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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/698,673	04/28/2015	Roger Ignon	EDGE.005C2	7926

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EXAMINER

KNAUSS, CHRISTIAN D

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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03/07/2016

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
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Sinclair Pharma Exhibit 1088
Sinclair Pharma, et al. v. HydraFacial
IPR2025-00145

Office Action Summary	Application No. 14/698,673	Applicant(s) IGNON ET AL.	
	Examiner CHRISTIAN KNAUSS	Art Unit 3731	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/5/16.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 2,4-6 and 8-21 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 2,4-6 and 8-21 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____. | 4) ☐ Other: ____. |

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Response to Amendment

2. Claims 2, 4-6, and 8-21 are pending in the application. Claims 1, 3, and 7 have been canceled. Claims 2, 8, 9, 11, 14, and 20 have been amended.

Claim Objections

3. Claim 9 is objected to because of the following informalities: Claim 9 is dependent on claim 1, which is canceled. For examination purposes, the Examiner has assumed that claim 9 is dependent on claim 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4-6 and 17-19 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

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6. Claim 4 recites the limitation "the at least one fluid container" in line 3. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

7. Claim 4 recites that the console comprises a display, which comprises a user input device to facilitate controlling a flow of treatment materials from the at least one fluid container to the handpiece assembly. It is unclear if this user input device is the same user input device from claim 1, or a different user input device. Appropriate correction is required.

8. Claim 5 is dependent on rejected claim 4, thus is also rendered indefinite. Appropriate correction is required.

9. Claim 6 recites the limitation "the at least one fluid container" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

10. Claim 17 recites the limitation "the at least one fluid container" in line 3. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

11. Claim 17 recites the limitation "console" in line 1. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

12. Claim 18 is dependent on rejected claim 17, thus is also rendered indefinite. Appropriate correction is required.

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13. Claim 19 recites the limitation "the at least one fluid container" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

14. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

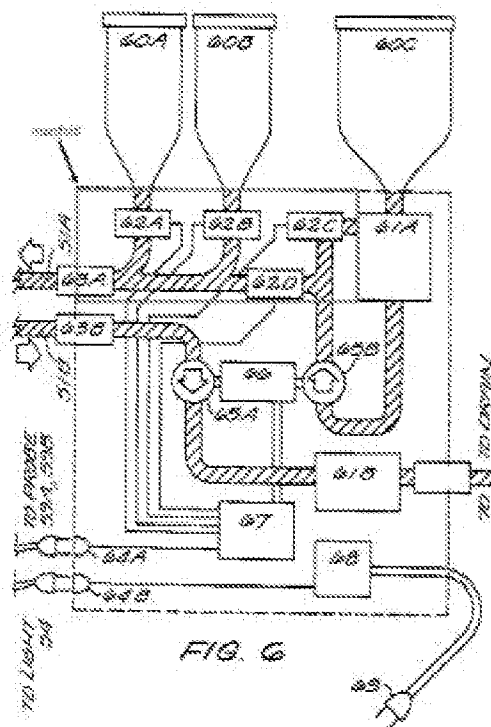
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 2, 4, 6, 8-12, 14-17, 19, and 20 are rejected under pre-AIA 35 U.S.C. 102(b) as anticipated by Coleman et al. (US 2001/0049511 A1) ("Coleman") or, in the alternative, under pre-AIA 35 U.S.C. 103(a) as obvious over Coleman et al. (US 2001/0049511 A1) ("Coleman") in view of Greenberg (US 2003/0093089 A1).

Regarding claim 2, Coleman discloses (Figures 4-6) a system for performing a skin treatment procedure, the system comprising: a console (Figure 6) including a manifold (see Figure 6 below), the manifold being in fluid communication with a first fluid container (60C) and at least a second fluid container (60B), the first fluid container and the at least second fluid container capable of containing a treatment material for a skin treatment procedure; a handpiece assembly (Figures 5A and 5B) comprising a tip, the tip capable of contacting a skin surface of a subject; a supply conduit (51A) placing the manifold of the console in fluid communication with the handpiece assembly, wherein a

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distal end of the supply conduit is configured to couple to the handpiece assembly; wherein the manifold is capable of controlling a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; a waste conduit (51B) in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to a vacuum source (64A); and a user input device (59A, 59B) capable of receiving instructions from a user; wherein the system is capable of permitting a user to select a treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly.



Regarding claim 8, Coleman discloses (Figure 6) that the manifold is configured to be placed in fluid communication with at least four fluid containers (60A, 60B, 60C, 61A).

Regarding claim 9, Coleman discloses that treatment materials from the first fluid container and the at least second fluid container are delivered to the supply conduit simultaneously (paragraph 0060).

Regarding claim 10, the console disclosed by Coleman is capable of being moved.

Regarding claim 11, Coleman discloses that the tip of the handpiece assembly is capable of exfoliating skin tissue as the handpiece assembly is moved relative to a skin surface of a subject (paragraphs 0009-0010).

Regarding claim 12, Coleman discloses (Figures 5A and 5B) that each of the supply conduit (51A) and the waste conduit (51B) connects to a corresponding connector along a proximal end of the handpiece assembly.

Regarding claim 14, Coleman discloses (Figures 4-6) a system for performing a skin treatment procedure, the system comprising: a manifold (see Figure 6 above) in fluid communication with at least two fluid containers (60B, 60C), each of the at least two fluid containers capable of containing a treatment material; a handpiece assembly (Figures 5A and 5B) comprising a tip, the tip capable of contacting a skin surface of a subject; and a supply conduit (51A) placing the manifold in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is capable of securing to the handpiece assembly; wherein the manifold is capable of controlling a flow of

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treatment material from each of the fluid containers through the supply conduit; wherein the system is capable of permitting a user to select the fluid container from which treatment material is delivered to the supply conduit.

Regarding claim 15, Coleman discloses (Figure 6) a waste conduit (51B) in fluid communication with the handpiece assembly capable of removing waste from a skin surface of a subject during a procedure, wherein the waste conduit is operatively couple to a vacuum source (65A).

Regarding claim 16, Coleman discloses (Figures 5A and 5B) a user input device (59A and 59B) for selecting a treatment material to be passed through the supply conduit to the handpiece assembly.

Regarding claim 20, Coleman discloses that the tip of the handpiece assembly is capable of exfoliating skin tissue as the handpiece assembly is moved relative to a skin surface of a subject (paragraphs 0009-0010).

In the alternative, regarding claims 2, 4, and 6, Coleman discloses (Figures 4-6) a system for performing a skin treatment procedure, the system comprising: a console (Figure 6) including a manifold (see Figure 6 below), the manifold being in fluid communication with a first fluid container (60C) and at least a second fluid container (60B), the first fluid container and the at least second fluid container capable of containing a treatment material for a skin treatment procedure; a handpiece assembly (Figures 5A and 5B) comprising a tip, the tip capable of contacting a skin surface of a subject; a supply conduit (51A) placing the manifold of the console in fluid

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communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly; wherein the manifold is capable of controlling a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; a waste conduit (51B) in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to a vacuum source (64A); and a user input device (59A, 59B) capable of receiving instructions from a user; wherein the system is capable of permitting a user to select a treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly. However, Coleman fails to disclose that the console comprises a display, wherein the display comprises a user input device to facilitate controlling a flow of treatment materials from the at least one fluid container to the handpiece assembly. Coleman further fails to disclose that the at least one fluid container is releasably coupled to the manifold.

Greenberg discloses (Figures 1 and 2) a system for performing a skin treatment procedure, the system comprising: a console (10) including a manifold, a fluid container (18), a handpiece assembly (16), a supply conduit (20), a waste conduit (20), a display (front surface of console containing 52, 56), wherein the display comprises a user input device (30, 32, 42, 48, 50) capable of facilitating controlling a flow of treatment materials from the at least one fluid container to the handpiece assembly. Greenberg discloses (Figure 2) that the fluid container is releasably coupled to the manifold.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the console to include a display, wherein the display comprises a user input device to facilitate controlling a flow of treatment materials from the at least one fluid container to the handpiece assembly, as taught by Greenberg. This modification would provide advantages such as a display including a timer to assist the operator in keeping track of time that the machine has been used for (paragraph 0063) and would allow the operator to make adjustments to features such as vacuum suction (paragraph 0059). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the at least one fluid container to be releasably coupled to the manifold, as taught by Greenberg. This modification would allow the operator to attach containers of different medical treatment materials to the manifold to be applied to the skin.

Regarding claims 14, 17, and 19, Coleman discloses (Figures 4-6) a system for performing a skin treatment procedure, the system comprising: a manifold (see Figure 6 above) in fluid communication with at least two fluid containers (60B, 60C), each of the at least two fluid containers capable of containing a treatment material; a handpiece assembly (Figures 5A and 5B) comprising a tip, the tip capable of contacting a skin surface of a subject; and a supply conduit (51A) placing the manifold in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is capable of securing to the handpiece assembly; wherein the manifold is capable of controlling a flow of treatment material from each of the fluid containers through the

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supply conduit; wherein the system is capable of permitting a user to select the fluid container from which treatment material is delivered to the supply conduit.

However, Coleman fails to disclose that the console comprises a display, wherein the display comprises a user input device to facilitate controlling a flow of treatment materials from the at least one fluid container to the handpiece assembly. Coleman further fails to disclose that the at least one fluid container is releasably coupled to the manifold.

Greenberg discloses (Figures 1 and 2) a system for performing a skin treatment procedure, the system comprising: a console (10) including a manifold, a fluid container (18), a handpiece assembly (16), a supply conduit (20), a waste conduit (20), a display (front surface of console containing 52, 56), wherein the display comprises a user input device (30, 32, 42, 48, 50) capable of facilitating controlling a flow of treatment materials from the at least one fluid container to the handpiece assembly. Greenberg discloses (Figure 2) that the fluid container is releasably coupled to the manifold.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the console to include a display, wherein the display comprises a user input device to facilitate controlling a flow of treatment materials from the at least one fluid container to the handpiece assembly, as taught by Greenberg. This modification would provide advantages such as a display including a timer to assist the operator in keeping track of time that the machine has been used for (paragraph 0063) and would allow the operator to make adjustments to features such as vacuum suction (paragraph 0059). It would have been obvious to one having ordinary skill in the

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art at the time the invention was made to modify the at least one fluid container to be releasably coupled to the manifold, as taught by Greenberg. This modification would allow the operator to attach containers of different medical treatment materials to the manifold to be applied to the skin.

16. Claims 5 and 18 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Coleman et al. (US 2001/0049511 A1) ("Coleman") in view of Greenberg (US 2003/0093089 A1) as applied to claims 4 and 17, respectively, above, and further in view of Duchon et al. (US 2003/0018252 A1) ("Duchon").

Regarding claims 5 and 18, Coleman as modified by Greenberg teaches the invention substantially as claimed. However, the combined teaching fails to teach that the user input device comprises a touch screen.

Duchon teaches that it was well-known in the art at the time the invention was made for a console to include a touch screen user input (432). Duchon teaches that a touch screen is an equivalent structure to a selector dial, keypad, button, etc. that can be used by a user for console input.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the user input device taught by Coleman in view of Greenberg to be a touch screen user input because Duchon teaches that a touch screen is an equivalent structure to a input knob, button, keypad, dial, etc. that is known in the art for entering input into a console system.

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17. Claims 13 and 21 rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Coleman et al. (US 2001/0049511 A1) ("Coleman") in view of Nelson et al. (US 3,865,352) ("Nelson") or in the alternative over Coleman et al. (US 2001/0049511 A1) ("Coleman") in view Greenberg (US 2003/0093089 A1) as applied to claims 2 and 14, respectively, above, and in further view of Nelson et al. (US 3,865,352) ("Nelson").

Regarding claims 13 and 21, Coleman discloses the invention substantially as highlighted in the rejections above. However, Coleman fails to disclose that the manifold of the console is configured to be placed in fluid communication with a container comprising an antimicrobial fluid, or other disinfecting agent for periodic flushing of the manifold.

Nelson teaches a device for mixing and dispensing materials, comprising: a manifold (25), the manifold in fluid communication with at least one fluid container (15, 16, 38), the at least one fluid container being configured to contain a fluid material; a handpiece assembly (10); the manifold and the handpiece assembly in fluid communication. Nelson further teaches that the manifold of the console is in fluid communication with a container (38) comprising a solvent for periodic flushing and cleaning of the manifold.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the manifold to be placed in fluid communication with a container comprising a solvent for periodic flushing of the manifold, as taught by Nelson.

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This modification would clean the manifold and supply conduit of the materials from the at least one fluid container (Column 2, lines 18-22).

Response to Arguments

18. Applicant's arguments filed 2/5/16 have been fully considered but they are not persuasive. During the interview held on 8/7/15, the Examiner provided a suggested strategy as to how to amend the claims to overcome the previous rejections. However, specific claim language was not agreed upon. After further review of the specification, the Examiner suggests that the Applicant amend the claims to recite that the system is configured to permit a user to individually/independently select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly, as disclosed in paragraph 0129.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN KNAUSS whose telephone number is (571)272-8641. The examiner can normally be reached on Monday-Friday 8:00 am - 5 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. K./
Examiner, Art Unit 3731

/RYAN J. SEVERSON/
Primary Examiner, Art Unit 3731