

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization

International Bureau

(43) International Publication Date
03 April 2025 (03.04.2025)



(10) International Publication Number
WO 2025/072096 A1

(51) International Patent Classification:

G06N 20/00 (2019.01) G06N 3/08 (2023.01)
A61B 5/00 (2006.01) G16H 50/20 (2018.01)

SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN,
GQ, GW, KM, ML, MR, NE, SN, TD, TG).

(21) International Application Number:

PCT/US2024/048008

Published:

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

(22) International Filing Date:

23 September 2024 (23.09.2024)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/540,270 25 September 2023 (25.09.2023) US

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(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG,
KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY,
MA, MD, MG, MK, MN, MU, MW, MX, MY, MZ, NA,
NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO,
RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH,
TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS,
ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, CV,
GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, ST,
SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ,
RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ,
DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT,
LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE,

(54) Title: DEVICE, SYSTEM AND METHOD FOR DISEASE MANAGEMENT

(57) Abstract: A mobile device and/or a web-browser-based computer-implemented system, and computer-implemented method using them, for tracking, processing and analyzing patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, and establishing and maintaining a database on patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, said mobile device and/or system are adapted to implement the following (and said method comprising): receiving patient data from patients with Pemphigus vulgaris and related conditions or Bullous pemphigoid and related conditions through user input; transmitting said patient data to a remote management server, which server is adapted to track, process and analyze the patient data and maintain the patient data in a database; retrieving said patient data from said database and displaying said data.



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DEVICE, SYSTEM AND METHOD FOR DISEASE MANAGEMENT

TECHNICAL FIELD

[0001] This disclosure relates to a digital database comprising patient data from patients with Pemphigus vulgaris.

BACKGROUND

[0002] At present, disease management cannot identify individuals at risk; cannot predict the extent or course of the disease; and cannot match treatment to expected responders. But clinical decisions must be better rooted in scientific rationale and tailored to a particular patient.

SUMMARY

[0003] In one aspect, this disclosure provides a mobile device for tracking, processing and analyzing patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, and establishing and maintaining a database on patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, said device comprising a mobile device processor, a mobile device memory, a mobile device display, a mobile device radio transceiver that supports voice and data interactions through a communication channel and a mobile device wireless fidelity (Wi-Fi) transceiver; said mobile device is adapted to implement the following: receiving, at a non-browser based application on said mobile device, said patient data through user input; wherein said data include one or more of the following: clinical data, biologic data, exposome data, social determinant of health survey data, social quality of life survey data, and microbiome data; wherein the non-browser based application is a mobile operating system platform based mobile application with a graphical user interface that is preinstalled or downloaded and installed on the mobile device, wherein the graphical user interface includes a graphical icon; transmitting said patient data to a remote management server, which server tracks, processes and analyzes the patient data and maintains the patient data in a database;

retrieving said patient data from said database and displaying said data on the mobile device display within the non-browser based application.

[0004] In another aspect, this disclosure provides a web-browser-based computer-implemented system for tracking, processing and analyzing patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, and establishing and maintaining a database on patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, said system comprising a processor, a memory, a display, a radio transceiver that supports voice and data interactions through a communication channel and a wireless fidelity (Wi-Fi) transceiver; said system is adapted to implement the following:

receiving, at a browser based application or website, said patient data through user input; wherein said data include one or more of the following: clinical data, biologic data, exposome data, social determinant of health survey data, social quality of life survey data; transmitting said patient data to a remote management server, which server tracks, processes, and analyzes the patient data and maintains the patient data in a database; retrieving said patient data from said database and displaying said data on the display on the website or within the browser based application.

[0005] In yet another aspect, this disclosure provides a computer-implemented method for tracking, processing and analyzing patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, and establishing and maintaining a database on patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, comprising: receiving, at a non-browser based application on a disclosed mobile device and/or a disclosed web-browser-based computer-implemented system, said patient data from patients through user input; wherein said data include one or more of the following: clinical data, biologic data, exposome data, social determinant of health survey data, social quality of life survey data, microbiome data; transmitting said patient data to a remote management server, which server tracks, processes, and analyzes the patient data and maintains the patient data in a database.

[0006] Numerous other aspects are provided in accordance with these and other aspects of the invention. Other features and aspects of the present invention will become more fully apparent from the following detailed description and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. 1 illustrates a block diagram of a communication system including a mobile device and a management server in accordance with one implementation.

[0008] FIG. 2 illustrates one implementation of the web-browser-based computer-implemented system for tracking, processing and analyzing patient data on patients with Pemphigus vulgaris, Bullous pemphigoid and related conditions and establishing and maintaining a database on patient data on patients with Pemphigus vulgaris, Bullous pemphigoid and related conditions

[0009] FIG. 3 is a block diagram of a data processing system suitable for storing and/or executing program code in accordance with one implementation.

DETAILED DESCRIPTION

[0010] As used herein, the word “a” or “plurality” before a noun represents one or more of the particular noun.

[0011] For the terms “for example” and “such as,” and grammatical equivalences thereof, the phrase “and without limitation” is understood to follow unless explicitly stated otherwise. As used herein, the term “about” is meant to account for variations due to experimental error. All measurements reported herein are understood to be modified by the term “about,” whether or not the term is explicitly used, unless explicitly stated otherwise. As used herein, the singular forms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise.

[0012] As used herein, an “individual,” a “patient” and a “subject” are interchangeable terms and may refer to a human patient/subject, a dog, a cat, a non-human primate, etc.

[0013] All ranges disclosed herein are to be understood to encompass any and all subranges subsumed therein. For example, a stated range of “1.0 to 10.0” should be considered to include any and all subranges beginning with a minimum value of 1.0 or more and ending with a maximum value of 10.0 or less, e.g., 1.0 to 5.3, or 4.7 to 10.0, or 3.6 to 7.9.

[0014] All ranges disclosed herein are also to be considered to include the end points of the range, unless expressly stated otherwise. For example, a range of “between 5 and 10” or “5 to 10” or “5-10” should be considered to include the end points 5 and 10.

[0015] It is further to be understood that the feature or features of one embodiment may generally be applied to other embodiments, even though not specifically described or illustrated in such other embodiments, unless expressly prohibited by this disclosure or the nature of the relevant embodiments. Likewise, compositions and methods described herein can include any combination of features and/or steps described herein not inconsistent with the objectives of the present disclosure. Numerous modifications and/or adaptations of the compositions and methods described herein will be readily apparent to those skilled in the art without departing from the present subject matter.

[0016] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Methods and materials are described herein for use in the present invention; other, suitable methods and materials known in the art can also be used. The materials, methods, and examples are illustrative only and not intended to be limiting. All publications, patent applications, patents, sequences, database entries, and other references mentioned herein are incorporated by reference in their entirety. In case of conflict, the present specification, including definitions, will control.

[0017] PEMPHIGUS VULGARIS, BULLOUS PHEMPHIGOID AND RELATED CONDITIONS

[0018] Autoimmune disease, prevalent in the population, is a major healthcare burden; an autoimmune disease is when a host's immune system attacks one or more self-antigens (auto-antigens).

[0019] There are over 100 known human autoimmune diseases, affecting between 5-10% of the population. Autoimmune diseases are the 2nd or 3rd leading cause of morbidity and mortality and cost the US healthcare system over \$100 billion annually. Lupus, myasthenia gravis, multiple sclerosis, type 1 diabetes, Pemphigus vulgaris and Bullous pemphigoid are some examples of autoimmune diseases.

[0020] Pemphigus and Pemphigoid fall within the broader group of autoimmune blistering disorders, representing diseases of stratified squamous epithelia, such as the skin and oral mucosa, in which acantholysis (the loss of cell adhesion) causes blisters and erosions. Pemphigus has three major subtypes: pemphigus vulgaris (and related variants), pemphigus foliaceus and paraneoplastic pemphigus, among others. Pemphigoid has several related variants as well, including: mucous membrane pemphigoid, linear IGA disease, and herpes gestationis, among others.

[0021] Pemphigus vulgaris (“PV”) is a potentially life-threatening IgG-mediated autoimmune blistering skin disease, characterized by intraepithelial (suprabasilar) acantholysis, which is a loss of cell-cell adhesion. Bullous pemphigoid (“BP”) is similarly a serious IgG-mediated autoimmune blistering skin disease, characterized by subepithelial acantholysis.

[0022] HLA genetic predisposition (HLA DRB1*0402 and DQB1*0503) for PV has been shown. T cell (Th₂ driven) and B cell subsets (producing IgG₄ autoantibodies) have been elucidated. And two main autoantibody targets (autoantigens) – Desmoglein (Dsg)-3 and Desmoglein-1 – have been identified, others have been identified as well. BP is similarly linked to select HLA genetic markers and dependent upon autoreactive T and B cell activation. Two main autoantibody targets (autoantigens) – BPAG1 and BPAG2 – have been identified in patients with BP. Other autoantigens have been identified as well.

[0023] Dsg3 and Dsg1 are keratinocyte-associated cell surface proteins relevant to cell-cell adhesion. Anti-Dsg3 and anti-Dsg1 autoantibodies can be detected in human PV patients and can be followed by ELISA. The titers roughly correlate with disease activity and serves as disease biomarkers. Similarly, BPAG1 and BPAG2 are keratinocyte-associated proteins relevant to cell-cell adhesion. Anti- BPAG1 and BPAG2 autoantibodies can be detected in human BP patients and can be followed by ELISA. The titers roughly correlate with disease activity and serves as disease biomarkers.

[0024] PV and related conditions and BP and related conditions, however, are complex diseases. They are polygenic diseases and can be influenced by environmental factors.

[0025] DISEASE MANAGEMENT

[0026] Disease management at present cannot identify individuals at risk; cannot predict the extent or course of the disease; and cannot match treatment to expected responders. Clinical decisions must be made rooted in scientific rationale and tailored to a patient.

[0027] The comprehensive set of factors, and interactions between these factors, that impact disease risk and diagnosis, disease prognosis, and treatment outcomes for PV, BP and related conditions and other complex diseases, need to be determined. Biological complexity of a disease like PV and related conditions and BP and related conditions must be addressed in the context of clinical complexity and heterogeneity.

[0028] MOBILE DEVICE, SYSTEM AND METHOD

[0029] There is a need to leverage powerful emerging genetic, genomic, and proteomic technologies to generate and integrate large scale clinical and biological data.

[0030] This disclosure provides a mobile device. The mobile device is a mobile communication device, such as a smart phone (for example, an iPhone, an android phone, etc.), a tablet computing device (for example, an iPad, an android tablet, etc.), a smart watch, a Fitbit, etc. The mobile device is for tracking, processing and analyzing patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, and establishing and maintaining a database on patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions. In some embodiments, the mobile device comprises a mobile device processor, a mobile device memory, a mobile device display, a mobile device radio transceiver that supports voice and data interactions through a communication channel and a mobile device wireless fidelity (Wi-Fi) transceiver. The mobile device is adapted to implement the following:

receiving, at a non-browser based application (“app”) on said mobile device, said patient data through user input; wherein said data include one or more of the following: clinical data, biologic data, exposome data, social determinant of health survey data, social quality of life survey data, and microbiome data;

wherein the non-browser based application is a mobile operating system platform based mobile application with a graphical user interface that is preinstalled or downloaded and installed on the mobile device, wherein the graphical user interface includes a graphical icon;

transmitting said patient data to a remote management server, which server is adapted to track, process and analyze the patient data and maintains the patient data in a database;

retrieving said patient data from said database and displaying said data on the mobile device display within the non-browser based application.

[0031] In some embodiments, the mobile device is further adapted to implement transmitting to the user via the non-browser based application an alert with clinical utility. In further embodiments, the alert with clinical utility is an alert for taking medication, an alert on clinical appointment, clinical trial opportunities and appointments, or an alert on sample collection time. Such alerts can be set up automatically by the app or manually by a user.

[0032] In some embodiments, the mobile device is further adapted to implement providing links to the user to one or more of expert providers, clinical trials, patient support groups, and educational resources. Provision of such links can be set up automatically by the app or manually by a user.

[0033] In some embodiments, the user is a patient or someone acting on behalf of the patient, a research investigator or someone acting on behalf of a research investigator, or a medical care provider or someone acting on behalf of a medical care provider.

[0034] In some embodiments, the patient data include links to patient information associated with a biological sample repository. In some embodiments, the biological sample repository is a repository of one or more DNA samples, RNA samples, serum, skin, and peripheral blood mononuclear cells. In some embodiments, the server analyzes the patient data using one or more of an analytic platform, an algorithm, and artificial intelligence. In some embodiments, the clinical data comprise one or more of a patient's medical history, medical diagnosis, demographics, laboratory data, medicine, family relationships. In certain embodiments, the biologic data comprise one or more genetic data, epigenetic data, transcriptomic data, auto-antibody data, cytokine data, immune cellular subset data, basic clinical blood work data, and basic clinical vitals data. In some embodiments, the exposome data comprise one or more of infection status data, vaccination status data, medication, sleep, food/nutrition, stress, and exercise. In some embodiments, the social determinants of health survey data comprises one or more of the following data: health care access and/or quality, education access and/or quality, social and community context, economic stability, and neighborhood and built environment. In some embodiments, the database comprises all these data.

[0035] This disclosure provides a web-browser-based computer-implemented system for tracking, processing and analyzing patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, and establishing and maintaining a database on patient data on patients with Pemphigus vulgaris and related

conditions or on patients with Bullous pemphigoid and related conditions. In some embodiments, the system comprises a processor, a memory, a display, a radio transceiver that supports voice and data interactions through a communication channel and a wireless fidelity (Wi-Fi) transceiver. In certain embodiments, the system includes a computer, such as a desk top computer or a laptop computer, a personal computer, a mini-computer, a mainframe computer, etc. The system includes a remote management server. The system is adapted to implement the following:

receiving, at a browser based application or website, said patient data through user input; wherein said data include one or more of the following: clinical data, biologic data, exposome data, social determinant of health survey data, social quality of life survey data; transmitting said patient data to a remote management server, which server is adapted to track, process, and analyze the patient data and maintains the patient data in a database; retrieving said patient data from said database and displaying said data on the display on the website or within the browser based application.

[0036] In some embodiments, the web-browser-based computer-implemented system is further adapted to implement transmitting to the user via the browser based application or website an alert with clinical utility. In further embodiments, the alert with clinical utility is an alert for taking medication, an alert on clinical appointment, or an alert on sample collection time. Such alerts can be set up automatically by the app or website or manually by a user.

[0037] In some embodiments, the system is further adapted to implement providing links to the user to one or more of expert providers, clinical trials, patient support groups, and educational resources. Provision of such links can be set up automatically by the app or website or manually by a user.

[0038] In some embodiments, the user is a patient or someone acting on behalf of the patient, a research investigator or someone acting on behalf of a research investigator, or a medical care provider or someone acting on behalf of a medical care provider.

[0039] In some embodiments, the patient data include links to patient information associated with a biological sample repository. In some embodiments, the biological sample repository is a repository of one or more DNA samples, RNA samples, serum, skin, and peripheral blood mononuclear cells. In some embodiments, the server analyzes the patient data using one or more of an analytic platform, an algorithm, and artificial intelligence. In some embodiments, the

clinical data comprise one or more of a patient's medical history, medical diagnosis, demographics, laboratory data, medicine, family relationships. In certain embodiments, the biologic data comprise one or more genetic data, epigenetic data, transcriptomic data, auto-antibody data, cytokine data, immune cellular subset data, basic clinical blood work data, and basic clinical vitals data. In some embodiments, the exposome data comprise one or more of infection status data, vaccination status data, medication, sleep, food/nutrition, stress, and exercise. In some embodiments, the social determinants of health survey data comprises one or more of the following data: health care access and/or quality, education access and/or quality, social and community context, economic stability, and neighborhood and built environment. In some embodiments, the database comprises all these data.

[0040] This disclosure provides a computer-implemented method for tracking, processing and analyzing patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, and establishing and maintaining a database on patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions. The method comprises: receiving, at a non-browser based application on a disclosed mobile device and/or a disclosed web-browser-based computer-implemented system, said patient data through user input; wherein said data include one or more of the following: clinical data, biologic data, exposome data, social determinant of health survey data, social quality of life survey data, microbiome data; transmitting said patient data to a remote management server, tracking, processing, and/or analyzing the patient data and maintaining the patient data in a database at the remote server.

[0041] In further embodiments, the computer-implemented method further comprises retrieving said patient data from said database and displaying said data on the mobile device display within the non-browser based application or on the website or within the browser based application.

[0042] In some embodiments, the method further comprises transmitting to the user via the non-browser based application an alert with clinical utility. In further embodiments, the alert with clinical utility is an alert for taking medication, an alert on clinical appointment, and alert on clinical trial opportunities or appointments, or an alert on sample collection time. Such alerts can be set up automatically by the app or website or manually by a user.

[0043] In some embodiments, the method further comprises providing links to the user to one or more of expert providers, clinical trials, patient support groups, and educational resources.

Provision of such links can be set up automatically by the app or website or manually by a user.

[0044] In some embodiments, the user is a patient or someone acting on behalf of the patient, a research investigator or someone acting on behalf of a research investigator, or a medical care provider or someone acting on behalf of a medical care provider.

[0045] In some embodiments, the patient data include links to patient information associated with a biological sample repository. In some embodiments, the biological sample repository is a repository of one or more DNA samples, RNA samples, serum, skin, and peripheral blood mononuclear cells. In some embodiments, the server analyzes the patient data using one or more of an analytic platform, an algorithm, and artificial intelligence. In some embodiments, the clinical data comprise one or more of a patient's medical history, medical diagnosis, demographics, laboratory data, medicine, family relationships. In certain embodiments, the biologic data comprise one or more genetic data, epigenetic data, transcriptomic data, auto-antibody data, cytokine data, immune cellular subset data, basic clinical blood work data, and basic clinical vitals data. In some embodiments, the exposome data comprise one or more of infection status data, vaccination status data, medication, sleep, food/nutrition, stress, and exercise. In some embodiments, the social determinants of health survey data comprises one or more of the following data: health care access and/or quality, education access and/or quality, social and community context, economic stability, and neighborhood and built environment. In some embodiments, the database comprises all these data.

[0046] The device, system and method disclosed herein result in a digital database of patients with PV. The larger the database the more powerful. The database constructs biological and clinical profiles to deconstruct disease complexity.

[0047] The database has biological profiles of patients with PV and related conditions or BP and related conditions. These profiles include genetic profiles, transcriptional profiles, cytokine profiles, and autoantibody profiles, microbiome profiles, basic blood value profiles, among others.

[0048] The database has clinical profiles of patients with PV and related conditions or BP and and related conditions. The clinical profiles provide dynamic parameters of disease, such as disease phase information, morphology of lesions, disease duration, therapy, and outcome, and

static parameters of disease, such as gender, age of onset, HLA type. Therapies and disease management can be tailored to each patient, depending on the patient's data and profiles, as compared to profiles and data already in the database.

[0049] The digital database provides structured data. The data provide a better understanding of disease processes, such as disease susceptibility/induction, disease expression/progression, and therapeutic outcomes. The digital database allows use of next generation medical technologies, such as immunoprofiling, exome/genome sequencing, deep transcriptomics, miRNA profiling, metabolomics, microbiome, structural imaging, and sensors/point of care. The digital database provides medical informatics, such as universal intake protocols, image capture, seamless EMR/blockchain, universal (robotic) biobanking, longitudinal monitoring, and real-time, mobile input/access.

[0050] The digital database allows for better clinical applications, such as biomarkers/digital disease maps – genetic /genomic/ proteomic - of disease with relevance to: diagnosis, prognosis, and response to treatment. Disease management/Treatment becomes targeted, specific and individualized.

[0051] The digital database allows medicine, biology, and high technology to merge, for patient benefit. Every patient encounter is designed for biological/clinical data generation. Investigation is interwoven into the “DNA of patient care,” allowing for interdisciplinary, team approach to science and patient care.

[0052] The disclosed mobile device, system, and method represent a digital solution to allow the collection of multi-sourced, large scale, real time data. The data collected include Clinical intake /Pemphigus disease activity index (PDAI)/Bullous Pemphigus disease and activity index (BPADAI), photo uploading, logs: medicine/food/sleep/stressors, among others. To the patients, alerts can be provided to appointments, medicine, sample collection. And to the patients, links can be provided to expert providers, clinical trials, support groups, educations resources.

[0053] The mobile application can be part of a sensor, such as being an application on a mobile device such as a smart watch, a glucose monitor, etc. The sensor can monitor and record in the digital database, in real time, a patient's data, including physical activity, mobility, hearing, heart rate, ECG, respiratory rate, sleep, vitals, blood sugar, body temperature, and blood oxygen saturation, among others.

[0054] The database includes link to patient information associated with sample repository (tube numbers, collection dates, location, volume, use, etc.). The samples include DNA, RNA, serum, skin biopsy, peripheral blood mononuclear cell sample.

[0055] The data can be inputted with varying frequency (daily, weekly, monthly, etc.), depending on the type of data, patient, access to data, etc.

[0056] The data can be analyzed using various analytic platforms, algorithms, artificial intelligence.

[0057] With a robust digital database, which can process data quickly and efficiently, a new patient's data can be inputted and matched to the relevant data in the database. The best treatment outcome and then be predicted and the treatment is applied to the patient.

[0058] Methods for making the disclosed mobile device and system are known in the art. The hardware (mobile device, personal computer, etc.) exists in the art; and the software for implementing the disclosed computing tasks can be written by a person skilled in the art.

[0059] These and other embodiments of the invention are described below with reference to **FIG. 1-FIG. 3**.

[0060] **FIG. 1** illustrates a block diagram of a communication system **100** including a mobile device **101** and a remote server **103** in accordance with one implementation. A user inputs patient data **104** on patients with Pemphigus vulgaris through an app **102** on the mobile device **101**. The patient data are transmitted from the mobile device app **102** to a remote management server **103**, which server is adapted to track, process and analyze the patient data and maintain the patient data in a database.

[0061] **FIG. 2** illustrates one implementation of the web-browser-based computer-implemented system **200** for tracking, processing and analyzing patient data on patients with Pemphigus vulgaris and establishing and maintaining a database on patient data on patients with Pemphigus vulgaris. The system **200** includes a computer **201**, which can be a desktop computer or a laptop computer, a personal computer, a mainframe computer, etc., and a remote server **205** in accordance with one implementation. A user inputs patient data **204** on patients with Pemphigus vulgaris through an app **203** or a website **202** on the computer **301**. The patient data are transmitted from the app **203** or the website **202** to a remote management server **205**, which server is adapted to track, process and analyze the patient data and maintain the patient data in a database.

[0062] FIG. 3 illustrates a block diagram of a data processing system 300 suitable for storing and/or executing program code in accordance with one implementation. Data processing system 300 includes a processor 302 coupled to memory elements 304A-B through a system bus 306. In other implementations, data processing system 300 may include more than one processor and each processor may be coupled directly or indirectly to one or more memory elements through a system bus. Memory elements 304A-B can include local memory employed during actual execution of the program code, bulk storage, and cache memories that provide temporary storage of at least some program code in order to reduce the number of times the code must be retrieved from bulk storage during execution. As shown, input/output or I/O devices 308A-B (including, but not limited to, keyboards, displays, pointing devices, etc.) are coupled to data processing system 300. I/O devices 308A-B may be coupled to data processing system 300 directly or indirectly through intervening I/O controllers (not shown).

[0063] In one implementation, a network adapter 310 is coupled to data processing system 300 to enable data processing system 300 to become coupled to other data processing systems or remote printers or storage devices through communication link 312. Communication link 312 can be a private or public network. Modems, cable modems, and Ethernet cards are just a few of the currently available types of network adapters.

[0064] It is to be understood that while the invention has been described in conjunction with the detailed description thereof, the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the scope of the appended claims. Thus, while only certain features of the invention have been illustrated and described, many modifications and changes will occur to those skilled in the art. It is therefore to be understood that the appended claims are intended to cover all such modifications and changes as fall within the true spirit of the invention.

CLAIMS

What is claimed is:

1. A mobile device for tracking, processing and analyzing patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, and establishing and maintaining a database on patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, said device comprising a mobile device processor, a mobile device memory, a mobile device display, a mobile device radio transceiver that supports voice and data interactions through a communication channel and a mobile device wireless fidelity (Wi-Fi) transceiver; said mobile device is adapted to implement the following:
receiving, at a non-browser based application on said mobile device, said patient data through user input; wherein said data include one or more of the following: clinical data, biologic data, exposome data, social determinant of health survey data, social quality of life survey data, and microbiome data;
wherein the non-browser based application is a mobile operating system platform based mobile application with a graphical user interface that is preinstalled or downloaded and installed on the mobile device, wherein the graphical user interface includes a graphical icon;
transmitting said patient data to a remote management server, which server is adapted to track, process and analyze the patient data and maintain the patient data in a database;
retrieving said patient data from said database and displaying said data on the mobile device display within the non-browser based application.
2. The mobile device of claim 1, wherein said device is further adapted to implement transmitting to the user via the non-browser based application an alert with clinical utility.
3. The mobile device of claim 2, wherein said alert with clinical utility is an alert for taking medication, an alert on clinical appointment, or an alert on sample collection time.

4. The mobile device of any of claims 1-3, wherein said device is further adapted to implement providing links to the user to one or more of expert providers, clinical trials, patient support groups, and educational resources.
5. The mobile device of any of claims 1-4, wherein said user is a patient or someone acting on behalf of the patient, a research investigator or someone acting on behalf of a research investigator, or a medical care provider or someone acting on behalf of a medical care provider.
6. The mobile device of any of claims 1-5, wherein said patient data include links to patient information associated with a biological sample repository.
7. The mobile device of claim 6, wherein the biological sample repository is a repository of one or more DNA samples, RNA samples, serum, skin, and peripheral blood mononuclear cells.
8. The mobile device of any of claims 1-7, wherein the server analyzes the patient data using one or more of an analytic platform, an algorithm, and artificial intelligence.
9. The mobile device of any of claims 1-8, wherein clinical data comprise one or more of a patient's medical history, medical diagnosis, demographics, laboratory data, medicine, family relationships.
10. The mobile device of any of claims 1-9, wherein the biologic data comprise one or more of genetic data, epigenetic data, transcriptomic data, auto-antibody data, cytokine data, immune cellular subset data, basic clinical blood work data, and basic clinical vitals data.
11. The mobile device of any of claims 1-10, wherein the exposome data comprise one or more of infection status data, vaccination status data, medication, sleep, food/nutrition, stress, and exercise.
12. The mobile device of any of claims 1-11, wherein the social determinants of health survey data comprises one or more of the following data: health care access and/or quality, education

access and/or quality, social and community context, economic stability, and neighborhood and built environment.

13. A web-browser-based computer-implemented system for tracking, processing and analyzing patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, and establishing and maintaining a database on patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, said system comprising a processor, a memory, a display, a radio transceiver that supports voice and data interactions through a communication channel and a wireless fidelity (Wi-Fi) transceiver; said system is adapted to implement the following:

receiving, at a browser based application or website, said patient data through user input; wherein said data include one or more of the following: clinical data, biologic data, exposome data, social determinant of health survey data, social quality of life survey data; transmitting said patient data to a remote management server, which server is adapted to track, process, and analyze the patient data and maintain the patient data in a database; retrieving said patient data from said database and displaying said data on the display on the website or within the browser based application.

14. The web-browser-based computer-implemented system of claim 13, wherein said system is further adapted to implement transmitting to the user via the browser based application or website an alert with clinical utility.

15. The web-browser-based computer-implemented system of claim 14, wherein said alert with clinical utility is an alert for taking medication, an alert on clinical appointment, or an alert on sample collection time.

16. The web-browser-based computer-implemented system of any of claims 13-15, wherein said system is further adapted to implement providing links to the user to one or more of expert providers, clinical trials, patient support groups, and educational resources.

17. The web-browser-based computer-implemented system of any of claims 13-16, wherein said user is a patient or someone acting on behalf of the patient, a research investigator or someone acting on behalf of a research investigator, or a medical care provider or someone acting on behalf of a medical care provider.

18. The web-browser-based computer-implemented system of any of claims 13-17, wherein said patient data include links to patient information associated with a biological sample repository.

19. The web-browser-based computer-implemented system of claim 18, wherein the biological sample repository is a repository of one or more DNA samples, RNA samples, serum, skin, and peripheral blood mononuclear cells.

20. The web-browser-based computer-implemented system of any of claims 13-19, wherein the server analyzes the patient data using one or more of an analytic platform, an algorithm, and artificial intelligence.

21. The web-browser-based computer-implemented system of any of claims 13-20, wherein clinical data comprise one or more of a patient's medical history, medical diagnosis, demographics, laboratory data, medicine, family relationships.

22. The web-browser-based computer-implemented system of any of claims 13-21, wherein the biologic data comprise one or more of genetic data, epigenetic data, transcriptomic data, auto-antibody data, cytokine data, immune cellular subset data, basic clinical blood work data, and basic clinical vitals data, among others.

23. The web-browser-based computer-implemented system of any of claims 13-22, wherein the exposome data comprise one or more of infection status data, vaccination status data, medication, sleep, food/nutrition, stress, and exercise, among others.

24. The web-browser-based computer-implemented system of any of claims 13-23, wherein the social determinants of health survey data comprises one or more of the following data: health

care access and/or quality, education access and/or quality, social and community context, economic stability, and neighborhood and built environment.

25. A computer-implemented method for tracking, processing and analyzing patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, and establishing and maintaining a database on patient data on patients with Pemphigus vulgaris and related conditions or on patients with Bullous pemphigoid and related conditions, comprising: receiving, at a non-browser based application on a mobile device of any of claims 1-13 and/or a web-browser-based computer-implemented system of any of claims 13-24, patient data from patients with Pemphigus vulgaris and related conditions or Bullous pemphigoid and related conditions, through user input; wherein said data include one or more of the following: clinical data, biologic data, exposome data, social determinant of health survey data, social quality of life survey data, microbiome data, among others; transmitting said patient data to a remote management server; tracking, processing, and/or analyzing the patient data and maintaining the patient data in a database at the remote server.

26. The computer-implemented method of claim 25, further comprising retrieving said patient data from said database and displaying said data on the mobile device display within the non-browser based application or on the website or within the browser based application.

27. The computer-implemented method of claim 25 or claim 26, further comprising transmitting to the user an alert with clinical utility.

28. The computer-implemented method of claim 27, wherein said alert with clinical utility is an alert for taking medication, an alert on clinical appointment, or an alert on sample collection time.

29. The computer-implemented method of any of claims 25-28, further comprising providing links to the user to one or more of expert providers, clinical trials, patient support groups, and educational resources.

30. The computer-implemented method of any of claims 25-29, wherein said user is a patient or someone acting on behalf of the patient, a research investigator or someone acting on behalf of a research investigator, or a medical care provider or someone acting on behalf of a medical care provider.

31. The computer-implemented method of any of claims 25-30, wherein said patient data include links to patient information associated with a biological sample repository.

32. The computer-implemented method of claim 31, wherein the biological sample repository is a repository of one or more DNA samples, RNA samples, serum, skin, and peripheral blood mononuclear cells.

33. The computer-implemented method of any of claims 25-32, wherein the server analyzes the patient data using one or more of analytic platform, algorithm, and artificial intelligence.

34. The computer-implemented method of any of claims 25-33, wherein clinical data comprise one or more of a patient's medical history, medical diagnosis, demographics, laboratory data, medicine, family relationships.

35. The computer-implemented method of any of claims 25-34, wherein the biologic data comprise one or more of genetic data, epigenetic data, transcriptomic data, auto-antibody data, cytokine data, immune cellular subset data, basic clinical blood work data, and basic clinical vitals data.

36. The computer-implemented method of any of claims 25-35, wherein the exposome data comprise one or more of infection status data, vaccination status data, medication, sleep, food/nutrition, stress, and exercise.

37. The computer-implemented method of any of claims 25-36, wherein the social determinants of health survey data comprises one or more of the following data: health care access and/or

quality, education access and/or quality, social and community context, economic stability, and neighborhood and built environment.

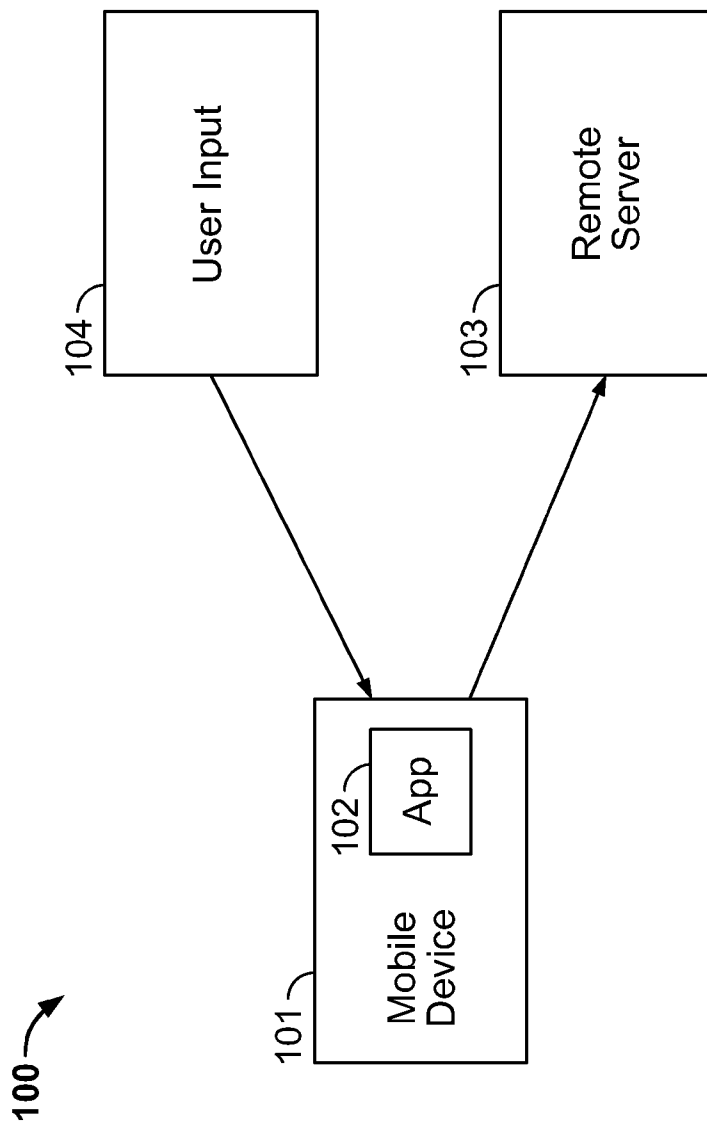


FIG. 1

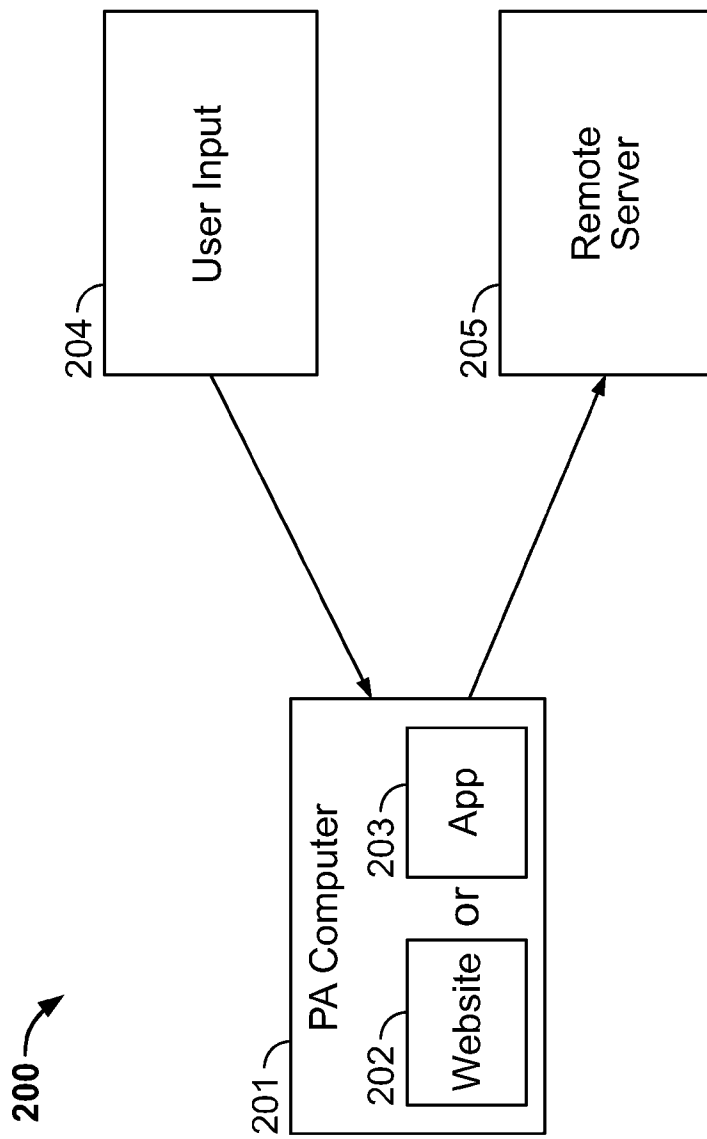


FIG. 2

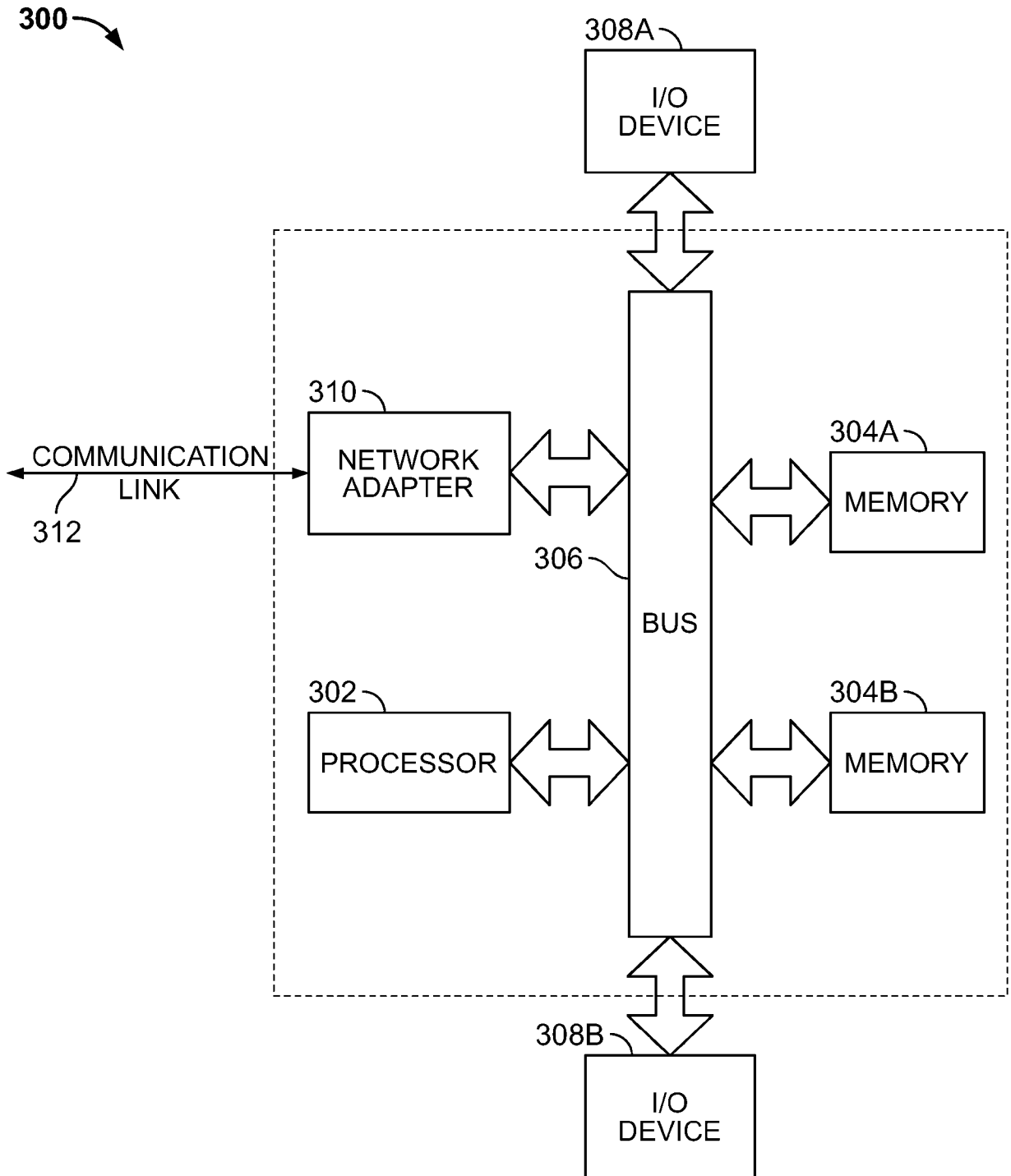


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 24/48008

A. CLASSIFICATION OF SUBJECT MATTER
 IPC - INV. G06N 20/00, A61B 5/00 (2024.01)
 ADD. G06N 3/08, G16H 50/20 (2024.01)

CPC - INV. G06N 20/00, A61B 5/4842
 ADD. A61B 5/4848, G06N 3/08, G16H 50/20

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)
 See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2022/0233860 A1 (Cala Health, Inc.) 28 July 2022 (28.07.2022), entire document, especially para [0024], [0200], [0207], [0209], [0212] - [0213], [0219], [0270], [0274], [0277], [0282], [0290], [0308]	1-4, 13-16
A	US 2021/0027897 A1 (DERMALA INC) 28 January 2021 (28.01.2021) entire document	1-4, 13-16

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	"I" 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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"D" document cited by the applicant in the international application	"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
"E" earlier application or patent but published on or after the international filing date	"&" document member of the same patent family
"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	

Date of the actual completion of the international search 05 November 2024 (05.11.2024)	Date of mailing of the international search report DEC 18 2024
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriguez Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 24/48008

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.: 5-12, 17-37
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:

- 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.:

- 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.