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[Continued on next page]

(54) Title: SYSTEMS AND METHODS FOR PHOTOTHERAPY CONTROL

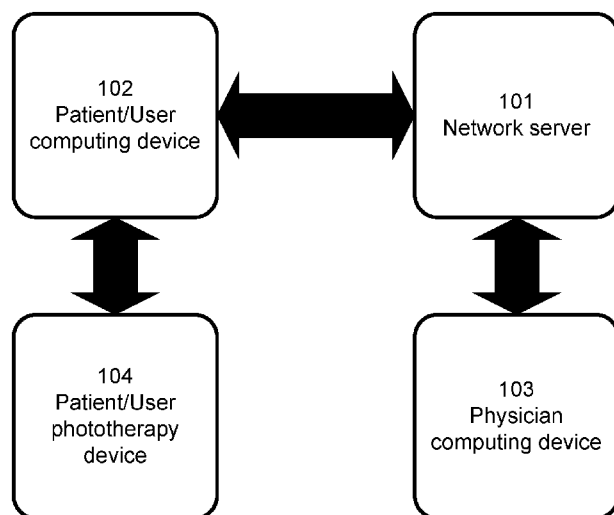


FIG. 1

(57) Abstract: The present disclosure relates to systems, methods, and uses of systems treating a skin condition with phototherapy. A system comprises (a) a phototherapy device comprising a phototherapy light source; (b) a patient computing device comprising a processor and a memory, the patient computing device configured to: transmit a first signal to the phototherapy device enabling operation of the phototherapy device according to one or more conditional prescription parameters, activate the phototherapy light source, and transmit a second signal reporting operation of the phototherapy device; and (c) a server configured to communicate with the patient computing device and receive the second signal. Also disclosed are systems, methods and compositions for controlling phototherapy treatments of the skin.

**Declarations under Rule 4.17:**

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

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16 March 2017

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- with international search report (Art. 21(3))

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US16/43378

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - G01J1/02, A61N5/06, G01J1/42, A61B5/00, A61K49/00, A61K8/92 (2016.01)

CPC - G01J1/0219, A61N2005/0628, A61B5/441, G01J1/429, G01J2001/4266, A61B5/4848

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) Classifications: G01J1/02, A615/06, G01J1/42, A61N5/06, A61K49/00, A61K8/92 (2016.01); CPC Classifications: G01J1/0219, A61N2005/0628, A61B5/441, G01J1/429, G01J2001/4266, A61B5/4848, A61N2005/0661, A61N5/0616, A61N2005/0627, A61K49/006

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Google Scholar, Pubmed, EBSCO  
Estimate, measure, detect, assess, ultraviolet, sun, UV, UVA, UVB, UVC, exposure, amount, phototherapy, photostimulation, photoactivation, prescribe, required, optimize, sensor, compare, monitor, absorb, fade, index, reducing, supplement, skin, indicator

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                                                                                                     | Relevant to claim No. |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X         | US 2013/0301034 A1 (GOODLUX TECHNOLOGY LLC) November 14, 2013; paragraphs [0060], [0071], [0074], [0084]-[0086]                                                                                                                                                                                                        | 1, 6-11               |
| Y         |                                                                                                                                                                                                                                                                                                                        | 2-5                   |
| X         | US 2006/0085053 A1 (ANDERSON, RR, et al.) April 20, 2006; paragraphs [0057], [0060], [0069], [0076]-[0079], [0084], [0087], [0095]                                                                                                                                                                                     | 13                    |
| Y         |                                                                                                                                                                                                                                                                                                                        | 14-16                 |
| Y         | US 2015/0177059 A1 (LIAN, J, et al.) June 25, 2015; paragraphs [0021], [0078], [0100]-[0101]; claim 1                                                                                                                                                                                                                  | 2-5                   |
| Y         | US 2010/0076529 A1 (TUCKER, G, et al.) March 25, 2010; paragraph [0083]                                                                                                                                                                                                                                                | 14                    |
| Y         | WO 2014/162271 A2 (NIKOLIC, B, et al.) October 09, 2014; paragraphs [0014], [0056]                                                                                                                                                                                                                                     | 15-16                 |
| Y         | US 2013/0245724 A1 (NATIONAL BIOLOGICAL CORPORATION) September 19, 2013; paragraphs [0016], [0020], [0021], [0023]-[0025], [0030]                                                                                                                                                                                      | 17                    |
| Y         | US 2014/0244292 A1 (WISER TOGETHER INC.) August 28, 2014; paragraphs [0010]-[0011], [0016], [0058], [0060], [0077]                                                                                                                                                                                                     | 17                    |
| Y         | ASZTALOS, ML, et al. The impact of emollients on phototherapy: A review. Journal of the American Academy of Dermatology. Vol. 68, No. 5, May 2013 [online]. [retrieved on 2016-12-05]. Retrieved from Internet: <http://www.jaad.org/article/S0190-9622(12)00636-6/> <DOI: 10.1016/j.jaad.2012.05.034>; pages 819, 822 | 18-22, 24-25          |



Further documents are listed in the continuation of Box C.



See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

08 December 2016 (08.12.2016)

Date of mailing of the international search report

26 JAN 2017

Name and mailing address of the ISA/

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PCT OSP: 571-272-7774

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US16/43378

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                    | Relevant to claim No. |
|-----------|-----------------------------------------------------------------------------------------------------------------------|-----------------------|
| Y         | WO 2014/040177 A1 (KLOX TECHNOLOGIES INC.) March 20, 2014; lines 18-28 page 6, lines 16-17 page 18, lines 1-5 page 26 | 18-22, 24-25          |
| A         |                                                                                                                       | 23                    |
| A         | US 2002/0022008 A1 (FOREST, SE, et al.) February 21, 2002; paragraph [0055]                                           | 23                    |
| A         | US 2007/0078501 A1 (ALTSHULER, GB, et al.) April 05, 2007; paragraph [0227]                                           | 23                    |
| A         | WO 2010/010321 A1 (UNIVERSITY OF STRATHCLYDE) January 28, 2010; lines 8-23 page 14                                    | 23                    |
| P,X       | US 2015/0217130 A1 (SKYLIT CORPORATION) August 06, 2015; entire document                                              | 14-16                 |

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US16/43378

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

The application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fee must be paid.

Group I: Claims 1-11 are directed towards a method to estimate or measure therapeutic UV exposure to the sun to fulfill treatment needs or to supplement a prescribed phototherapy treatment comprising: measuring or estimating UV exposure received by an individual, communicating UV exposure information to a computing device, and comparing the UV exposure to the prescribed phototherapy treatment.

---Continued Within the Next Supplemental Box---

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:  
  
1-11, 13-25
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

\*\*\*-Continued from Box No. III -\*\*\*

Group II: Claim 12 is directed towards a method to determine the erythema level of unaffected skin within a treatment area comprising: taking a photographic image of the treatment area and surrounding skin, pre-processing the image to remove non-skin background areas, identifying the treated and untreated regions, by using image processing techniques such as boundary shape identification, computing the red color difference between skin on either side of the boundary, and comparing the red color difference to threshold values to determine whether unaffected skin is normal, pink or red.

Group III: Claims 13-16 are directed towards a method to guide a targeted phototherapy treatment sequence comprising: communicating between a phototherapy device and a computing device to synchronize a phototherapy sequence plan to be administered, communicating information from the phototherapy device to the computing device during treatment, providing current status of the treatment sequence using audio or visual cues, communicating from the phototherapy device to the computing device when a treatment has been completed, or was interrupted, and communicating the next treatment location to the administrator on the computing device using audio or visual cues.

Group IV: Claim 17 is directed towards a method to develop evidence-based treatment recommendations from a connected system of phototherapy devices comprising: collecting outcomes of phototherapy treatments from a plurality of patients using phototherapy devices on the connected system; determining patient criteria of interest such as disease type, severity, age, skin type, years with disease, treatment area locations, geographical location, comorbidities, lifestyle, medical history; determining treatment criteria of interest such as dose control method, treatment frequency, missed treatments, dose levels, treatment history, other medications; correlating patient criteria and treatment criteria to positive outcomes and negative outcomes; and providing evidence based recommendations on treatment plan adjustments for an individual based on correlation evidence.

Group V: Claims 18-25 are directed towards a composition for application to a region of a patient's skin including an area of a skin affected by a skin condition, in association with application of UV light to the affected area of skin for UV phototherapeutic treatment of the skin condition, the composition comprising: an emollient base for facilitating the absorbance of the applied UV light into the affected area of skin; and a UV-fading dye, the UV-fading dye present in the composition in a concentration suitable for temporarily staining the patient's skin upon application of the composition to the patient's skin, and for fading upon exposure to the applied UV light, thereby indicating where the UV light has been applied to the patient's skin.

The inventions listed as Groups I, II, III, IV, and V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Group I has at least communicating UV exposure information to a computing device, and comparing the UV exposure to the prescribed phototherapy treatment that Groups II-V do not have.

Group II has at least taking a photographic image of the treatment area and surrounding skin, pre-processing the image to remove non-skin background areas, identifying the treated and untreated regions, by using image processing techniques such as boundary shape identification, computing the red color difference between skin on either side of the boundary, and comparing the red color difference to threshold values to determine whether unaffected skin is normal, pink or red that Groups I, III-V do not have.

Group III has at least communicating between a phototherapy device and a computing device to synchronize a phototherapy sequence plan to be administered, communicating information from the phototherapy device to the computing device during treatment, providing current status of the treatment sequence using audio or visual cues, communicating from the phototherapy device to the computing device when a treatment has been completed, or was interrupted, and communicating the next treatment location to the administrator on the computing device using audio or visual cues that Groups I-II, IV-V do not have.

Group IV has at least collecting outcomes of phototherapy treatments from a plurality of patients using phototherapy devices on the connected system; determining patient criteria of interest such as disease type, severity, age, skin type, years with disease, treatment area locations, geographical location, comorbidities, lifestyle, medical history; determining treatment criteria of interest such as dose control method, treatment frequency, missed treatments, dose levels, treatment history, other medications; correlating patient criteria and treatment criteria to positive outcomes and negative outcomes; and providing evidence based recommendations on treatment plan adjustments for an individual based on correlation evidence that Groups I-III, V do not have.

Group V has at least an emollient base for facilitating the absorbance of the applied UV light into the affected area of skin that Groups I-IV do not have.

The common technical features of Groups I-V are measuring or estimating UV exposure received by an individual and phototherapy treatment with a phototherapy device.

These common features are disclosed by US 2007/0049996 A1 to Black, J (hereinafter 'Black'). Black discloses a method for measuring or estimating UV exposure received by an individual (monitoring method for tissue treatment that processes images to measure/estimate UV dose amount, abstract, paragraphs [0012] and [0029]) and for performing a phototherapy treatment with a phototherapy device (tissue treatment using phototherapy apparatus, abstract).

Since the common technical features are previously disclosed by the Black reference, these common features are not special and so Groups I-V lack unity.