connected to the positive side of the voltage; 176 as the negative node and electrode, as it is attached to the negative side of the power supply); and wherein the power supply delivers a current through each positive electrode and current returns to the power supply through each negative electrode (see figure 8a, paragraph 179).
Avrahmi is silent regarding wherein the applicator head is adapted to be detachable from the applicator.
Sigma teaches an applicator head is adapted to be detachable from the applicator (paragraph 207, the impulse and sensing head 2202 may further include an elongated and generally cylindrical housing 2228... The housing 2228 and the closed end 2234 may be separately connected by a screw threaded connection to provide access into the interior of the housing 2228 and to separate the components of the facial stimulator instrument 106 for repair, replacement and the like; therefore separating the head, as a component of 106).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Avrahami with the teaching of Sigma in order to repair the head easily (Sigma, paragraph 207).

Regarding Claim 16, Avrahami discloses the device of claim 15, further comprising a voltage control adapted to modulate a frequency of the voltage (paragraph 174, the driving frequency is cyclically modulated between two endpoints (e.g., 2 kHz and 15 kHz) [2,000 Hz and 15,000 Hz] during application of the electric field; therefore modulating the frequency of the voltage).

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Regarding Claim 17, Avrahami discloses the device of claim 16, wherein the voltage control is adapted to modulate the frequency of the voltage between 1,000 Hz and 350,000 Hz (paragraph 174, the driving frequency is cyclically modulated between two endpoints (e.g., 2 kHz and 15 kHz) [2,000 Hz and 15,000 Hz] during application of the electric field; therefore modulating the frequency of the voltage).

Regarding Claim 19, Avrahami discloses the device of claim 15, wherein the applicator head further comprises a convex surface (ablation head 402 is convex, see figure 12), wherein the first node and the second node are disposed on the convex surface (see figure 12, nodes as electrodes 320 attached to the surface).

Regarding Claim 20, Avrahami discloses the device of claim 15, wherein the power supply is adapted to deliver a periodic voltage comprising of a first period of positive voltage through at least one positive electrode followed by a second period of no voltage through any of the electrodes (paragraph 184, During the positive phase, a diode 224 in electrolyte cell 230 passes current to cause alternating node 226 to act as an anode and common node 240 to act as a cathode [first period of positive voltage, therefore a positive electrode]... during the negative phase, diode 224 blocks conduction through alternating node 226 [second period of no voltage through any of the electrode 226]).

Claims 1-32 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.