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)*	06 FEB 2020
Applicant's or agent's file reference 1446-3WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2019/064104	03 December 2019	04 December 2018

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 18/14; A61B 18/04; A61B 18/08; A61B 18/12; A61B 18/16; A61C 3/00 (2020.01)
CPC - A61B 18/149; A61B 18/04; A61B 18/08; A61B 18/082; A61B 18/12; A61B 18/14; A61B 2018/1405; A61B 2018/1407; A61B 18/16; A61C 3/00 (2020.01)

Applicant STANLEY II, ROBERT JAMES

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

- [x] 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
- [x] 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
- [x] 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	20 January 2020	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2019/064104

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:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2019/064104

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	11, 13, 16, 19, 21, 22, 24-26, 30, 38, 40, 43, 47, 49-54	YES
	Claims	see claims below	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-45, 47-56	NO
Industrial applicability (IA)	Claims	1-45, 47-56	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-9, 14, 20, 23, 27-29, 31-36, 41, 48, 55, and 56 lack novelty under PCT Article 33(2) as being anticipated by Otech Industry SRL.

Regarding Claim 1, Otech Industry SRL discloses a method for treating a tissue of a subject (Figs. 1-4; Para. [0022] regarding an active electrode with energy transfer that vaporizes epithelial cells), the method comprising: providing an electrode (active electrode 18, Fig. 3) having a contact surface (lower surface of active electrode 18, Fig. 3, active electrode 18 comes into contact with the tissue of body "B" of the patient, Para. [0020]), optionally wherein the contact surface has a curved profile; placing the contact surface (lower surface of active electrode 18) in contact with tissue (the tissue, Para. [0020]) of the subject (patient's body B); and sliding (along cut C) the contact surface (lower surface of active electrode 18) across and in contact with the tissue (the tissue, Para. [0020]) while applying electrosurgical currents (electrosurgical apparatus 10, Para. [0018], electric charges and currents are typically generated in electrosurgical apparatuses, Para. [0027]) to the tissue (the tissue, Para. [0020]) via the contact surface (lower surface of active electrode 18) to thereby remove (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]) a portion of the tissue (the tissue, Para. [0020]) from the subject (patient's body B) and form a treated area (at cut C) of the tissue (the tissue, Para. [0020]).

Regarding Claim 2, Otech Industry SRL discloses the method of Claim 1 wherein the portion of the tissue removed (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]) from the subject (patient's body B, Fig. 3) comprises one or more epithelial layers (the epithelial cells, Para. [0022]).

Regarding Claim 3, Otech Industry SRL discloses the method of Claim 1 wherein the step of sliding (along cut C, Fig. 3) the contact surface (lower surface of active electrode 18) across and in contact with the tissue (the tissue, Para. [0020]) exposes a tissue layer (below cut C) below the portion of the tissue removed (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]) from the subject (patient's body B), optionally wherein the tissue layer (below cut C) comprises a layer of connective tissue and/or a dermal layer (a cut "C" on the skin of a patient's body, Para. [0099]).

Regarding Claim 4, Otech Industry SRL discloses the method of Claim 1 wherein the step of sliding (along cut C, Fig. 3) the contact surface (lower surface of active electrode 18) across and in contact with the tissue (the tissue, Para. [0020]) comprises vaporizing and ablating the portion (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]) of the tissue (the tissue, Para. [0020]) removed from the subject (patient's body B).

Regarding Claim 5, Otech Industry SRL discloses the method of Claim 1 wherein the subject (patient's body B, Fig. 3) is a human (body "B" of a human, Para. [0018]).

Regarding Claim 6, Otech Industry SRL discloses the method of Claim 1 wherein the subject (patient's body B, Fig. 3) is an animal (e.g., a dog, cat, horse, etc.) (body "B" of a . . . animal patient, Para. [0018]).

Regarding Claim 7, Otech Industry SRL discloses the method of Claim 1 wherein the tissue (the tissue, Para. [0020]) is skin (a cut "C" on the skin of a patient's body, Para. [0099]) and/or a mucous membrane.

Regarding Claim 8, Otech Industry SRL discloses the method of Claim 1 wherein the portion of the tissue removed (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]) from the subject (patient's body B, Fig. 3) comprises a skin lesion (a cut "C" on the skin of a patient's body, Para. [0099], different tissues subjected to cutting, Para. [0076]) and/or mucosal lesion.

Regarding Claim 9, Otech Industry SRL discloses the method of Claim 1 wherein the portion of the tissue removed (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]) from the subject (patient's body B, Fig. 3) comprises a cancerous tissue (e.g., a basal cell carcinoma) or premalignant tissue (vaporizes, through thermal effect, the epithelial cells, Para. [0022], different tissues subjected to cutting, Para. [0076]).

Regarding Claim 14, Otech Industry SRL discloses the method of Claim 1 wherein the step of sliding (along cut C, Fig. 3) the contact surface (lower surface of active electrode 18) across and in contact with the tissue (the tissue, Para. [0020]) includes ablating the tissue without cutting the tissue (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022], an abrasion, not a cut, on the tissue, Para. [0008]).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2019/064104

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 40 and 46 are objected under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 40 and 46 are indefinite for the following reasons:

With regard to claim 40, the claim language "the first dimension" lacks antecedent basis but would have antecedent basis by depending from claim 39. As it pertains to claim 40 the analyst is interpreting the claim as best understood to actually depend from claim 39 and it is treated as such in this Opinion.

Claim 46 is missing from the claim set. Therefore, claim 46 is not provided in the written opinion.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2019/064104

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Regarding Claim 20, Otech Industry SRL discloses the method of Claim 1 wherein the tissue (the tissue, Para. [0020]) is skin tissue (a cut "C" on the skin of a patient's body, Para. [0099]).

Regarding Claim 23, Otech Industry SRL discloses the method of Claim 1 including using the electrode (active electrode 18, Fig. 3) to remove an epithelium layer (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]) of the tissue (the tissue, Para. [0020]) while leaving an underlying connective tissue layer and/or dermal layer (below cut C, Fig. 3, a cut "C" on the skin of a patient's body, Para. [0099]) substantially undamaged in the treated area (at cut C).

Regarding Claim 27, Otech Industry SRL discloses a method of removing one or more epithelial layers from a tissue of a subject (Figs. 1-4; Para. [0022] regarding an active electrode with energy transfer that vaporizes epithelial cells), the method comprising: providing an electrode (active electrode 18, Fig. 3) having a contact surface (lower surface of active electrode 18, Fig. 3, active electrode 18 comes into contact with the tissue of body "B" of the patient, Para. [0020]), optionally wherein the contact surface has a curved profile; placing the contact surface (lower surface of active electrode 18) in contact with a first epithelial layer (the epithelial cells that come into contact with active electrode 18, Para. [0022]) of the tissue (the tissue, Para. [0020]) of the subject (patient's body B); and sliding (along cut C) the contact surface (lower surface of active electrode 18) across and in contact with the first epithelial layer (the epithelial cells that come into contact with active electrode 18, Para. [0022]) while applying electrosurgical currents (electrosurgical apparatus 10, Para. [0018], electric charges and currents are typically generated in electrosurgical apparatuses, Para. [0027]) to the first epithelial layer (the epithelial cells, Para. [0022]) via the contact surface (lower surface of active electrode 18) to thereby remove (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]) the one or more epithelial layers (the epithelial cells, Para. [0022]) from the tissue (the tissue, Para. [0020]) of the subject (patient's body B).

Regarding Claim 28, Otech Industry SRL discloses the method of Claim 27 wherein, responsive to the step of sliding (along cut C, Fig. 3) the contact surface (lower surface of active electrode 18) across and in contact with the first epithelial layer (the epithelial cells that come into contact with active electrode 18, Para. [0022]) while applying electrosurgical currents (electrosurgical apparatus 10, Para. [0018], electric charges and currents are typically generated in electrosurgical apparatuses, Para. [0027]) to the first epithelial layer (the epithelial cells, Para. [0022]) via the contact surface (lower surface of active electrode 18), a tissue layer (below cut C) is exposed that was below the first epithelial layer (the epithelial cells, Para. [0022]), optionally wherein the tissue layer (below cut C) comprises a layer (below cut C) of connective tissue and/or a dermal layer (a cut "C" on the skin of a patient's body, Para. [0099]).

Regarding Claim 29, Otech Industry SRL discloses the method of Claim 28 further comprising isolating (a cut "C" on the skin of a patient's body, Para. [0099], making cuts, Para. [0055]) the tissue layer (below cut C, Fig. 3) from the subject (patient's body B) to thereby provide an isolated tissue layer (a cut "C" on the skin of a patient's body, Para. [0099], making cuts, Para. [0055]).

Regarding Claim 31, Otech Industry SRL discloses the method of Claim 27 wherein the step of sliding (along cut C, Fig. 3) the contact surface (lower surface of active electrode 18) across and in contact with the first epithelial layer (the epithelial cells that come into contact with active electrode 18, Para. [0022]) comprises vaporizing and ablating the one or more epithelial layers (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]).

Regarding Claim 32, Otech Industry SRL discloses the method of Claim 27 wherein the subject (patient's body B, Fig. 3) is a human (body "B" of a human, Para. [0018]).

Regarding Claim 33, Otech Industry SRL discloses the method of Claim 27 wherein the subject (patient's body B, Fig. 3) is an animal (e.g., a dog, cat, horse, etc.) (body "B" of a . . . animal patient, Para. [0018]).

Regarding Claim 34, Otech Industry SRL discloses the method of Claim 27 wherein the tissue (the tissue, Para. [0020]) is skin (a cut "C" on the skin of a patient's body, Para. [0099]) and/or a mucous membrane.

Regarding Claim 35, Otech Industry SRL discloses the method of Claim 27 wherein the one or more epithelial layers removed (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]) from the subject (patient's body B, Fig. 3) comprise a skin lesion (a cut "C" on the skin of a patient's body, Para. [0099], different tissues subjected to cutting, Para. [0076]) and/or mucosal lesion.

Regarding Claim 36, Otech Industry SRL discloses the method of Claim 27 wherein the one or more epithelial layers removed (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]) from the subject (patient's body B, Fig. 3) comprise a cancerous tissue (e.g., a basal cell carcinoma) or premalignant tissue (vaporizes, through thermal effect, the epithelial cells, Para. [0022], different tissues subjected to cutting, Para. [0076]).

Regarding Claim 41, Otech Industry SRL discloses the method of Claim 27 wherein the step of sliding (along cut C, Fig. 3) the contact surface (lower surface of active electrode 18) across and in contact with the first epithelial layer (the epithelial cells that come into contact with active electrode 18, Para. [0022]) includes ablating the one or more epithelial layers without cutting the one or more epithelial layers (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022], an abrasion, not a cut, on the tissue, Para. [0008]).

Regarding Claim 48, Otech Industry SRL discloses the method of Claim 27 wherein the tissue (the tissue, Para. [0020]) is skin tissue (a cut "C" on the skin of a patient's body, Para. [0099]).

Regarding Claim 55, Otech Industry SRL discloses the method of Claim 27 wherein the method is used to remove epidermis (a cut "C" on the skin of a patient's body, Para. [0099]) from the subject's (patient's body B, Fig. 3) tissue (the tissue, Para. [0020]).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2019/064104

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
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Regarding Claim 56, Otech Industry SRL discloses the method of Claim 27 further comprising placing the contact surface (lower surface of active electrode 18, Fig. 3) in contact with a second epithelial layer (the epithelial cells that come into contact with active electrode 18, Para. [0022], making cuts, Para. [0055]) of the tissue (the tissue, Para. [0020]) of the subject (patient's body B); and sliding (along cut C) the contact surface (lower surface of active electrode 18) across and in contact with the second epithelial layer (the epithelial cells that come into contact with active electrode 18, Para. [0022], making cuts, Para. [0055]) while applying electrosurgical currents (electrosurgical apparatus 10, Para. [0018], electric charges and currents are typically generated in electrosurgical apparatuses, Para. [0027]) to the second epithelial layer (the epithelial cells, Para. [0022], making cuts, Para. [0055]) via the contact surface (lower surface of active electrode 18) to thereby remove at least one additional epithelial layer (the epithelial cells, Para. [0022], making cuts, Para. [0055]) from the tissue (the tissue, Para. [0020]) of the subject (patient's body B).

Claims 1-5, 7-10, 12, 14, 15, 17, 18, 23, 27-29, 31, 32, 34-37, 39, 41, 42, 44, 45, and 56 lack novelty under PCT Article 33(2) as being anticipated by Sixto, JR. et al. (hereinafter Sixto, JR.).

Regarding Claim 1, Sixto, JR. discloses a method for treating a tissue of a subject (Fig. 5A; Para. [0041] regarding an electrosurgical device that comes in contact with tissue), the method comprising: providing an electrode (crescent shaped electrode 96, Fig. 5A) having a contact surface (convex lower surface 98), optionally wherein the contact surface (convex lower surface 98) has a curved profile (curved profile of convex lower surface 98); placing the contact surface (convex lower surface 98) in contact with tissue (the tissue, Para. [0041]) of the subject (patient, Para. [0064]); and sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98) across and in contact with the tissue (the tissue, Para. [0041]) while applying electrosurgical currents (an electrosurgical device 90, Para. [0041], current density at the electrode, Para. [0006]) to the tissue (the tissue, Para. [0041]) via the contact surface (convex lower surface 98) to thereby remove (the lower surface 98 is the working portion which comes in contact with the tissue during vaporization, Para. [0041]) a portion of the tissue (the tissue, Para. [0041]) from the subject (patient, Para. [0064]) and form a treated area (in contact, Para. [0041]) of the tissue (the tissue, Para. [0041]).

Regarding Claim 2, Sixto, JR. discloses the method of Claim 1 wherein the portion of the tissue removed (the tissue during vaporization, Para. [0041]) from the subject (patient, Para. [0064]) comprises one or more epithelial layers (the walls of the uterus, Para. [0064]).

Regarding Claim 3, Sixto, JR. discloses the method of Claim 1 wherein the step of sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98, Fig. 5A) across and in contact with the tissue (the tissue, Para. [0041]) exposes a tissue layer (ablate a tumor from the walls of the uterus, Para. [0064], contacting the target tissue during a procedure, Para. [0036]) below the portion of the tissue removed (the lower surface 98 is the working portion which comes in contact with the tissue during vaporization, Para. [0041]) from the subject (patient, Para. [0064]), optionally wherein the tissue layer (ablate a tumor from the walls of the uterus, Para. [0064], contacting the target tissue during a procedure, Para. [0036]) comprises a layer of connective tissue (ablate a tumor from the walls of the uterus, Para. [0064], contacting the target tissue during a procedure, Para. [0036]) and/or a dermal layer.

Regarding Claim 4, Sixto, JR. discloses the method of Claim 1 wherein the step of sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98, Fig. 5A) across and in contact with the tissue (the tissue, Para. [0041]) comprises vaporizing and ablating the portion of the tissue removed (the lower surface 98 is the working portion which comes in contact with the tissue during vaporization, Para. [0041], ablate a tumor from the walls of the uterus, Para. [0064]) from the subject (patient, Para. [0064]).

Regarding Claim 5, Sixto, JR. discloses the method of Claim 1 wherein the subject is a human (patient, Para. [0064]).

Regarding Claim 7, Sixto, JR. discloses the method of Claim 1 wherein the tissue (the tissue, Para. [0041]) is skin and/or a mucous membrane (ablate a tumor from the walls of the uterus, Para. [0064]).

Regarding Claim 8, Sixto, JR. discloses the method of Claim 1 wherein the portion of the tissue removed (the tissue during vaporization, Para. [0041]) from the subject (patient, Para. [0064]) comprises a skin lesion and/or mucosal lesion (ablate a tumor from the walls of the uterus, Para. [0064]).

Regarding Claim 9, Sixto, JR. discloses the method of Claim 1 wherein the portion of the tissue (the tissue, Para. [0041]) removed (the tissue during vaporization, Para. [0041]) from the subject (patient, Para. [0064]) comprises a cancerous tissue (e.g., a basal cell carcinoma) or premalignant tissue (ablate a tumor from the walls of the uterus, Para. [0064]).

Regarding Claim 10, Sixto, JR. discloses the method of Claim 1 wherein: the contact surface (convex lower surface 98, Fig. 5A) has a curved profile (curved profile of convex lower surface 98) and the curved profile (curved profile of convex lower surface 98) of the contact surface (convex lower surface 98) extends along a first axis (axis perpendicular to axis 93); the contact surface (convex lower surface 98) has a linear profile (linear profile along convex lower surface 98) along a second axis (axis 93) perpendicular to the first axis (axis perpendicular to axis 93); and the step of sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98) across and in contact with the tissue (the tissue, Para. [0041]) includes sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98) across and in contact with the tissue (the tissue, Para. [0041]) in a direction substantially parallel to the first axis (axis perpendicular to axis 93) while applying electrosurgical currents (an electrosurgical device 90, Para. [0041], current density at the electrode, Para. [0006]) to the tissue (the tissue, Para. [0041]) via the contact surface (convex lower surface 98) to thereby remove (the tissue during vaporization, Para. [0041]) the portion of the tissue (the tissue, Para. [0041]) from the subject (patient, Para. [0064]) and form the treated area (in contact, Para. [0041]) of the tissue (the tissue, Para. [0041]).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2019/064104

Supplemental Box

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Regarding Claim 12, Sixto, JR. discloses the method of Claim 1 wherein: the step of sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98, Fig. 5A) across and in contact with the tissue (the tissue, Para. [0041]) includes sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98) across and in contact with the tissue (the tissue, Para. [0041]) in a brushing direction (as shown in Fig. 5A) while applying electrosurgical currents (an electrosurgical device 90, Para. [0041], current density at the electrode, Para. [0006]) to the tissue (the tissue, Para. [0041]) via the contact surface (convex lower surface 98) to thereby remove (the tissue during vaporization, Para. [0041]) the portion of the tissue (the tissue, Para. [0041]) from the subject (patient, Para. [0064]) and form the treated area (in contact, Para. [0041]) of the tissue (the tissue, Para. [0041]); an engagement interface (bottom of convex lower surface 98, Fig. 5A, the lower surface 98 is the working portion which comes in contact with the tissue, Para. [0041]) between the contact surface (convex lower surface 98) and the tissue (the tissue, Para. [0041]) defines a contact band (along bottom of convex lower surface 98) having a first dimension (dimension perpendicular to axis 93) parallel to the brushing direction (along axis perpendicular to axis 93) and a second dimension (dimension along axis 93) perpendicular to the first dimension (dimension perpendicular to axis 93); and the second dimension (dimension along axis 93) is greater (as shown in Fig. 5A) than the first dimension (dimension perpendicular to axis 93).

Regarding Claim 14, Sixto, JR. discloses the method of Claim 1 wherein the step of sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98, Fig. 5A) across and in contact with the tissue (the tissue, Para. [0041]) includes ablating the tissue without cutting the tissue (ablate a tumor from the walls of the uterus, Para. [0064]).

Regarding Claim 15, Sixto, JR. discloses the method of Claim 1 wherein: the electrode (crescent shaped electrode 96, Fig. 5A) further includes a lateral edge (lateral edge of convex lower surface 98); and the method further includes scraping residual tissue from the treated area (the lower surface 98 is the working portion which comes in contact with the tissue during vaporization, Para. [0041], resection of tissues, Para. [0064]) using the lateral edge (lateral edge of convex lower surface 98).

Regarding Claim 17, Sixto, JR. discloses the method of Claim 1 wherein: the electrode (crescent shaped electrode 96, Fig. 5A) includes first (right lateral edge of convex lower surface 98) and second opposed lateral edges (left lateral edge of convex lower surface 98); and the method includes monitoring (the lower surface 98 is the working portion which comes in contact with the tissue during vaporization, Para. [0041], positioned under observation, Para. [0063]) the first lateral edge (right lateral edge of convex lower surface 98) to determine a location of the second lateral edge (left lateral edge of convex lower surface 98) relative to the subject (patient, Para. [0064]).

Regarding Claim 18, Sixto, JR. discloses the method of Claim 1 wherein: the electrode (crescent shaped electrode 96, Fig. 5A) includes a bottom wall (bottom wall of convex lower surface 98) and a top wall (top wall of upper surface 97) overlying the bottom wall (bottom of convex lower surface 98); the contact surface (convex lower surface 98) is on the bottom wall (bottom wall of convex lower surface 98); the top wall (top wall of upper surface 97) includes a planar surface (at top edges of upper surface 97) overlying the contact surface (convex lower surface 98); and the method includes monitoring (the lower surface 98 is the working portion which comes in contact with the tissue during vaporization, Para. [0041], positioned under observation, Para. [0063]) the planar surface (at top edges of upper surface 97) to determine a depthwise location of the contact surface (convex lower surface 98) relative to the tissue (the tissue, Para. [0041]).

Regarding Claim 23, Sixto, JR. discloses the method of Claim 1 including using the electrode (crescent shaped electrode 96, Fig. 5A) to remove (the tissue during vaporization, Para. [0041]) an epithelium layer (the walls of the uterus, Para. [0064]) of the tissue (the tissue, Para. [0041]) while leaving an underlying connective tissue layer (ablate a tumor from the walls of the uterus, Para. [0064], contacting the target tissue during a procedure, Para. [0036]) and/or dermal layer substantially undamaged in the treated area (in contact, Para. [0041]).

Regarding Claim 27, Sixto, JR. discloses a method of removing one or more epithelial layers from a tissue of a subject (Fig. 5A; Para. [0041] regarding an electrosurgical device that comes in contact with tissue), the method comprising: providing an electrode (crescent shaped electrode 96, Fig. 5A) having a contact surface (convex lower surface 98), optionally wherein the contact surface (convex lower surface 98) has a curved profile (curved profile of convex lower surface 98); placing the contact surface (convex lower surface 98) in contact with a first epithelial layer (ablate a tumor from the walls of the uterus, Para. [0064]) of the tissue (the tissue, Para. [0041]) of the subject (patient, Para. [0064]); and sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98) across and in contact with the first epithelial layer (ablate a tumor from the walls of the uterus, Para. [0064]) while applying electrosurgical currents (an electrosurgical device 90, Para. [0041], current density at the electrode, Para. [0006]) to the first epithelial layer (ablate a tumor from the walls of the uterus, Para. [0064]) via the contact surface (convex lower surface 98) to thereby remove (the lower surface 98 is the working portion which comes in contact with the tissue during vaporization, Para. [0041]) the one or more epithelial layers (ablate a tumor from the walls of the uterus, Para. [0064]) from the tissue (the tissue, Para. [0041]) of the subject (patient, Para. [0064]).

Regarding Claim 28, Sixto, JR. discloses the method of Claim 27 wherein, responsive to the step of sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98, Fig. 5A) across and in contact with the first epithelial layer (ablate a tumor from the walls of the uterus, Para. [0064]) while applying electrosurgical currents (an electrosurgical device 90, Para. [0041], current density at the electrode, Para. [0006]) to the first epithelial layer (ablate a tumor from the walls of the uterus, Para. [0064]) via the contact surface (convex lower surface 98), a tissue layer (ablate a tumor from the walls of the uterus, Para. [0064], contacting the target tissue during a procedure, Para. [0036]) is exposed that was below the first epithelial layer (ablate a tumor from the walls of the uterus, Para. [0064]), optionally wherein the tissue layer (ablate a tumor from the walls of the uterus, Para. [0064], contacting the target tissue during a procedure, Para. [0036]) comprises a layer of connective tissue (ablate a tumor from the walls of the uterus, Para. [0064], contacting the target tissue during a procedure, Para. [0036]) and/or a dermal layer.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2019/064104

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Regarding Claim 29, Sixto, JR. discloses the method of Claim 28 further comprising isolating the tissue layer (resect or ablate a tumor from the walls of the uterus, Para. [0064], contacting the target tissue during a procedure, Para. [0036]) from the subject (patient, Para. [0064]) to thereby provide an isolated tissue layer (resect or ablate a tumor from the walls of the uterus, Para. [0064], contacting the target tissue during a procedure, Para. [0036]).

Regarding Claim 31, Sixto, JR. discloses the method of Claim 27 wherein the step of sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98, Fig. 5A) across and in contact with the first epithelial layer (ablate a tumor from the walls of the uterus, Para. [0064]) comprises vaporizing and ablating (the lower surface 98 is the working portion which comes in contact with the tissue during vaporization, Para. [0041], ablate a tumor from the walls of the uterus, Para. [0064]) the one or more epithelial layers (ablate a tumor from the walls of the uterus, Para. [0064]).

Regarding Claim 32, Sixto, JR. discloses the method of Claim 27 wherein the subject is a human (patient, Para. [0064]).

Regarding Claim 34, Sixto, JR. discloses the method of Claim 27 wherein the tissue (the tissue, Para. [0041]) is skin and/or a mucous membrane (ablate a tumor from the walls of the uterus, Para. [0064]).

Regarding Claim 35, Sixto, JR. discloses the method of Claim 27 wherein the one or more epithelial layers (the walls of the uterus, Para. [0064]) removed (the tissue during vaporization, Para. [0041]) from the subject comprise a skin lesion and/or mucosal lesion (ablate a tumor from the walls of the uterus, Para. [0064]).

Regarding Claim 36, Sixto, JR. discloses the method of Claim 27 wherein the one or more epithelial layers (the walls of the uterus, Para. [0064]) removed (the tissue during vaporization, Para. [0041]) from the subject (patient, Para. [0064]) comprise a cancerous tissue (e.g., a basal cell carcinoma) or premalignant tissue (ablate a tumor from the walls of the uterus, Para. [0064]).

Regarding Claim 37, Sixto, JR. discloses the method of Claim 27 wherein: the contact surface (convex lower surface 98, Fig. 5A) has a curved profile (curved profile of convex lower surface 98) and the curved profile (curved profile of convex lower surface 98) of the contact surface (convex lower surface 98) extends along a first axis (axis perpendicular to axis 93); the contact surface (convex lower surface 98) has a linear profile (linear profile along convex lower surface 98) along a second axis (axis 93) perpendicular to the first axis (axis perpendicular to axis 93); and the step of sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98) across and in contact with the first epithelial layer (the walls of the uterus, Para. [0064]) includes sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98) across and in contact with the first epithelial layer (the walls of the uterus, Para. [0064]) in a direction substantially parallel to the first axis (axis perpendicular to axis 93) while applying electrosurgical currents (an electrosurgical device 90, Para. [0041], current density at the electrode, Para. [0006]) to the first epithelial layer (the walls of the uterus, Para. [0064]) via the contact surface (convex lower surface 98) to thereby remove (the tissue during vaporization, Para. [0041]) the one or more epithelial layers (the walls of the uterus, Para. [0064]).

Regarding Claim 39, Sixto, JR. discloses the method of Claim 27 wherein: the step of sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98, Fig. 5A) across and in contact with the first epithelial layer (the walls of the uterus, Para. [0064]) includes sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98) across and in contact with the first epithelial layer (the walls of the uterus, Para. [0064]) in a brushing direction (as shown in Fig. 5A) while applying electrosurgical currents (an electrosurgical device 90, Para. [0041], current density at the electrode, Para. [0006]) to the first epithelial layer (the walls of the uterus, Para. [0064]) via the contact surface (convex lower surface 98) to thereby remove the one or more epithelial layers (the walls of the uterus, Para. [0064]); an engagement interface (bottom of convex lower surface 98, Fig. 5A, the lower surface 98 is the working portion which comes in contact with the tissue, Para. [0041]) between the contact surface (convex lower surface 98) and the first epithelial layer (the walls of the uterus, Para. [0064]) defines a contact band (along bottom of convex lower surface 98) having a first dimension (dimension perpendicular to axis 93) parallel to the brushing direction (along axis perpendicular to axis 93) and a second dimension (dimension along axis 93) perpendicular to the first dimension (dimension perpendicular to axis 93); and the second dimension (dimension along axis 93) is greater (as shown in Fig. 5A) than the first dimension (dimension perpendicular to axis 93).

Regarding Claim 41, Sixto, JR. discloses the method of Claim 27 wherein the step of sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98, Fig. 5A) across and in contact with the first epithelial layer (the walls of the uterus, Para. [0064]) includes ablating the one or more epithelial layers without cutting the one or more epithelial layers (ablate a tumor from the walls of the uterus, Para. [0064]).

Regarding Claim 42, Sixto, JR. discloses the method of Claim 28 wherein: the electrode (crescent shaped electrode 96, Fig. 5A) further includes a lateral edge (lateral edge of convex lower surface 98); and the method further includes scraping residual tissue from the tissue layer (the lower surface 98 is the working portion which comes in contact with the tissue during vaporization, Para. [0041], resection of tissues, Para. [0064]) using the lateral edge (lateral edge of convex lower surface 98).

Regarding Claim 44, Sixto, JR. discloses the method of Claim 27 wherein: the electrode (crescent shaped electrode 96, Fig. 5A) includes first (right lateral edge of convex lower surface 98) and second opposed lateral edges (left lateral edge of convex lower surface 98); and the method includes monitoring (the lower surface 98 is the working portion which comes in contact with the tissue during vaporization, Para. [0041], positioned under observation, Para. [0063]) the first lateral edge (right lateral edge of convex lower surface 98) to determine a location of the second lateral edge (left lateral edge of convex lower surface 98) relative to the subject (patient, Para. [0064]).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2019/064104

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Regarding Claim 45, Sixto, JR. discloses the method of Claim 27 wherein: the electrode (crescent shaped electrode 96, Fig. 5A) includes a bottom wall (bottom wall of convex lower surface 98) and a top wall (top wall of upper surface 97) overlying the bottom wall (bottom wall of convex lower surface 98); the contact surface (convex lower surface 98) is on the bottom wall (bottom wall of convex lower surface 98); the top wall (top wall of upper surface 97) includes a planar surface (at top edges of upper surface 97) overlying the contact surface (convex lower surface 98); and the method includes monitoring (the lower surface 98 is the working portion which comes in contact with the tissue during vaporization, Para. [0041], positioned under observation, Para. [0063]) the planar surface (at top edges of upper surface 97) to determine a depthwise location of the contact surface (convex lower surface 98) relative to the first epithelial layer (the tissue, Para. [0041]).

Regarding Claim 56, Sixto, JR. discloses the method of Claim 27 further comprising placing the contact surface (convex lower surface 98, Fig. 5A) in contact with a second epithelial layer (to resect or ablate a tumor from the walls of the uterus, Para. [0064]) of the tissue (the tissue, Para. [0041]) of the subject (patient, Para. [0064]); and sliding (same functions as a roller electrode, Para. [0041], moved along the treatment path, Para. [0063]) the contact surface (convex lower surface 98) across and in contact with the second epithelial layer (to resect or ablate a tumor from the walls of the uterus, Para. [0064]) while applying electrosurgical currents (an electrosurgical device 90, Para. [0041], current density at the electrode, Para. [0006]) to the second epithelial layer (to resect or ablate a tumor from the walls of the uterus, Para. [0064]) via the contact surface (convex lower surface 98) to thereby remove at least one additional epithelial layer (to resect or ablate a tumor from the walls of the uterus, Para. [0064]) from the tissue (the tissue, Para. [0041]) of the subject (patient, Para. [0064]).

Claims 11, 13, 38, and 40 lack an inventive step under PCT Article 33(3) as being obvious over Sixto, JR. et al. (hereinafter Sixto, JR.).

Regarding Claim 11, Sixto, JR. discloses the method of Claim 1 wherein the contact surface (convex lower surface 98, Fig. 5A) has a curved profile (curved profile of convex lower surface 98). Sixto, JR. fails to explicitly disclose wherein the curved profile is a curved profile that has a minimum arc radius of at least 1.5 mm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the curved profile be a curved profile that has a minimum arc radius of at least 1.5 mm, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to have the area of the lower surface be increased using the convex surface and thereby ensure that the area of the working portion is large enough to vaporize the tissue.

Regarding Claim 13, Sixto, JR. discloses the method of Claim 12. Sixto, JR. fails to explicitly disclose wherein: the first dimension is in the range of from about 1 mm to about 3 mm; and the second dimension is in the range of from about 1 mm to about 4 mm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the first dimension be in the range of from about 1 mm to about 3 mm; and the second dimension be in the range of from about 1 mm to about 4 mm, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to have the area of the lower surface be limited to a target zone and thereby ensure that the area of the working portion is sized to vaporize a width of the tissue.

Regarding Claim 38, Sixto, JR. discloses the method of Claim 27 wherein the contact surface (convex lower surface 98, Fig. 5A) has a curved profile (curved profile of convex lower surface 98). Sixto, JR. fails to explicitly disclose wherein the curved profile is a curved profile that has a minimum arc radius of at least 1.5 mm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the curved profile be a curved profile that has a minimum arc radius of at least 1.5 mm, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to have the area of the lower surface be increased using the convex surface and thereby ensure that the area of the working portion is large enough to vaporize the tissue.

Regarding Claim 40 (as best interpreted), Sixto, JR. discloses as best understood the method of Claim 39. Sixto, JR. fails to explicitly disclose wherein: the first dimension is in the range of from about 1 mm to about 3 mm; and the second dimension is in the range of from about 1 mm to about 4 mm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the first dimension be in the range of from about 1 mm to about 3 mm; and the second dimension be in the range of from about 1 mm to about 4 mm, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to have the area of the lower surface be limited to a target zone and thereby ensure that the area of the working portion is sized to vaporize a width of the tissue.

Claims 22 and 50 lack an inventive step under PCT Article 33(3) as being obvious over Otech Industry SRL.

Regarding Claim 22, Otech Industry SRL discloses the method of Claim 1 including using the electrode (active electrode 18, Fig. 3) to remove (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]) tissue (the tissue, Para. [0020]) to a depth (Fig. 3 showing a depth at cut C) in the treated area (at cut C). Otech Industry SRL fails to explicitly disclose wherein the depth is a depth in the range of from about 0.01 mm to about 0.15 mm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the depth be a depth in the range of from about 0.01 mm to about 0.15 mm, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to vaporize the upper cells of the skin that come into contact with the active electrode and thereby ensure that the cutting is limited to the epithelial cells.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2019/064104

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Regarding Claim 50, Otech Industry SRL discloses the method of Claim 27 wherein the method removes (an energy transfer that vaporizes, through thermal effect, the epithelial cells that come into contact with active electrode 18, Para. [0022]) tissue (the tissue, Para. [0020]) to a depth (Fig. 3 showing a depth at cut C). Otech Industry SRL fails to explicitly disclose wherein the depth is a depth in the range of from about 0.01 mm to about 0.15 mm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the depth be a depth in the range of from about 0.01 mm to about 0.15 mm, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The motivation for doing so would have been to vaporize the upper cells of the skin that come into contact with the active electrode and thereby ensure that the cutting is limited to the epithelial cells.

Claims 16, 26, and 43 lack an inventive step under PCT Article 33(3) as being obvious over Sixto, JR. et al. (hereinafter Sixto, JR.) in view of The Board Of Regents Of The University Of Oklahoma.

Regarding Claim 16, Sixto, JR. discloses the method of Claim 1. Sixto, JR. fails to explicitly disclose further including: mounting a wiping insert on the electrode; and wiping residual tissue from the treated area using the wiping insert. The Board Of Regents Of The University Of Oklahoma is in the art of a surgical accessory tool (Para. [0031]) and teaches further including: mounting a wiping insert (at cleaning material 144, Fig. 20c) on an electrode (able to clean charred tissue off of cautery tools, Para. [0056]); and wiping residual tissue from a treated area (able to clean charred tissue off, Para. [0056]) using the wiping insert (at cleaning material 144). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Sixto, JR. with the teaching of The Board Of Regents Of The University Of Oklahoma for the purpose of providing cleaning materials for cleaning a surgical tool and thereby ensure that charred tissue on a cautery tool can be cleaned off (The Board Of Regents Of The University Of Oklahoma, Para. [0056]).

Regarding Claim 26, Sixto, JR. discloses a method for performing electrosurgery on tissue of a subject (Fig. 5A; Para. [0041] regarding an electrosurgical device that comes in contact with tissue), the method comprising: providing an electrosurgical apparatus (electrosurgical device 90, Fig. 5A) including: an electrode (crescent shaped electrode 96) including a contact surface (convex lower surface 98) and a socket (at upper surface 97) defined in the electrode (crescent shaped electrode 96); contacting the contact surface (convex lower surface 98) with the tissue (the tissue, Para. [0041]) while applying electrosurgical currents (an electrosurgical device 90, Para. [0041], current density at the electrode, Para. [0006]) to the tissue (the tissue, Para. [0041]) via the contact surface (convex lower surface 98) to thereby electrosurgically treat (the lower surface 98 is the working portion which comes in contact with the tissue during vaporization, Para. [0041]) the tissue (the tissue, Para. [0041]). Sixto, JR. fails to explicitly disclose a wiping insert removably mounted in the socket; and thereafter wiping the tissue using the wiping insert in the socket. The Board Of Regents Of The University Of Oklahoma is in the art of a surgical accessory tool (Para. [0031]) and teaches a wiping insert (at cleaning material 144, Fig. 20c) removably mounted in a socket (at end portion 142, Fig. 20b); and thereafter wiping a tissue (able to clean charred tissue off of cautery tools, Para. [0056]) using the wiping insert (at cleaning material 144, Fig. 20c) in the socket (at end portion 142, Fig. 20b). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Sixto, JR. with the teaching of The Board Of Regents Of The University Of Oklahoma for the purpose of providing cleaning materials for cleaning a surgical tool and thereby ensure that charred tissue on a cautery tool can be cleaned off (The Board Of Regents Of The University Of Oklahoma, Para. [0056]).

Regarding Claim 43, Sixto, JR. discloses the method of Claim 28. Sixto, JR. fails to explicitly disclose further including: mounting a wiping insert on the electrode; and wiping residual tissue from the tissue layer using the wiping insert. The Board Of Regents Of The University Of Oklahoma is in the art of a surgical accessory tool (Para. [0031]) and teaches further including: mounting a wiping insert (at cleaning material 144, Fig. 20c) on an electrode (able to clean charred tissue off of cautery tools, Para. [0056]); and wiping residual tissue from a tissue layer (able to clean charred tissue off, Para. [0056]) using the wiping insert (at cleaning material 144). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Sixto, JR. with the teaching of The Board Of Regents Of The University Of Oklahoma for the purpose of providing cleaning materials for cleaning a surgical tool and thereby ensure that charred tissue on a cautery tool can be cleaned off (The Board Of Regents Of The University Of Oklahoma, Para. [0056]).

Claims 19 and 47 lack an inventive step under PCT Article 33(3) as being obvious over Sixto, JR. et al. (hereinafter Sixto, JR.) in view of Malis et al. (hereinafter Malis).

Regarding Claim 19, Sixto, JR. discloses the method of Claim 1. Sixto, JR. fails to explicitly disclose including: providing an electrode set including a plurality of electrodes having contact surfaces of different widths from one another, optionally wherein each of the electrodes have a curved profile; and selecting the electrode from the set of electrodes. Malis is in the art of electrosurgical instruments (Col. 1, Lns. 5-10) and teaches including: providing an electrode set (at metal blank 115, Fig. 8) including a plurality of electrodes (electrode tips 161-168, Fig. 8, FIG. 8 shows eight electrode tips 161 through 168 fabricated from a single metal blank 115, Col. 8, Lns. 35-37) having contact surfaces of different widths from one another (each electrode tip 161 through 168 has a different width and height combination, Col. 8, Lns. 37-39), optionally wherein each of the electrodes (electrode tips 161-168) have a curved profile (curved profiles of electrode tips 161-168); and selecting an electrode (install a particular electrode tip 16, Col. 8, Lns. 47-49) from the set of electrodes (electrode tips 161-168). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Sixto, JR. with the teaching of Malis for the purpose of providing plural electrode tips of different width simultaneously fabricated and thereby ensure that significant manufacturing efficiencies are achieved (Malis, Col. 8, Lns. 30-34).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2019/064104

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Regarding Claim 47, Sixto, JR. discloses the method of Claim 27. Sixto, JR. fails to explicitly disclose including: providing an electrode set including a plurality of electrodes having contact surfaces of different widths from one another, optionally wherein each of the electrodes have a curved profile; and selecting the electrode from the set of electrodes. Malis is in the art of electrosurgical instruments (Col. 1, Lns. 5-10) and teaches including: providing an electrode set (at metal blank 115, Fig. 8) including a plurality of electrodes (electrode tips 161-168, Fig. 8, FIG. 8 shows eight electrode tips 161 through 168 fabricated from a single metal blank 115, Col. 8, Lns. 35-37) having contact surfaces of different widths from one another (each electrode tip 161 through 168 has a different width and height combination, Col. 8, Lns. 37-39), optionally wherein each of the electrodes (electrode tips 161-168) have a curved profile (curved profiles of electrode tips 161-168); and selecting an electrode (install a particular electrode tip 16, Col. 8, Lns. 47-49) from the set of electrodes (electrode tips 161-168). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Sixto, JR. with the teaching of Malis for the purpose of providing plural electrode tips of different width simultaneously fabricated and thereby ensure that significant manufacturing efficiencies are achieved (Malis, Col. 8, Lns. 30-34).

Claims 21, 24, 25, 49, and 51-53 lack an inventive step under PCT Article 33(3) as being obvious over Otech Industry SRL in view of Syneron Medical Ltd. (hereinafter Syneron Medical).

Regarding Claim 21, Otech Industry SRL discloses the method of Claim 1. Otech Industry SRL fails to explicitly disclose wherein the tissue is gum tissue. Syneron Medical is in the art of oral treatment procedures (Para. [0001]) and teaches wherein tissue is gum tissue (suitable for treatment or prevention of gingival tissue (gum) recession, Para. [0043]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Otech Industry SRL with the teaching of Syneron Medical for the purpose of treating gingival tissue with the applicator and thereby ensure that the applicator provides cosmetic treatments (Syneron Medical, Para. [0043]).

Regarding Claim 24, modified Otech Industry SRL discloses the method of Claim 21. Otech Industry SRL fails to explicitly disclose wherein the method is used to remove gingiva hyperplasia from the subject's gums. Syneron Medical is in the art of oral treatment procedures (Para. [0001]) and teaches wherein a method is used to remove (ablate the epithelium, Para. [0042]) gingiva hyperplasia (new epithelial growth could also expand the gingival tissue, Para. [0037]) from a subject's gums (suitable for treatment or prevention of gingival tissue (gum) recession, Para. [0043]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Otech Industry SRL with the teaching of Syneron Medical for the purpose of treating gum recession with the applicator and thereby ensure that the applicator provides cosmetic treatments (Syneron Medical, Para. [0043]).

Regarding Claim 25, modified Otech Industry SRL discloses the method of Claim 21. Otech Industry SRL fails to explicitly disclose wherein the method is used to remove racial pigmentation from the subject's gums. Syneron Medical is in the art of oral treatment procedures (Para. [0001]) and teaches wherein a method is used to remove racial pigmentation (can be used for gingiva de-pigmentation procedures, Para. [0043]) from a subject's gums (suitable for treatment or prevention of gingival tissue (gum) recession, Para. [0043]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Otech Industry SRL with the teaching of Syneron Medical for the purpose of de-pigmentation of gingival tissue with the applicator and thereby ensure that the applicator provides cosmetic treatments (Syneron Medical, Para. [0043]).

Regarding Claim 49, Otech Industry SRL discloses the method of Claim 27. Otech Industry SRL fails to explicitly disclose wherein the tissue is gum tissue. Syneron Medical is in the art of oral treatment procedures (Para. [0001]) and teaches wherein tissue is gum tissue (suitable for treatment or prevention of gingival tissue (gum) recession, Para. [0043]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Otech Industry SRL with the teaching of Syneron Medical for the purpose of treating gingival tissue with the applicator and thereby ensure that the applicator provides cosmetic treatments (Syneron Medical, Para. [0043]).

Regarding Claim 51, modified Otech Industry SRL discloses the method of Claim 49.
Otech Industry SRL fails to explicitly disclose including using the electrode to ablate an epithelium layer of the gum tissue while leaving an underlying connective tissue layer substantially undamaged. Syneron Medical is in the art of oral treatment procedures (Para. [0001]) and teaches including using an electrode to ablate an epithelium layer of gum tissue (gingiva RF voltage application elements 112 arranged along a strip 250 and configured to deliver to gingival epithelium RF voltage sufficient to ablate the epithelium and bring about a removal of gingival epithelium, Para. [0042]) while leaving an underlying connective tissue layer substantially undamaged (during gingival pigment removal procedure only a superficial cell layer is removed, Para. [0053]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Otech Industry SRL with the teaching of Syneron Medical for the purpose of de-pigmentation of gingival tissue with the application elements of the applicator and thereby ensure that the applicator provides cosmetic treatments (Syneron Medical, Para. [0043]).

Regarding Claim 52, modified Otech Industry SRL discloses the method of Claim 49.
Otech Industry SRL fails to explicitly disclose wherein the method is used to remove gingiva hyperplasia from the subject's gums. Syneron Medical is in the art of oral treatment procedures (Para. [0001]) and teaches wherein a method is used to remove (ablate the epithelium, Para. [0042]) gingiva hyperplasia (new epithelial growth could also expand the gingival tissue, Para. [0037]) from a subject's gums (suitable for treatment or prevention of gingival tissue (gum) recession, Para. [0043]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Otech Industry SRL with the teaching of Syneron Medical for the purpose of treating gum recession with the applicator and thereby ensure that the applicator provides cosmetic treatments (Syneron Medical, Para. [0043]).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2019/064104

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Regarding Claim 53, Otech Industry SRL discloses the method of Claim 27. Otech Industry SRL fails to explicitly disclose wherein the method is used to remove areas of hyperpigmentation from the subject's tissue. Syneron Medical is in the art of oral treatment procedures (Para. [0001]) and teaches wherein a method is used to remove areas of hyperpigmentation (can be used for gingiva de-pigmentation procedures, Para. [0043]) from a subject's tissue (suitable for treatment or prevention of gingival tissue (gum) recession, Para. [0043]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Otech Industry SRL with the teaching of Syneron Medical for the purpose of de-pigmentation of gingival tissue with the applicator and thereby ensure that the applicator provides cosmetic treatments (Syneron Medical, Para. [0043]).

Claim 30 lacks an inventive step under PCT Article 33(3) as being obvious over Otech Industry SRL in view of Stoller et al. (hereinafter Stoller).

Regarding Claim 30, Otech Industry SRL discloses the method of Claim 29. Otech Industry SRL fails to explicitly disclose wherein the isolated tissue layer comprises acellular dermis and/or is used to prepare acellular dermis. Stoller is in the art of electrosurgical cutting (Para. [0056]) and teaches wherein an isolated tissue layer comprises acellular dermis (the debris removed can include cellular and/or acellular material(s) . . . the tissue surface can comprise . . . an external bodily surface, Para. [0019]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Otech Industry SRL with the teaching of Stoller for the purpose of removing debris from an external body surface and thereby ensure that the various materials are removed from the tissue surface (Stoller, Para. [0019]).

Claim 54 lacks an inventive step under PCT Article 33(3) as being obvious over Otech Industry SRL in view of Guided Therapy Systems, LLC (hereinafter Guided Therapy Systems).

Regarding Claim 54, Otech Industry SRL discloses the method of Claim 27. Otech Industry SRL fails to explicitly disclose wherein the method is used to remove areas of hypopigmentation from the subject's tissue. Guided Therapy Systems is in the art of a therapeutic energy field using an electrode (Para. [0059]) and teaches wherein a method is used to remove areas of hypopigmentation from a subject's tissue (the systems and methods described herein can be used in the treatment of hypopigmentation . . . the epidermis at the light colored areas of the skin, Para. [0150]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Otech Industry SRL with the teaching of Guided Therapy Systems for the purpose of providing energy to the area of skin having a light color and thereby ensure that the skin has a more even coloring pattern at the treatment location (Guided Therapy Systems, Para. [0150]).

Claims 1-45 and 47-56 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.