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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 August 2020 (27.08.2020)

WIPO | PCT

(10) International Publication Number
WO 2020/172484 A1

(51) International Patent Classification:
*B65D 75/36* (2006.01) *B65D 83/04* (2006.01)
*A61J 1/03* (2006.01)

(21) International Application Number:
PCT/US2020/019141

(22) International Filing Date:
21 February 2020 (21.02.2020)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/808,446 21 February 2019 (21.02.2019) US

(71) Applicant: **ACCOY PHARMACEUTICALS, INC.** [US/US]; 3801 PGA Blvd., Suite 600, Palm Beach Gardens, FL 33410 (US).

(72) Inventor: **VALENTINE, Edmund L.**; c/o 439 Savoie Drive, Palm Beach Gardens, FL 33410 (US).

(74) Agent: **MAHONEY, Joseph A.**; Mayer Brown LLP, P.O. Box 2828, Chicago, Illinois 60690-2828 (US).

(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, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, 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, GH, GM, KE, LR, LS, MW, MZ, NA, RW, 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, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**Published:**
— *with international search report (Art. 21(3))*
— *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))*

(54) Title: POINT OF CARE PHARMACY APP CONTROLLED BLISTER PACK DRUG DISPENSER

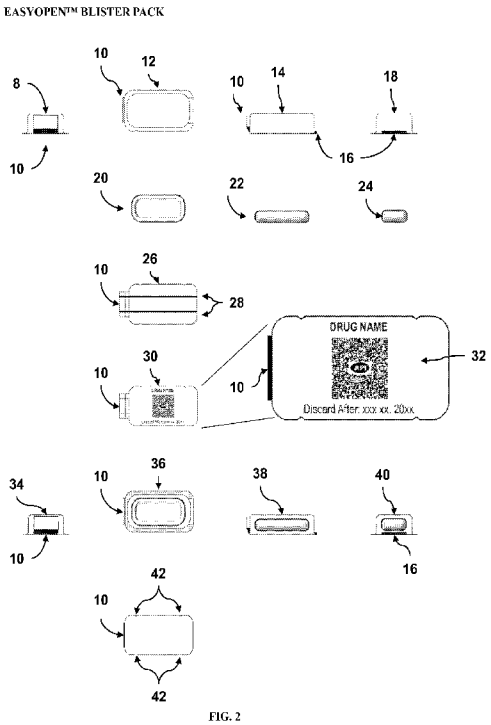



FIG. 2

(57) Abstract: The present invention describes a novel Tamper Resistant disposable or reusable Point of Care Pharmacy™ App Controlled Blister Pack Drug Dispenser and EasyOpen™ single use blister pack design configured to control Dose-by-Dose Dispensing and to capture sensor data to enable Point of Care Pharmacy.

WO 2020/172484 A1

# POINT OF CARE PHARMACY APP CONTROLLED BLISTER PACK DRUG DISPENSER

## CROSS REFERENCE TO RELATED APPLICATIONS

**[0001]** The contents of U.S. Provisional Patent Application No. 62/203,638 filed on August 11, 2015, U.S. Provisional Patent Application No. 62/252,966 filed on November 9, 2015, U.S. Provisional Patent Application No. 62/294,585 filed on February 12, 2016, U.S. Provisional Patent Application No. 62/325,012 filed on April 20, 2016, U.S. Provisional Patent Application No. 62/375,192 filed on August 15, 2016, U.S. Provisional Patent Application No. 62/375,256 filed on August 15, 2016, U.S. Provisional Patent Application No. 62/416,972 filed on November 3, 2016, U.S. Provisional Patent Application No. 62/427,919 filed on November 30, 2016, U.S. Provisional Patent Application No. 62/432,292 filed on December 9, 2016, U.S. Provisional Patent Application No. 62/432,248 filed on December 9, 2016, U.S. Provisional Patent Application No. 62/432,358 filed on December 9, 2016, U.S. Provisional Patent Application No. 62/432,394 filed on December 9, 2016, International Patent Application No. PCT/US16/46491 filed on August 11, 2016, and International Patent Application No. PCT/US2017/017665 filed on February 13, 2017 are incorporated herein by reference in their entirety to the full extent permitted by law.

## FIELD OF THE INVENTION

**[0002]** The present disclosure relates to a novel app-controlled Blister Pack pill dispenser that enables Point of Care Pharmacy through Dose-by-Dose Dispensing control. The tamper-proof design deters Medication Diversion and accidental ingestion. The integrated Intrusion Detection alerting system is an intrusion deterrent. Biometric Authentication ensures only the Patient has access to the Medication, decreasing Medication Diversion. The app interface precludes misuse and facilitates in identifying Patients who Abuse the Medication. The unit dose Blister Pack design

allows Medication tracking down to the Patient level and assists the Patient in opening the Blister Pack. The Blister Pack protects the Medication from degradation, moisture, and outside contaminants. Sensors monitor storage temperature and humidity to ensure proper storage. The dispenser housing is designed to be Moisture Resistant, accommodate a prescribed number of doses, fit in the Patient's pocket or purse, facilitate Electronics Recycling and unused Drug disposal. The design is scalable to accommodate different pill sizes, shapes and quantities in the smallest possible footprint. The dose dispensing system can be configured to store and dispense more than one type of Medication.

## BACKGROUND OF THE INVENTION

**[0003]** There were 5.8 billion dispensed Prescriptions in 2017, up 1.7% over 2016 when adjusted for Prescription length. Adverse Drug events (ADEs) due to misuse pose substantial risk for Patients, including emergency department (ED) visits and hospitalizations. Misuse of Prescription Drugs means taking a Medication in a manner or dose other than prescribed. As an example, emergency department (ED) visits among children usually were due to ADEs caused by antibiotics and antipsychotics while three fourths of ADEs among older adults were caused by anticoagulants, antiplatelet agents, antidiabetic Drugs, and opioid analgesics.

**[0004]** The three classes of Medication most commonly misused are: 1) opioids—usually prescribed to treat pain, 2) central nervous system [CNS] depressants (this category includes tranquilizers, sedatives, and hypnotics)—used to treat anxiety and sleep disorders, and 3) stimulants—most often prescribed to treat attention-deficit hyperactivity disorder (ADHD). Misuse can also occur due to a Patient forgetting they took the Medication and then inadvertently taking another dose.

**[0005]** The societal cost of Prescription Drug ADEs are significant. As an example, an ED visit averages $6,000 and an opioid overdose hospitalization more than $92,400 (in 2015). The numbers are staggering, 1.4 million annual ED opioid Drug ADE visits cost more than $8.4 billion and just the Prescription opioid overdose hospitalizations more than $3.7 billion – and this excludes non-hospital related medical costs.

## BRIEF SUMMARY OF THE INVENTION

**[0006]** The present invention describes a novel app-controlled Blister Pack Tamper Resistant Drug dispensing device and EasyOpen™ Blister Pack designed to enable app-controlled Point of Care Pharmacy™. The app and dispenser are integrated to ensure: 1) the Medication is only dispensed to or (in the case of a minor) for the Patient for whom the Drug is prescribed (avoid divergence); 2) that the Prescription is only dispensed per the Prescription instructions (preclude misuse); and 3) that the dispensing of each dose is controlled by the app.

**[0007]** The present invention is able to use various Drug Dispenser configurations, designs, and sizes. They can be limited to a single Drug or configured to dispense multiple Drugs. The Drug Dispenser can be a disposable unit or a reusable unit. It can be a standalone unit with a resident app or a Tethered Drug Dispenser controlled by an app resident on an Interface Device (e.g., smartphone, computer, tablet, or similar devices or a combination thereof).

**[0008]** The dispenser dispenses unit dose Blister Packs.

**[0009]** The dispenser can be filled at the factory or configured to be filled at the pharmacy or other authorized location.

**[00010]** Each Drug Dispenser is designed to: (i) fit in a pants pocket and/or purse, (ii) be water, and dust resistant, (iii) withstand being dropped and/or banged, (iv) operate and withstand

hot and cold temperatures within defined temperature ranges, (v) be powered by a Battery with a life equal to or greater than the Medications' expiration date, (vi) have a Drug Cassette containing a the desired quantity of the Medication that is integrated into the dispenser housing or that docks into the dispenser housing, (vii) have a Tamper Resistant dispenser housing that becomes an integral unit with no access to the Medication except for when the single dose is dispensed via a small dispenser port, (viii) remains Locked from dispensing unless the dispensing device receives an encrypted signal authorization from the App to dispense a dose, and (ix) one click dose dispensing.

**[00011]** When the Drug dispensing sequence begins, the Drug Dispenser (i) effectuates a Handshake with the app and then transmits the following information since starting from the last time the information was uploaded to the app (ii) current and historic dispenser temperatures and humidity levels, (iii) unsuccessful dispensing attempts, (iv) dispenser intrusion attempts, (v) dispensing problem alerts, and (vi) date and time the previous dose or doses were dispensed.

**[00012]** The Drug Dispenser dose dispensing is effectuated by the "Dispense Button". The Dispense Button is shut off until it is turned on by the app for the specific dose or per the Prescription dosing schedule allowed between required app sign on.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[00013]** Advantages of embodiments of the present invention will be apparent from the following detailed description of the exemplary embodiments thereof, which description should be considered in conjunction with the accompanying drawings in which:

**[00014]** FIG. 1a and 1b is an exemplary embodiment of commonly available oral Medications, e.g., pills, Tablets, caplets, capsules, dissolving films.

**[00015]** FIG. 2 is an exemplary embodiment of an EasyOpen Blister Pack.

**[00016]** FIG. 3 is an exemplary embodiment of the outside of the dispenser housing.

**[00017]** FIG. 4 is an exemplary embodiment of the integrated tamper sensor.

**[00018]** FIG. 5 is an exemplary embodiment of the integrated dispense button and LED indicator lights.

**[00019]** FIG. 6 is an exemplary embodiment of the Blister Pack pills dividers and guides.

**[00020]** FIG. 7 is an exemplary embodiment of the interior and exterior of the integrated dispenser house and where the front and back housing sections are bonded together.

**[00021]** FIG. 8 is an exemplary embodiment of how the dispenser unit, PCB, Battery, and pills fit into the Drug Dispenser.

**[00022]** FIG. 9 is an exemplary embodiment of the components that make up the Blister Pack dispenser unit.

**[00023]** FIG. 10 is an exemplary embodiment of Drug Dispenser's electronic components.

**[00024]** FIG. 11 is an exemplary embodiment of the Drug Dispenser sensor placements.

**[00025]** FIG. 12a and 12b is an exemplary embodiment of Drug Dispenser Firmware logic.

## DETAILED DESCRIPTION OF THE INVENTION

### I. Terms and Acronyms

**[00026]** Terms used in this document, AKA denotes terms used interchangeably:

**[00027]** Abuse (AKA Substance Abuse, Medication Abuse, Drug Abuse, Opioid Abuse) refers to the act or practice of improperly using Medications (examples include but are not limited to opioids, anxiolytics, antidepressants, stimulants). It also refers to the compulsive, excessive, and self-damaging use of habit-forming Drugs or of using opioids and other Medications in

harmful amounts, leading to addiction or Dependence, serious physiological injury (such as damage to kidneys, liver, heart) and/or psychological harm (such as dysfunctional behavior patterns, hallucinations, memory loss), or death.

**[00028]** App Controlled refers to a Blister Pack Drug Dispenser whose dose dispensing is controlled by an App. The App may reside on an Interface Device or be resident on a standalone Drug Dispenser.

**[00029]** Battery refers to rechargeable and disposable batteries commonly used for consumer medical products that have the long shelf life/lifespan, discharge profile, high beam light support, low probability of leakage, able to function for limited times in cold climates profiles. These may include but are not limited to Alkaline, High-Drain Alkaline, Lithium, Carbon Zinc, Zinc Chloride, Nikel-Metal Hydride (NiMH), LSD NIMH (low self-discharge), Nickel-Zinc (NiZn), Rechargeable Alkaline, or similar Battery technologies. The objective is to have the Battery life, under normal dispensing conditions, that is equal to or exceeds the Medication's shelf life/dating.

**[00030]** Biometric Authentication (AKA Biometric Identification, Biometric Sign On, Voice Print, Face Recognition, Iris Scan, Retinal Scan, Eye Scan, Palm Scan, Motion Pattern Recognition, Heart Rhythm, Fingerprint Scan, Log On Name, PIN Number, Authentication PIN, Two-Factor Authentication, 2FA, Multi-Factor Authentication, MFA) encompasses but is not limited to biometric technologies that digitally capture fingerprint, palm, full-hand, voice, facial, iris, retina, eye, motion pattern, heart rhythm, and/or PIN numbers to limit access to the Patient. In this document the term also incorporates any system, while not biometric, that allows access via the use of two-factor (2FA) or multi-factor authentication (MFA) which may incorporate a Login Name in combination with a Password and/or any additional security information, a

computer-generated password that is sent by a server via email and/or text message. Biometric Authentication also refers to the use of two or more of these biometric technologies in combination.

**[00031]** Blister Pack for this invention refers to unit dose Blister Packs used for Tablets, pills, caplets, capsules, and/or lozenges. It also refers to unit dose sublingual film packaging. The blister is made up of a pocket made from a formable web, usually a thermoformed plastic joined to a paperboard backing and/or a lidding seal of aluminum foil or plastic or similar material. The Blister Packs protect the Medication against external factors, such as humidity and contamination for extended periods of time. Opaque blisters also protect light-sensitive products against UV rays. The back of the lidding material allows printing to facilitate identification, dating and traceability.

**[00032]** 30 Day Drug Supply refers to the design requirement of being able to house 60 large Blister Pack Tablets (e.g., .8 inches long by .36 inches wide by .16 inches high) in a Drug Dispenser that can fit in someone's pocket. Smaller Tablets means the dispenser can handle more pills or that the dispenser can be smaller in size.

**[00033]** Compliance (AKA Adherence, Prescription Compliance, Medication Compliance, Drug Compliance) describes the degree to which a Patient correctly follows the Prescription's Drug dosing, dispensing and storage instructions.

**[00034]** Consolidation App (AKA Multiunit Dispenser App) is an App designed to recognize other Drug Specific Apps resident on a standalone dispenser or Interface Device and then to consolidate the requisite digitally captured information, Patient Self-Assessment screens and/or Patient Self-Test screens and/or Patient Self-Reported screens into a single interface for the control and dispensing of multiple Drugs from the same Drug Dispenser.

**[00035]** Dependence (AKA Physical Dependence) refers to the physiological adaptation of the body to the presence of a substance, examples include but are not limited to opioids,

barbiturates, benzodiazepines, hypnotics, gamma-hydroxybutyric acid, carisoprodol, baclofen, chloral hydrate, glutethimide, clomethiazole, methaqualone, gabapentin, antiepileptics, antipsychotics, antidepressants, blood pressure Medications, androgenic-anabolic steroids, glucocorticoids. It is defined by the development of withdrawal symptoms when the substance is discontinued or when the dose is reduced abruptly or, specifically in the case of opioids, when an antagonist (for example naloxone) or an agonist-antagonist (for example pentazocine) is administered. Physical Dependence is a normal and expected aspect of certain Medications and does not necessarily imply that the Patient is addicted.

**[00036]** Dispenser Button (AKA On/Off Button, Biometric Button, Finger Scan Button) is the switch and/or sensor on the Drug Dispenser that may be used to initially turn the dispenser on and dispense each Medication dose. The App controls the power to the Dispenser Button. Dispensing may constitute different configurations – some examples include but are not limited to: 1) a simple on/off switch that is depressed by the Patient to dispense a Blister Pack when the App has authorized the Drug Dispenser to dispense the dose and indicates to the Patient he/she can dispense the dose, 2) a Biometric on/off switch that dispenses a Blister Pack when the App authorized dose dispensing upon Patient authentication, 3) a Biometric Authentication device that authenticates the patient and then dispenses the authorized dose, 4) a button where the Firmware is programmed to allow the Patient to dispense a number of doses between Patient App interfaces, 5) a Dispenser Button where the Firmware is programmed to allow the Patient to dispense a number of doses, in keeping with Prescription intervals, between Patient App interfaces, 6 a Dispenser Button where the Firmware checks to see if an interface device is connected before dispensing a Blister Pack that is authorized to be dispensed by the prescription and to be dispensed

without Biometric authentication and screening by the App. This may or may not require integrated Biometric Authentication.

**[00037]** Dispenser Door is the slide that closes the dispenser housing opening required for Blister Pack dispensing.

**[00038]** Dispensing Mechanism refers to the electrical/mechanical unit designed to dispense a Blister Pack.

**[00039]** Diversion (AKA Drug Diversion) is a medical and legal concept involving the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use.

**[00040]** Dose-by-Dose Dispensing (AKA Dose Dispensing) refers to the Drug Dispenser's ability to control dose dispensing as well as the ability of the tethered App to be able to exercise dose dispensing control on a dose-by-dose basis.

**[00041]** Drug (AKA pharmaceutical, Medication, medicament, OTC Drug, supplement, or herbal remedy)

**[00042]** Drug Cassette is either a reusable or disposable unit that contains Blister Pack Medications to be dispensed over a defined period of time per the Prescription instructions that is designed as an integral part of a Drug Dispenser or as a cassette that docks into a Drug Dispenser. The Drug Cassette may come either prefilled with the Medication from the Drug manufacturer or be filled by a medical professional at the pharmacy or at any location which is authorized to dispense the Medication.

**[00043]** Drug Dispenser (AKA Point of Care App Controlled Blister Pack Drug Dispenser, Blister Pack Drug Dispenser, Disposable Point of Care App Controlled Blister Pack Drug Dispenser, Disposable Blister Pack Drug Dispenser, Dispensing Device, Standalone Dispenser,

Dispenser Unit, Dispensing Unit, Disposable Drug Dispenser, Disposable Dispenser, Reusable Drug Dispenser, Refillable Drug Dispenser, Drug Dispensing Unit, Tethered Drug Dispenser) refers to the disposable or reusable Drug Dispensing Unit with a Docked or Integrated Drug Cassette whose dispensing is controlled by a Medication Specific App or a Standalone Drug Dispenser with a resident Medication Specific App or a Drug dispensing program that controls dose Drug dispensing.

**[00044]** Drug Dispensing Unit (AKA Reusable Drug Dispenser, Drug Dispensing Unit, Drug Dispensing Device, Drug Delivery Device, Standalone Drug Delivery Device, Standalone Drug Dispenser, Disposable Drug Dispenser, Multiple Drug Dispenser) is the device where the Drug Cassette is resident in the Dispensing Unit and whose dispensing mechanism (lock, unlock, and dispensing) are activated by Firmware controlled by a Medication and/or Patient Specific App and/or Drug and/or Patient Specific Apps resident in the Standalone Drug Dispenser.

**[00045]** Drug Dispensing Software refers to dispensing software resident on an Interface Device or Standalone Drug Dispenser that: 1) requires Biometric Authentication, and 2) controls dose dispensing by a Drug Dispenser's Drug Dispensing Unit.

**[00046]** Electronics Recycling refers to the Drug Dispenser design which allows easy access to the electronic components for future recycling or disposal. This includes the recycling of the Dispenser Unit, the PCB, and wiring harness, and easy disposal of the Battery and any unused Medication.

**[00047]** Firmware is embedded systems software contained in the Drug Dispenser's memory to Handshake with the App, communicate with the App, provide operating systems control, sensor information capture, alerts, and control Dose-by-Dose Dispensing per the App instructions.

**[00048]** Handshake (AKA Digital Handshake) refers to an exchange of signals between devices ensuring synchronization whenever a connection, as with another device, is initially established.

**[00049]** Interface Device refers to the smartphone, tablet, computer, or standalone Drug Dispenser, or similar device with Internet communications capabilities or like communications capabilities where the App resides.

**[00050]** Intrusion Detection refers to three Drug Dispenser design features: 1) the Intrusion Detection sensor integrated into the Drug Dispenser's front and back shells, 2) the detection of a buildup in resistance/heat when the linear dispenser that controls the opening and closing of the dispensing door is precluded from closing by some kind of physical force, and 3) a pressure sensor if someone is trying to pry the dispensing door open.

**[00051]** Locked indicates the Drug cannot be dispensed by the Dispensing Device until the Medication Specific App or the standalone device's dispensing software unlocks the Dispensing unit and allows it to dispense the Medication.

**[00052]** Long Acting Medications (AKA Sustained Release, SR, Controlled Release, CR, Extended Release, ER) are slowly effective Medications after initial dosage, but maintaining its effects over a long period of time, being slowly absorbed and persisting in the tissues before being excreted. These can come in various forms, but by reference in this patent, refer to oral or transdermal formulations.

**[00053]** Medication (AKA Drug, Pharmaceutical) refers to a substance used for medical treatment, specifically a medicine, legal or illegal Drugs, OTC Medications, vitamins, dietary supplements, herbal medicines, and/or recreational Drugs.

**[00054]** Moisture Resistant refers to the Drug Dispenser standard of protecting the Drugs housed in the Drug Dispenser from contact with harmful dust and the ability of being able to immerse the Drug Dispenser more than one meter in water for a few minutes without having water intrusion into the Drug Dispenser.

**[00055]** Patient refers to the individual that is prescribed and is taking one or more Medications.

**[00056]** Patient Specific Medication Specific App (AKA Patient and Medication Specific App, Patient and Drug Specific App, Drug Specific App, Medication Specific App) refers to an App used to control Drug Dispenser dose dispensing.

**[00057]** PCB (AKA Printed Circuit Board, Motherboard, Logic Board) mechanically supports and electrically connects electronic components.

**[00058]** Point of Care App Controlled Blister Pack Drug Dispenser (AKA Drug Dispenser, Drug Dispensing Unit) Refer to Drug Dispenser definition.

**[00059]** Point of Care Pharmacy™ refers to a system comprised of an App (Patient and/or Drug specific), a Drug Dispenser, and 24 hours per day and 365 days per year App, Drug Dispenser, and Medication support. It is designed to ensure: 1) the dispensed Medication is effective for the Patient, 2) only dispensed per the Prescription, 3) uses a dispensing algorithm which utilizes the Patient's digitally captured and/or Patient tested/reported/entered (Patient entered) physiological, psychological, lifestyle, environmental, and/or concomitant Medication information to control Drug dose dispensing, 4) captures key point-of-care information to enable Medication management and better disease/condition management. It also refers to the ability of the system to prevent dispensing a prescribed dose, even it would otherwise be allowed by the

Prescription, if the digitally captured and/or Patient entered data indicate the Patient may suffer an untoward Medication mediated adverse event if the Patient took the dose.

**[00060]** Polypharmacy is the practice of administering or using multiple Medications especially concurrently (as in the treatment of a single disease or of several coexisting conditions).

**[00061]** Prescriber is defined as any healthcare professional authorized by an individual country or state to write a Prescription for a Drug. Examples include but are not limited to physicians, physician assistants, nurse practitioners, nurses, pharmacists.

**[00062]** Prescription (AKA ePrescription, Paper Prescription, Manually Entered Prescription, Digital Prescription, Drug Prescription, Medication Prescription) is an instruction electronically entered or manually written by an authorized medical practitioner that authorizes a Patient to be provided a medicine or treatment.

**[00063]** Routines (AKA Software Program, Software Routines, Subroutine, Procedure, Function, Method, Subprogram) is a portion of software code within a larger program that performs a specific task and is relatively independent of the remaining code.

**[00064]** Serial Number (AKA Unique Device Identifier, UDI, Serial No., SN, S/N, Identification Number, Tracking Number, Identifier) is a unique number used for identification, tracking, and/or inventory purposes.

**[00065]** Short Acting Medications (AKA Immediate Release, IR) are quickly effective Medications that require regular repeated doses for long-term treatment. They are rapidly absorbed, distributed in the body, and excreted.

**[00066]** Tablets as used in this invention refers to all types of solid oral dose Medications and all the various shapes and sizes. This includes but is not limited to Tablets, pills, caplets, lozenges, hard capsules, soft capsules, gel caps, and medication strips.

**[00067]** Tamper Proof is a combination of the Disposable Drug Dispenser design features integrated to preclude dose dispensing unless it is authorized by the Prescription and the App. The Disposable Drug Dispenser has an Intrusion Detection sensor integrated into the Drug Dispenser container shell, as are the Dispense Button and the indicator lights. After component assembly and filling with the desired number of Blister Pack pills, the front and back halves are bonded together to create a single unit. The only opening is the small Dispenser Door. This door is precluded from being able to be forced open by the linear actuator opening and closing design. Any excessive pressure that is applied to open or keep the Dispenser Door open is picked up by a pressure sensor and/or Dispenser Door motor control software. The pressure sensor as well as the Intrusion Detection sensor are designed to create an alert if an intrusion attempt or intrusion is detected. Tamper Proof refers to the combination of the Drug Dispenser housing and the integrated Intrusion Detection sensors (housing and Dispenser Door) and the related software to record and report intrusion attempts and intrusions.

**[00068]** Tamper Resistant refers to a design: 1) that precludes the Drug Dispenser from being opened without destroying it, 2) that makes it difficult to change, open, or remove the Drug Cassette from the Drug Dispenser except for authorized users, or 3) that results in damaging the Drug Dispenser when an unauthorized person attempts to open the Drug Dispenser.

**[00069]** Tethered Drug Dispenser is a Drug Dispenser that utilizes the Interface Device's capabilities to offer functionality and ease of use that would not otherwise be possible in a Standalone Drug Dispenser with the same outside dimensions, the same size, or a battery life equal to or greater than the medication's shelf life. It also refers to a Drug Dispenser that cannot function without being tethered to an App.

## II. List of Medications the Invention in its Various Embodiments is Applicable To

**[00070]** The invention and its various embodiments can enable better dose dispensing control, decreasing misuse, Diversion and accidental ingestion. This improves the Drug's safety profile and should decrease Drug mediated healthcare professional interventions, emergency department (ED) visits, and hospitalizations.

**[00071]** The invention is applicable to all Tablets, as defined, that are marketed or in development. Drug compounds of interest are listed in: Goodman & Gilman's, *The Pharmacological Basis of Therapeutics* (13th Ed) (Goodman et al. eds) (McGraw-Hill) (2018); and latest *mobile*PDR (formerly *Physician's Desk Reference); Cortellis Clinical Trials Intelligence* databases by Clarivate Analytics; *Adis Insight* databases by Springer; and/or Pharmaprojects databases by Citeline, and databases by IQVIA. These Drugs are encompassed in the embodiment of the invention by reference.

## III. Point of Care Pharmacy App Controlled Blister Pack Drug Dispenser

**[00072]** Various embodiments will be described hereinafter with reference to the accompanying drawings. These embodiments are illustrated and described by example only and are not intended to be limiting. Alternate embodiments may be devised without departing from the spirit or the scope of the invention. Additionally, well-known elements of exemplary embodiments of the invention will not be described in detail or will be omitted so as not to obscure the relevant details of the invention. Further, to facilitate an understanding of the description discussion of several terms used herein follows.

**[00073]** The word "exemplary" is used herein to mean "serving as an example, instance, or illustration". Any embodiment described herein as "exemplary" or "example" is not necessarily

to be construed as preferred or advantageous over other embodiments. Likewise, the term "embodiments of the invention" does not require that all embodiments of the invention include the discussed feature, advantage or mode of operation.

**[00074]** Further, many embodiments are described in terms of sequences of actions to be performed by, for example, elements of a computing device. It will be recognized that various actions described herein can be performed by specific circuits (e.g., application specific integrated circuits (ASICs)), by program instructions being executed by one or more processors, or by a combination of both. Additionally, these sequences of actions described herein can be considered to be embodied entirely within any form of computer readable storage medium having stored therein a corresponding set of computer instructions that upon execution would cause an associated processor to perform the functionality described herein. Thus, the various aspects of the invention may be embodied in a number of different forms, all of which have been contemplated to be within the scope of the claimed subject matter. In addition, for each of the embodiments described herein, the corresponding form of any such embodiments may be described herein as, for example, "logic configured to" perform the described action.

**[00075]** **FIG. 1a** and **1b** illustrate an exemplary embodiment of the invention and how the Blister Pack design has to be configurable to accommodate different Tablet shapes and sizes **2**, **4, 6**. These are exemplary Tablets. Pharmaceuticals science is evolving, and different shapes and sizes are expected to be introduced as pharmaceutical and manufacturing technologies, such as 3D pill printing, will make new Tablet designs available.

**[00076]** **FIG. 2** illustrates an exemplary embodiment of an EasyOpen™ individual Blister Pack. The top row illustrates different views of the see-through or opaque plastic blister that is preformed to contain the Tablet **20**, **22**, **24**. The left side illustration of the plastic blister **8** and the

height of EasyOpen Tab **10**. It shows the relative width of the EasyOpen Tab **10** to the top of the plastic blister **8**. The top view **12** shows the margins around the preformed container. The side view **14** shows the relationship of the EasyOpen Tab **10** and the Reinforced Dispense Ridge **16**. The right end view **18** shows the width and height of the Reinforced Dispense Ridge.

**[00077]** The second row shows a large pill, (for example, .36 inches wide **20, by** .8 inches long **22** by .16 inches high **24**) that fits in the cavity **14** of the preformed blister used for this exemplary illustration.

**[00078]** The back lid of the blister **26** illustrates the two imbedded reinforcing strings **28** which support the pill when it is laying on the dispenser glide and assist in opening the Blister Pack when the EasyOpen Tab **10** is pushed down or pulled and broken away from the blister by the Patient.

**[00079]** The lid's paper backing **30** is designed to incorporate: 1) the Drugs name (proprietary and generic), a QR code that shows, for example: i) the manufacturer, ii) manufacturing location, iii) batch number, vi) fill date, and vii) a unique pill identification number, and 2) Discard After date **32**. This allows traceability of the individual pill from the time it is manufactured down to the Patient.

**[00080]** The pill in the EasyOpen Blister Pack is illustrated from the left side **34**, top view **36**, side view **38**, and right end view **40**.

**[00081]** The bottom view shows the dispenser guide indents **42** designed to ensure the Blister Pack is properly oriented for dispensing.

**[00082]** **FIG. 3** is an exemplary embodiment depicting the left side of the dispenser housing **44**, the front **46**, the dispensing port **48**, the windows **50** to view how many pills are remaining, the

Dispense Button **52**, and the Power, Dispense, and Battery LEDs **54**, the back of the dispenser **56** and the right side **58**.

**[00083]** **FIG. 4** is an exemplary embodiment of the Intrusion Detection sensor **60** that is embedded into the dispenser housing during manufacturing. The electrical connectors **62** complete the circuits between the front and back halves of the dispenser housing and provide a plug in for connecting the sensor to the wiring harness used to connect the sensor to the processor (PCB).

**[00084]** **FIG. 5** is an exemplary embodiment depicting the Dispenser Button **52** and the LED lights **54** that are imbedded into the Dispenser Housing **Fig. 3**.

**[00085]** **FIG. 6** is an exemplary embodiment of Blister Pack dividers **56** on the front and back halves of the Drug Dispenser housing. It also illustrates the Blister Pack guides **58** which line up with the Blister Pack indents **42** to ensure the Blister Packs are correctly oriented to facilitate dispensing. The Blister Cap stops **62** are designed to stop the spring cap **82** from dropping too low and blocking the dispensing tunnel once the column of pills has been dispensed. The support rail **64** acts as a top seat for the dispensing assembly **72** and as a floor for the dispensing tunnel used to dispense the Blister Packs.

**[00086]** **FIG. 7** is an exemplary embodiment of Blister Pack dispenser housing inside front **66**, inside back **68**, left side **44**, outside front **46**, outside back **56**, right side **58**, and the dividing line **70** where the two sections come together.

**[00087]** **FIG. 8** is an exemplary embodiment of how the Blister Pack Dispenser is assembled. First the Dispenser Unit **72** is clicked into place, then the PCB is connected to the wiring harness and clicked into pace **74**, then the Battery **76** is connected and slid into place. The unit is then filled with Blister Packed pills by first putting the Springs **80** and their Spring Cap **82** into the unit

between the respective guides and then inserting the pill columns **84** into place so they are aligned between the Blister Pack Dividers **56** and are aligned with the Blister Pack Guides **58**.

**[00088]** **FIG. 9** is an exemplary embodiment of the design and components of the Dispenser Unit. The Dispensing Door **86** is controlled by a linear slide actuator that moves the door up and down. The end view of the assembly without the respective dispensing door and the linear slide motor is shown **88**, as are the top of the dispenser unit **90**, the right end view **92**, the side of the unit without the dispensing door **94**, and the bottom of the unit **96**. The side view with the dispensing door closed **98** illustrates the assembled unit.

**[00089]** Each dispensing unit is comprised of the dispensing door **100**, the linear slide unit that moves the dispensing door **102**, the gear assembly **104** that transfers the power from the stepper motor **106** to the spindle **108**, and the sensor plate **110** that is used to properly position the dispensing arm **112** for dispensing from each of the respective Blister Pack columns.

**[00090]** **FIG. 10** is an exemplary embodiment of the components comprising the Blister Pack Drug Dispenser logic board. The major components are the low energy high performance processor **114**, the Bluetooth Low Energy module **116**, the temperature sensor **118**, the humidity sensor **120**, the intrusion sensor **122**, the pressure sensor **124**, the Dispense Button **126**, the pill counter switch **128**, the dispense door open stop switch **130**, the dispense door close stop switch **132**, the dispensing arm return switch **134**, the dispensing arm stop for Blister Pack column one switch **136**, the dispensing arm stop for Blister Pack column two switch **138**, the dispensing arm stop for Blister Pack column three switch **140**, the Battery life gas gauge **142**, the Battery **144**, the Clock **146**, the dispenser motor **148**, the dispense door linear motor **150**, and the status LEDs **152**.

**[00091]** **FIG. 11** is an exemplary embodiment illustrates where the respective sensors or switches that do not reside on the logic board are placed on the Drug Dispenser: the intrusion

sensor **124**, the pressure sensor (it is part of the intrusion sensor system) **124**, the Dispense Button **126**, the pill counter switch **128**, the dispense door open stop switch **130**, the dispense door close stop switch **132**, the dispensing arm return switch **134**, the dispensing arm stop for Blister Pack column one switch **136**, the dispensing arm stop for Blister Pack column two switch **138**, and the dispensing arm stop for Blister Pack column three switch **140.**

**[00092]** **FIG. 12a and 12b** are exemplary embodiments of dispenser Firmware logic.

## IV. EXAMPLES

**[00093]** The embodiment of the invention, when coupled with a Drug and/or Patient specific app, can be utilized, for among other uses, 1) to improve the Drug's safety profile by ensuring proper Patient personalized prescribing and Prescription management (e.g., personalized dispensing), 2) to ensure the Medication is efficacious, 3) as a diagnostic aid/tool, 4) to titrate the Medication, 5) to preclude Drug mediated adverse events, 6) to preclude over dosing, 7) to preclude under dosing, 8) to decrease the chance of misuse, 9) to decrease the chance of Abuse, 10) to decrease the chance of overdosing, 11) to increase Prescription Compliance, 12) to prevent the Patient from inadvertently taking a duplicate dose, 13) to decrease the chance of addiction, 14) to decrease the chance of Dependence, 15) to better manage Medication tolerance, 16) to manage Medication withdrawal, 17) to enable PRN dosing, - manage "Patient Controlled Oral Analgesia™" (PCOA™), 18) to preclude Drug divergence, 19) to guard against accidental ingestion, 20) to avoid Drug-Drug interactions, 21) to better manage Medication mediated side-effects, 22) and to promote Prescription persistence. In short, to personalize oral Medication therapy by improving the Medication's Drug/safety profile – to provide Point of Care Pharmacy.

**[00094]** Ideal Medication management would have the physician evaluate the Patient each time prior to allowing the Patient to take his prescribed dose/Medication. The physician would ascertain how well the current dose manages the Patient's condition/symptoms and would be looking for signs of side effects, addiction, Dependence, Misuse, Abuse, possible bad Drug-Drug combinations, or similar indicators prior to authorizing the Patient to take the dose. That way, the physician could change/refine the dosage for the Patient and/or preclude the Patient from taking the dose in the event the physician ascertained that the dose was not warranted and/or that the dose may lead to a serious Medication mediated event and/or undesirable side effect.

**[00095]** Having a physician approve each dose before it is taken by the Patient is neither realistic nor cost effective, the embodiment of the invention incorporates an App Controlled Drug Dispenser that enables Dose-by-Dose Dispensing control and captures certain critical data to ensure Compliance with the Prescription, improve Medication management, and enable Point-of Care Pharmacy.

**[00096]** In one embodiment, the App Controlled Drug Dispenser enables Dose-by-Dose Dispensing control, measures the blood oxygen saturation (SpO2) and monitors respiratory rate to ascertain if a drug is leading to a depressed respiratory rate and to maintain healthy SpO2 levels is through breathing.

**[00097]** In yet another embodiment, the App Controlled Drug Dispenser estimates the amount of oxygen in the blood as an indicator of potential hypoxia which may be caused by a drug induced respiratory depression.

**A. Opioids**

**[00098]** Opioids serve as an excellent exemplary of how the embodiment of the invention can be utilized to improve opioids and other Medications' management and Patient outcomes.

**B. Background**

**[00099]** The following describes some, but not all, of the key opioid side effects as background for the subsequent opioid examples of the embodiment:

**[000100]** Cognitive Impairment - It is well known that larger doses of opioids are markedly impairing, leading to drowsiness, lethargy, and even death. At least one prospective study has demonstrated that those with chronic pain on opioid therapy have cognitive deficits including reduced spatial memory capacity and impaired performance in working memory assessment (Schiltenwolf et al., 2014).

**[000101]** Respiratory depression - Opioids adversely affect the respiratory system. Carbon dioxide ($CO_2$) levels in the blood stimulate our respiratory drive. As breathing slows down, $CO_2$ levels increase, which stimulates the brainstem to increase the respiratory rate.

**[000102]** Low oxygen levels do not stimulate breathing so sensitivity to $CO_2$ levels is an important function of nerve cells in the brainstem. Opioids block that feedback loop. When an individual overdoses on an opioid, the high levels of opioid will decrease alertness and induce sleep. During sleep, it is the $CO_2$ feedback loop that keeps people breathing. However, when blocked by the high levels of an opioid, breathing slows or stops and the person who has overdosed literally suffocates.

**[000103]** Heart Rate - Heart rate may become either rapid or very slow. Some opioid users may also develop postural hypotension or a severe fall in blood pressure on standing up from a sitting or lying position.

**[000104]** This is also problematic for individuals with lung disease or sleep apnea. People with chronic lung disease often need elevated carbon dioxide levels to stimulate them to breathe more

deeply. Taking opioids will blunt this response, causing people with lung disease to breathe slower and therefore have low oxygen levels.

**[000105]** Sleep apnea is similar as people periodically stop breathing at night until their carbon dioxide levels get high enough to stimulate their brain to signal them to gasp for breath. When opioids interfere with this response the effect can be life threatening. Opioids have been shown to worsen the apnea episodes in those with sleep apnea (Jungquist, Flannery, Perlis, & Grace, 2012).

**[000106]** Miosis – Opioid use results in the formation of small, constricted pupils, similar to how pupils respond to bright light.

**[000107]** Constipation - Opioids cause sluggish peristaltic movements in the digestive tract. This causes stasis or loss of movement of the intestinal contents and leads to severe constipation, especially in the case of long-term use.

**[000108]** Drowsiness or Sedation - Opioids, and in particular morphine, are known to cause severe sedation and drowsiness.

**[000109]** Myoclonus – High doses of opioids can result in muscle rigidity and abnormal movement of the limbs and muscles.

**[000110]** Hyperalgesia - Opioid-induced hyperalgesia (OIH) is another side effect of the use of opioids. Opioid hyperalgesia is a phenomenon where the body develops an increased sensitivity to pain secondary to opioid use (hyper – over or excess, algesia – sensitivity to pain).

**[000111]** Pain is an important part of our body's defense system, warning us of current or impending damage or injury. As opioids decrease our brain's sensitivity to pain signals coming from the rest of the body, our brain begins to compensate by increasing our recognition of and sensitivity to pain. The pain neurons going to the brain actually change to make them more responsive to pain and increase our perception of pain. This change is called neuroplasticity of

the nerve cell. Many mechanisms are believed to be involved in these changes (M. Lee, Silverman, Hansen, Patel, & Manchikanti, 2011). The result of this change is that after opioid levels decrease, our pain fibers are more sensitive than before consuming the opioid which results in an increase in pain.

**[000112]** Unfortunately, increasing pain can also mean disease progression or the development of tolerance to the current opioid dose. For these conditions, opioid doses are usually increased. In contrast, the treatment of opioid hyperalgesia is the decrease or discontinuation of opioids.

**[000113]** Tolerance and withdrawal - Tolerance occurs when the body has developed physiologic (both neuroplastic and chemical) changes that result in decreased effectiveness of the medicine necessitating a higher dose to get the same effect. Withdrawal is the unpleasant symptoms that develop upon decrease or discontinuation of that medicine. Brain changes and measurable withdrawal symptoms can occur after one dose of opioid (Rothwell, Thomas, & Gewirtz, 2012).

**[000114]** In clinical practice, withdrawal symptoms can occur after five to seven days of opioid Medication (Anand et al., 2010). Withdrawal symptoms may consist of myalgia (muscle pain), chills, sweats, anxiety, increased pain, rapid heartbeat, dilated pupils, yawning, diarrhea and nausea.

**[000115]** Withdrawal is extremely unpleasant and can be relieved by taking another opioid dose. Tolerance and withdrawal are not considered addiction. Tolerance occurs because of the physiologic changes resulting from exposure to opioids. Withdrawal is the unpleasant physical and emotional symptoms that occur upon withdrawal of the opioid after tolerance has developed.

**[000116]** Addiction - Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response.

**[000117]** Death - There is one factor that is often not considered when prescribing opioid pain Medications – the overall increase in deaths. Opioids account for more deaths than any other Medication. The medical ethical principle of non-maleficence (do not harm) now extends beyond the exam room: the interaction between a physician and his/her Patient may adversely affect the life and health of someone else who is not a part of the medical decision. Impairment from opioids may lead to unintentional death by motor vehicle crashes or workplace safety incidents. Opioid use may also lead to falls and increase mortality rates in the elderly.

**[000118]** Benzodiazepines - It is also important to realize that the risk of death is markedly increased when opioids are taken with benzodiazepine Medications. The combination of opioids and benzodiazepines are the leading cause of overdose deaths when multiple Medications are involved (Calcaterra, Glanz, & Binswanger, 2013). Despite this danger, benzodiazepines are prescribed to about 30% of people on chronic opioid therapy (Nowak, Abou-Nader, & Stettin, 2014).

## C. Opioids App

**[000119]** The Patient and/or opioid specific App utilizes digitally captured and Patient entered point-of-care and trended data to screen for potential overdose or side effects, (see side effects above) to ascertain whether or not it is safe for the Patient to dispense a dose. The integration of digital sensor information will be via specific Application Program Interfaces (APIs) to translate the value into dispensing algorithm usable data.

**[000120]** If it is safe to dispense, then the App utilizes the App Tethered Drug Dispenser sensor data/information to ensure: 1) the opioid has been properly stored, 2) to ascertain when the last dose was dispensed to ascertained if the dose is authorized, and then, if the Prescription authorizes, dispensing the dose. If the decision is that the dose should not be dispensed, the decision can be remotely overwritten by the 24 hours per day 365 days per year Support Center within established guidelines after the Support Center talks with and evaluates the Patient.

**D. The Drug Dispenser**

**[000121]** The Drug Dispenser is the physical device that enables App Dose-by-Dose Dispensing control – playing a gatekeeper role in preventing opioid misuse. Drug Dispenser Sensors provide date and time stamped: 1) temperature and humidity readings to ensure the Medication is being/has been properly stored, ensuring its efficacy 2) intrusion and intrusion attempts alerts to decrease opioid divergence and as an indicator of potential tolerance, 3) dose dispensed to track the number of remaining pills, and 4) dose dispensing to enable correlation with other reported data to empower better Patient specific pain and opioid tolerance management. The Drug Dispenser electronics: 1) enables communications with the App (via Bluetooth, Low Energy Bluetooth, Wi-Fi, or similar low energy communications technologies), 2) tethers the Drug Dispenser to the App, 3) manages the Dispenser Button, which may be a simple on/off switch to dispense the dose and power down the Drug Dispenser to lower Battery drain or a Biometric logon (examples include fingerprint scan, voice scan, face scan, iris scan, retina scan, PIN, two-factor or multi-factor authentication or any combination thereof) to dispense the dose and then power down the drug dispenser to lower Battery drain, 4) manages Battery power to ensure the Patient is alerted before running out of power that will prevent dose dispensing, 5) tracks and reports unauthorized dose dispensing attempts, 6) stores sensor values, 7) communicates sensor values, and 8) controls

Dose-by-Dose Dispensing. It is designed to: 1) only be filled by authorized personnel to prevent opioid Diversion. 2) contain a course of treatment and/or a designated number of days of Medication, 3) fit in the Patient's pocket or purse to facilitate Medication access, 4) facilitate Electronics Recycling and responsible Battery and opioids disposal (which decreases opioid Diversion).

## CLAIMS

What is claimed:

1. A single use Blister Pack designed to be dispensed by a Blister Pack Drug Dispenser comprised of:
2. The single use Blister Pack according to claim 1 wherein the see-through or opaque plastic blister is made of thermoformed plastic and is specifically designed to hold and protect a specific Tablet or Tablet size and shape.
3. The single use Blister Pack according to claim 1 wherein the Tablet may be any oral dose medication.
4. The single use Blister Pack according to claim 1 wherein the Tablet may be any size or shape.
5. The single use Blister Pack according to claim 1 wherein the lidding material is made up of paperboard, aluminum foil, plastic or a combination thereof.
6. The single use Blister Pack according to claim 1 wherein the back lid is reinforced by two imbedded reinforcing strings/arms attached to a breakaway Dispensing Tab.
7. The single use Blister Pack according to claim 1 wherein the Dispensing Tab is designed to allow the patient to push down or pull the tab down to break the tab away from the blister to allow the two imbedded reinforcing strings/arms to cut through the lidding material to easily peal the lidding away from the blister to provide access to the Tablet.
8. The single use Blister Pack according to claim 1 wherein the back of the Blister Pack where the plastic blister and the lidding material come together is formed to provide a reinforced surface to accommodate pushing the Blister Pack during the dispensing operation.
9. The single use Blister Pack according to claim 1 wherein the lidding material is backed by a surface designed for rapid printing to enable Tablet identification and the use of a tracking

code to track the drug dose from the time it is filled into the Blister Pack down to the individual patient.

10. The single use Blister Pack according to claim 1 wherein the Blister Pack is designed with indentions to allow dispensing guides to fit into the groves (indentions) to ensure the proper alignment of the Blister Pack during the dispensing operation.
11. An App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing and to capture sensor data to enable Point of Care Pharmacy comprised of:
12. The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Dispenser is disposable or reusable.
13. The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Dispenser is designed to dispense single use Blister Packs.
14. The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the dispenser housing and its related Dispenser Door is Tamper Proof.
15. The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the dispenser housing, inclusive of the Dispenser Door, is Moisture Resistant.
16. The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the dispenser housing is designed and manufactured with an embedded intrusion detection sensor.
17. The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the dispenser housing is designed and

manufactured to allow the two housing halves to be bonded together to form a single integrated housing.

18. The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Dispenser housing shell is designed to act as a Drug Dispenser or where the Drug Dispenser housing shell is designed to dock with a Drug Cassette.

**19.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Cassette contains dividers to separate columns of Blister Packs.

**20.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Cassette contains Blister Pack guides to ensure each Blister Pack is properly positioned for dispensing.

**21.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Cassette accommodates a Spring at the top of each Blister Pack column to maintain downward pressure on the Blister Pack column to properly position each Blister Pack for dispensing.

**22.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Dispenser accommodates a Spring Cap to protect the top of the Blister Pack from being damaged by the Spring and to stop above the dispensing tunnel when the column of Blister Packs has been dispensed.

**23.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Dispenser accommodates Spring Cap stop guides to preclude the Spring Cap from dropping into the dispensing tunnel and blocking

dispensing of Blister Packs from other Blister Pack Columns once the Blister Packs from the particular Blister Pack column have been dispensed.

**24.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Cassette is designed to contain one or more columns of Blister Pack Tablets.

**25.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Dispenser housing has a clear or opaque see through column in front of each column of Blister Packs to enable the Patient to see how many Blister Pack doses are remaining.

**26.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Dispenser can contain more than one medication, each contained in a separate Blister Pack column.

**27.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein Tablet dispensing is effectuated by a Dispenser Button. The Dispenser Button may be one that is integrated with Biometric Authentication.

**28.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein there is a low voltage LED power indicator, as an example a red LED, to indicate the Drug Dispenser is working when the Dispense Button is touched, finger scanned, and/or pressed but when the prescription or the App does not allow dispensing. The LED remains lit for a limited time to conserve Battery power.

**29.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein there is a low voltage LED Dispense indicator, as an example a green LED, to indicate a dose is ready to be dispensed upon the Patient

touching, finger scanning, and/or pressing the Dispense Button. The LED shuts off after a limited time or upon dispensing of the dose to conserve Battery power.

**30.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein there is a low Battery LED, as an example a yellow LED, to indicate that there is insufficient battery life remaining to dispense all the remaining Blister Packs. The warning light comes on when the Dispense Button is depressed and stays on for a short period of time thereafter to conserve Battery power.

**31.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein each Blister Pack is individually dispensed by the Dispensing Mechanism.

**32.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Dispenser housing has a Dispenser Door that is automatically opened when the Dispenser Button allows an authorized dispensing of a Blister Pack – and automatically closes the Dispenser Door when the Blister Pack is removed from the Drug Dispenser's Dispenser Door opening.

**33.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Dispenser is powered by a Battery.

**34.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein communications is via Bluetooth Low Energy or a similar low energy communications technology that allows conservation of battery power.

**35.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein a low power microcontroller compatible with the

low energy Bluetooth or other low energy communications module controls the drug dispenser.

**36.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the low power microcontroller has sufficient Firmware memory to support the App instructions and data storage.

**37.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the PCB is designed to support and electronically connect the: 1) low energy processor, 2) low energy Bluetooth or other low energy communications device, 3) temperature sensor, 4) humidity sensor, 5) intrusion sensor, 6) pressure sensor, 7) Dispense Button, 8) pill counter, 9) Dispenser Door open sensor, 10) Dispenser Door close sensor, 11) Drug Dispenser mechanism return sensor, 12) Drug Dispenser stop sensors, 13) Battery life remaining gauge, 14) Battery, 15) clock, 16) Drug Dispenser motor, 17) Dispenser Door motor, and 18) status LEDs.

**38.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the following Drug Dispenser components are designed to click into place, so they are securely held in place by the Dispenser Housing: the Dispenser Unit, the wiring harness, the PCB, the Springs and their related Spring Caps. the Blister Pack Tablet columns, and the Battery.

**39.** The App Controlled Blister Pack Drug Dispenser designed to control Dose-by-Dose Dispensing according to claim 11 wherein the Drug Dispenser can be easily cut apart to enable electronics recycling and proper Tablet disposal.

DIFFERENT SAMPLE PILL AND CAPSULE SIZES AND SHAPES AND DISSOLVING FILMS

2

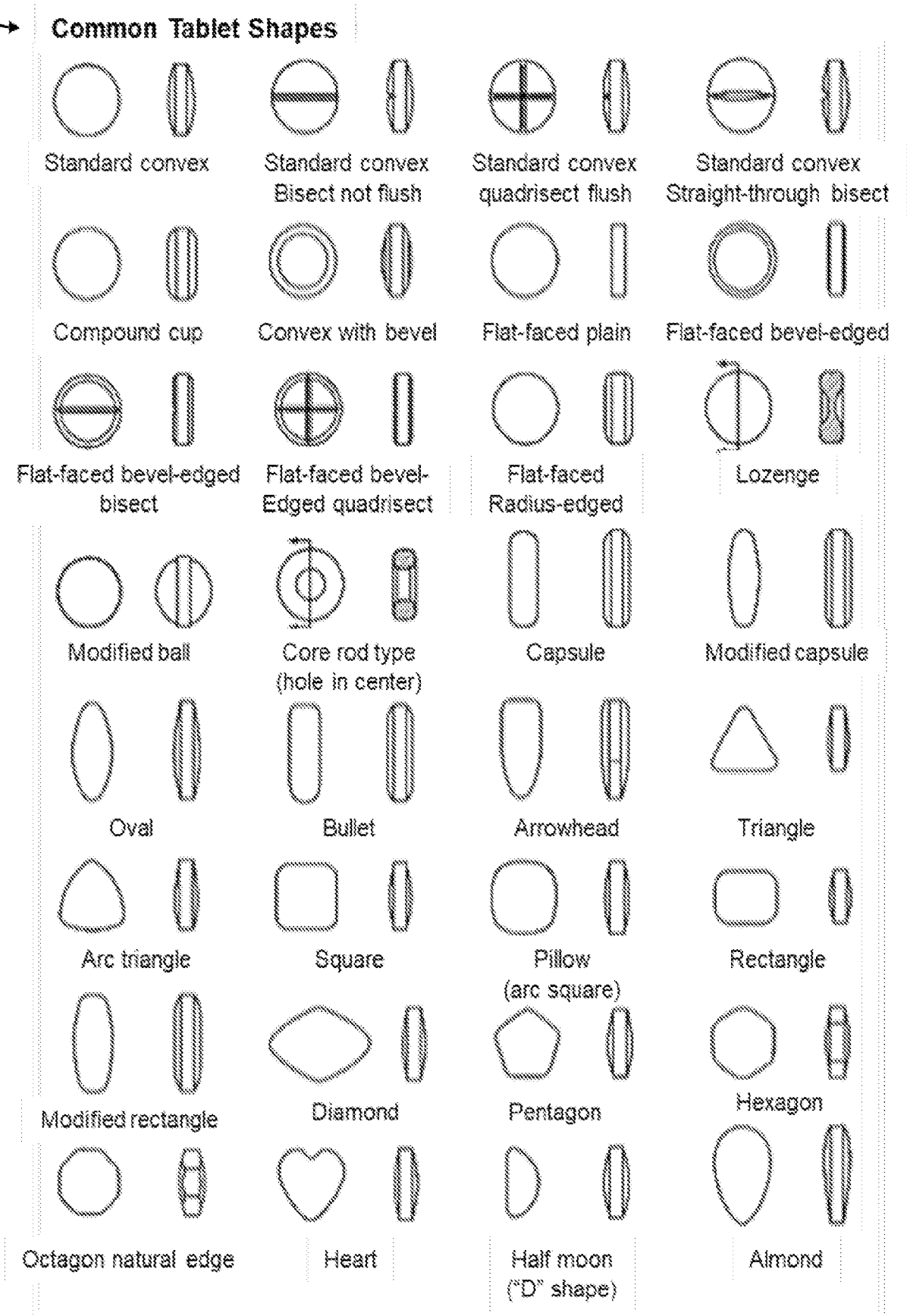
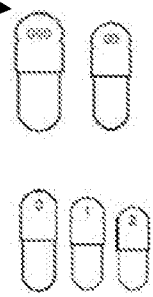



FIG. 1a

4



| Representative (approximate) Capsule Sizes | Capsule Size | Typical Fill Weights(mg) Actual Fill Weights may vary and depend on powder characteristics | | | Volume Theoretical | Locked Length | | External Diameter | Cut Length | Single Wall Thickness | Weight (Avg of 10) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Powder Density | | | (ml) | +/- 0.76 (mm) | Tolerance Component | (mm) | +/- 0.51 (mm) | +/- 0.03 (mm) | +/- 10% (mg) |
| | | 0.45 (Light) | 0.70 (Typical) | 1.00 (Heavy) | | | | | | | |
| | 000 | 615 | 960 | 1370 | 1.37 | 26.14 | Cap | 9.91 | 12.95 | 0.112 | 163 |
| | | | | | | | Body | 9.55 | 22.20 | 0.110 | |
| | 00 | 430 | 665 | 950 | 0.95 | 23.30 | Cap | 8.53 | 11.74 | 0.109 | 118 |
| | | | | | | | Body | 8.13 | 20.22 | 0.107 | |
| | 0 | 305 | 475 | 680 | 0.68 | 21.70 | Cap | 7.65 | 10.72 | 0.107 | 96 |
| | | | | | | | Body | 7.34 | 18.44 | 0.104 | |
| | 1 | 225 | 350 | 500 | 0.50 | 19.40 | Cap | 6.91 | 9.78 | 0.104 | 76 |
| | | | | | | | Body | 6.63 | 16.61 | 0.102 | |
| | 2 | 165 | 260 | 370 | 0.37 | 18.00 | Cap | 6.35 | 8.94 | 0.102 | 61 |
| | | | | | | | Body | 6.07 | 15.27 | 0.099 | |
| | 3 | 135 | 210 | 300 | 0.30 | 15.90 | Cap | 5.82 | 8.08 | 0.092 | 48 |
| | | | | | | | Body | 5.56 | 13.59 | 0.090 | |
| | 4 | 95 | 145 | 210 | 0.21 | 14.30 | Cap | 5.31 | 7.21 | 0.096 | 38 |
| | | | | | | | Body | 5.05 | 12.19 | 0.091 | |
| | 5 | 60 | 90 | 130 | 0.13 | 11.10 | Cap | 4.91 | 6.20 | 0.089 | 28 |
| | | | | | | | Body | 4.66 | 9.32 | 0.086 | |

6

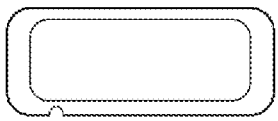


FIG. 1b

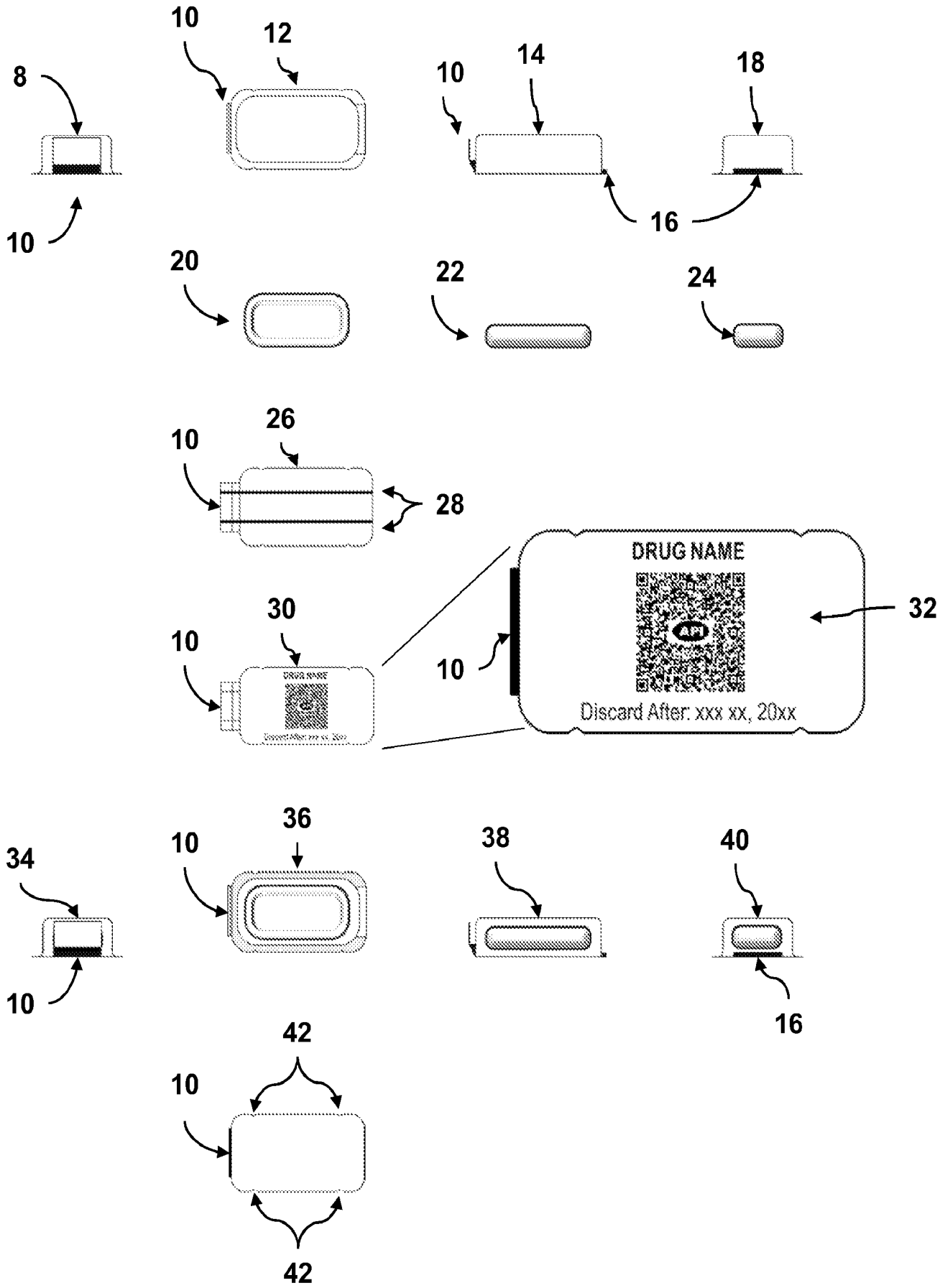

8
10
10
12
10
14
16
18
20
22
24
10
26
28
10
30
DRUG NAME
10
32
Discard After: xxx xx, 20xx
34
10
10
36
38
40
16
10
42
42

FIG. 2

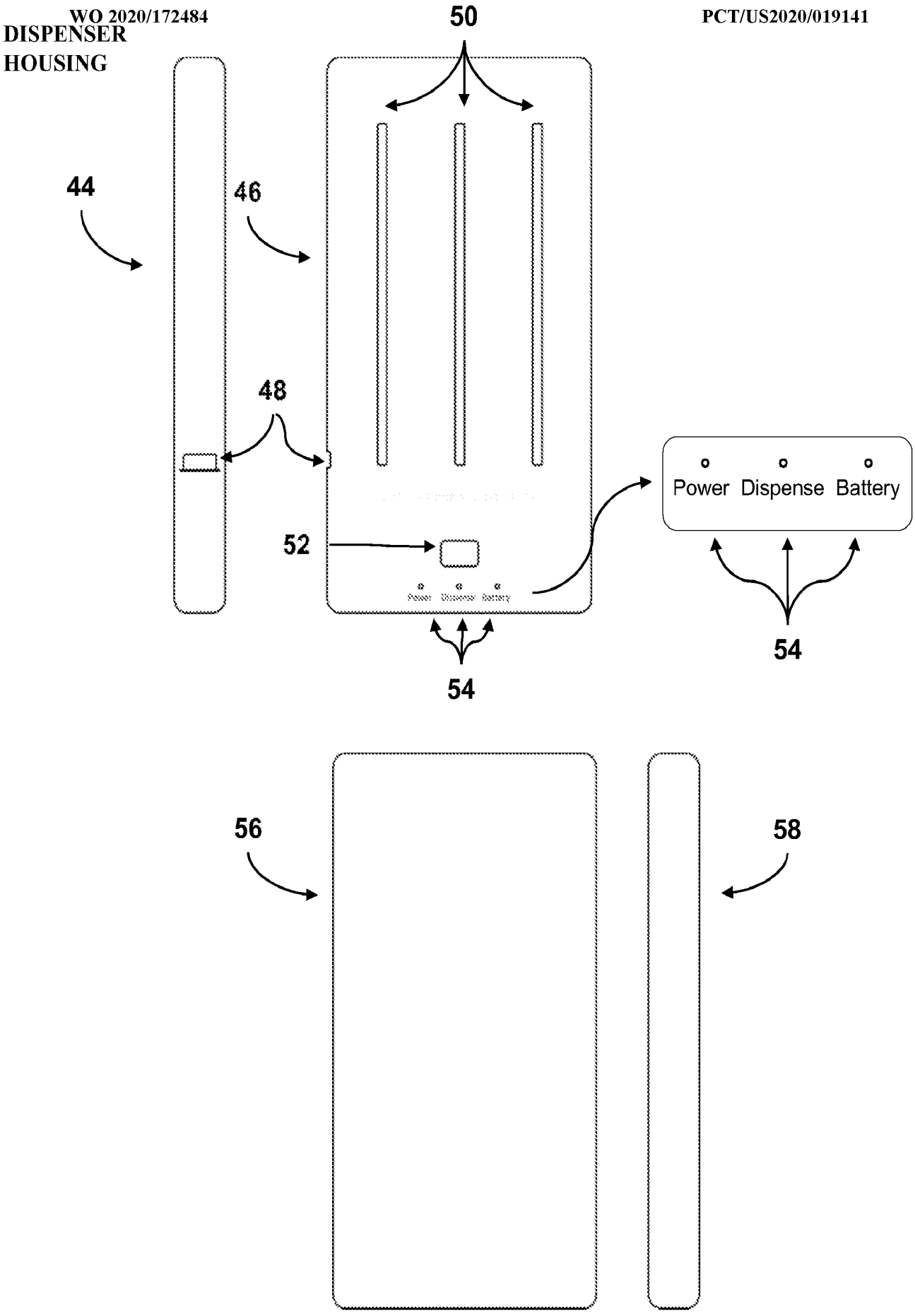

DISPENSER HOUSING
50
44
46
48
52
Power
Dispense
Battery
54
54
56
58

FIG. 3

INTEGRATED
INTRUSION DETECTION
SENSOR

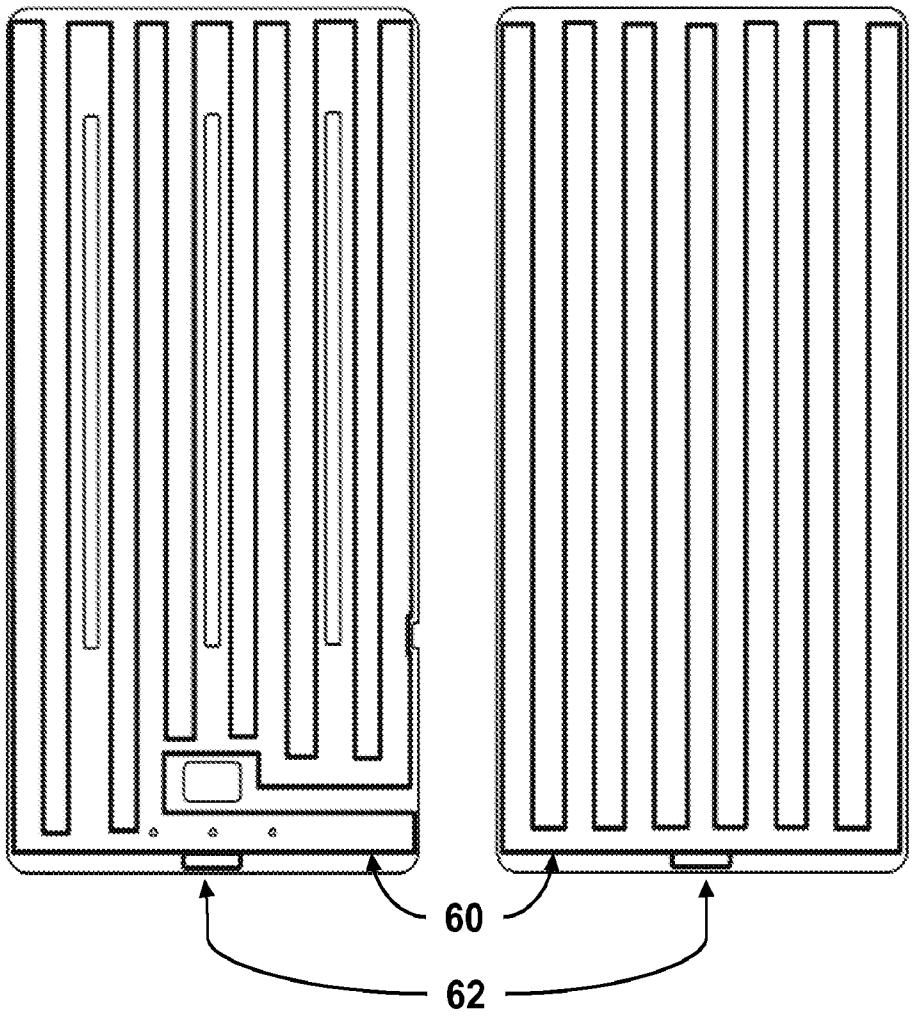



FIG. 4

INTEGRATED
DISPENSE BUTTON
AND LED LIGHTS

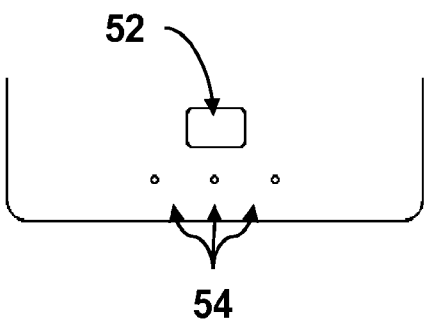



FIG. 5

**BLISTER PACK**
**DIVIDERS & GUIDES**

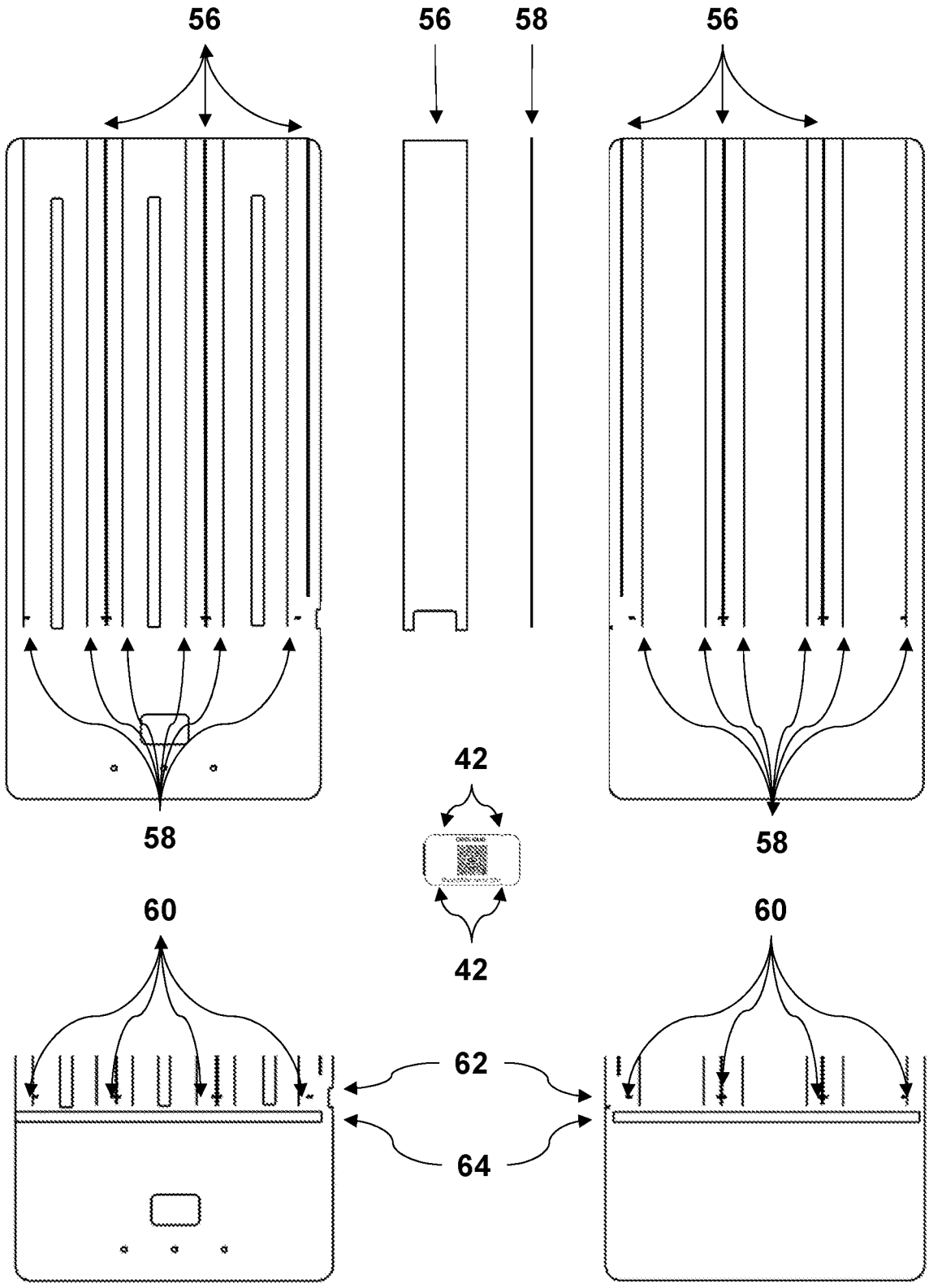



**FIG. 6**

BLISTER PACK
DISPENSER
HOUSING

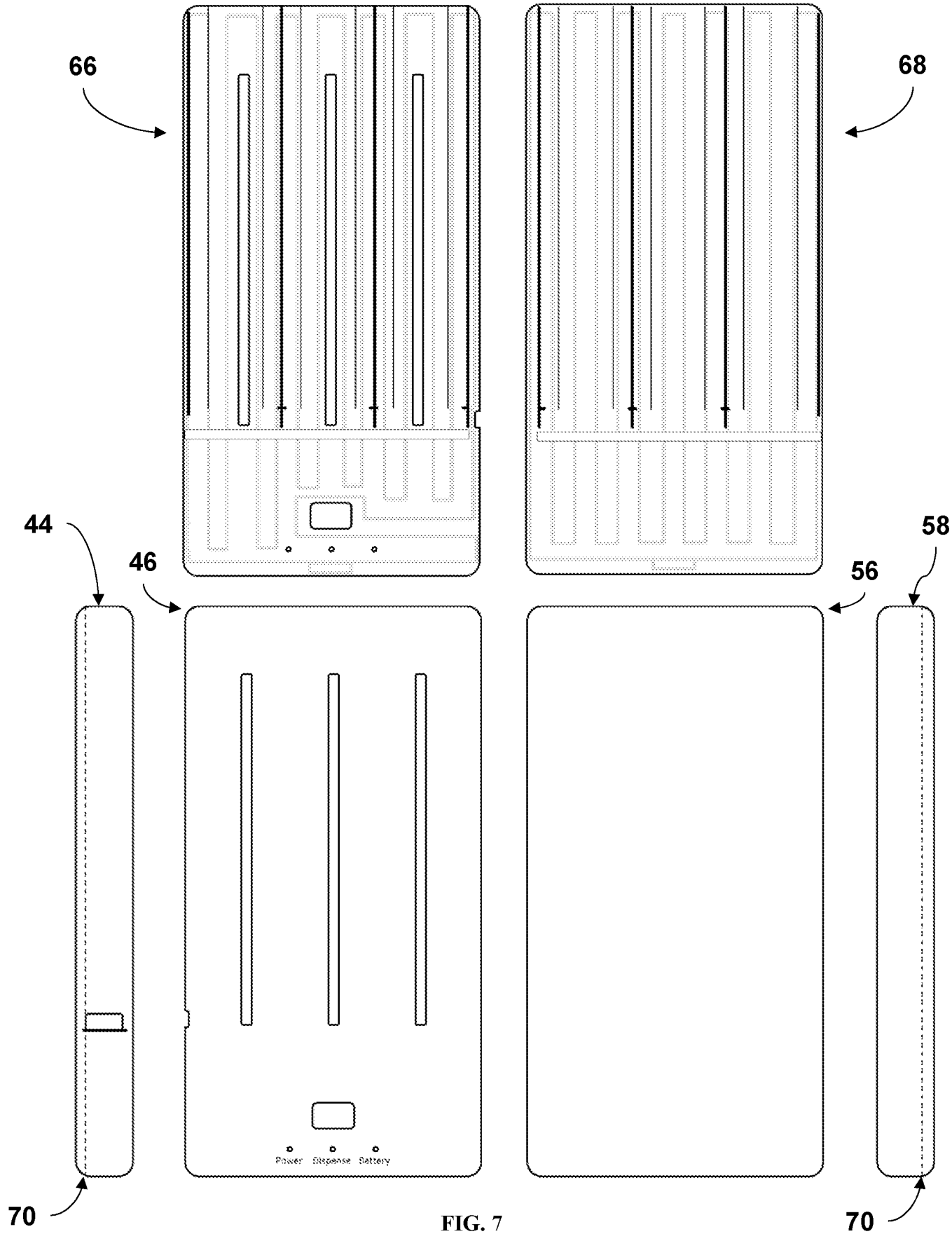



FIG. 7

BLISTER PACK ASSEMBLY

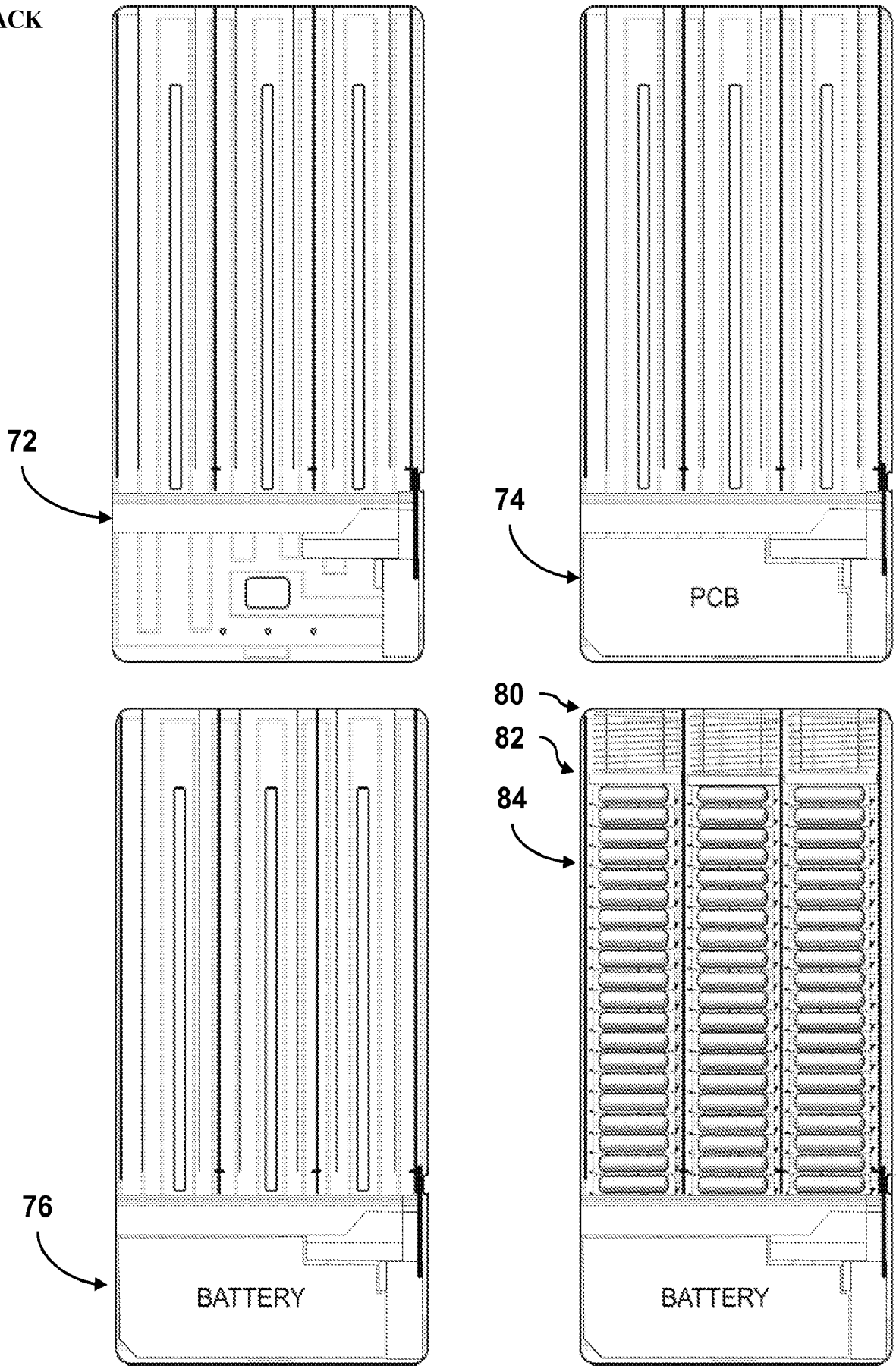



FIG. 8

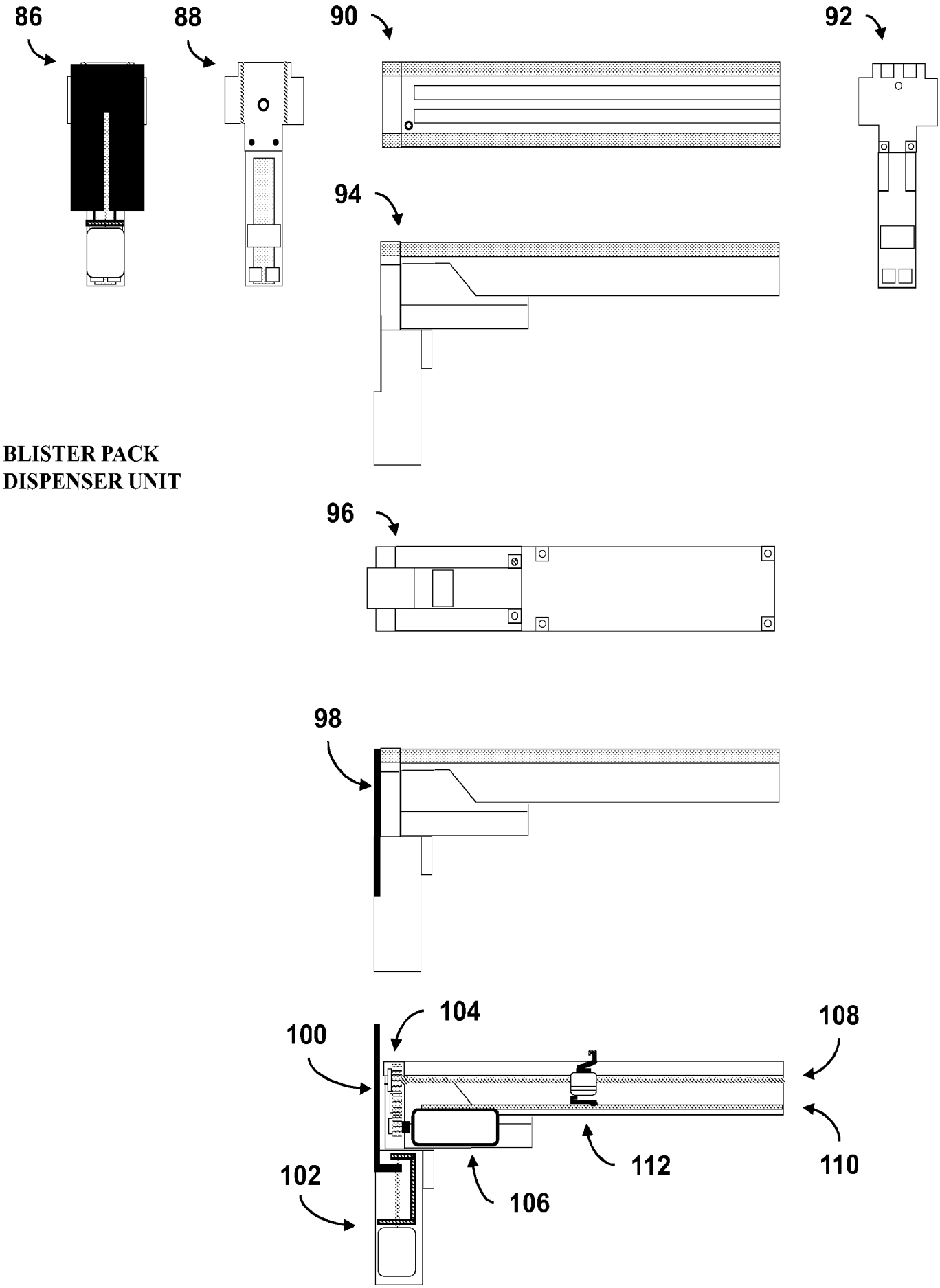

86
88
90
92
94
BLISTER PACK
DISPENSER UNIT
96
98
104
100
108
112
110
102
106

FIG. 9

ELECTRONICS

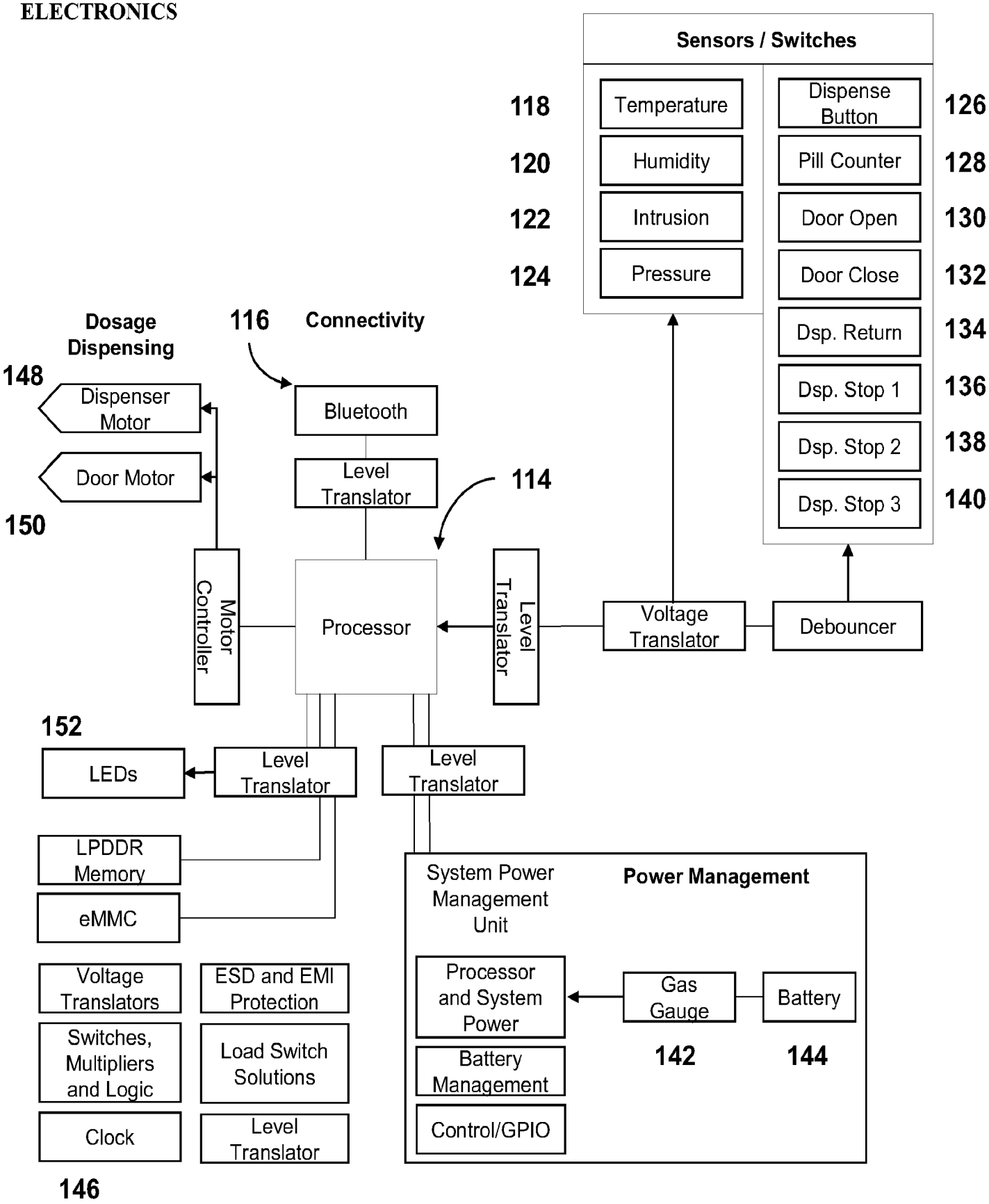



FIG. 10

SENSORS AND
SWITCHES

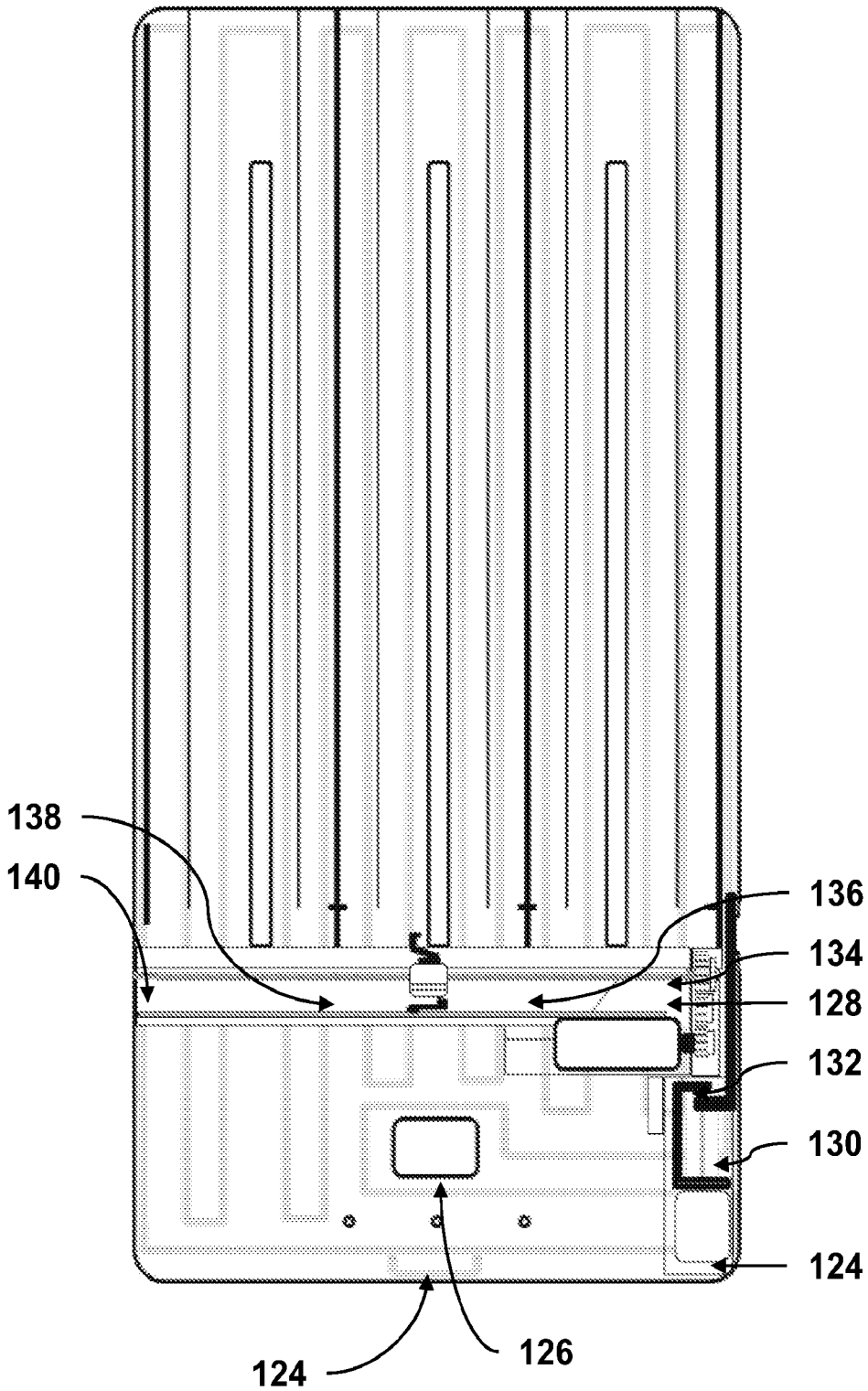



FIG. 11

ACCOY DISPENSER
DISPENSE SEQUENCE

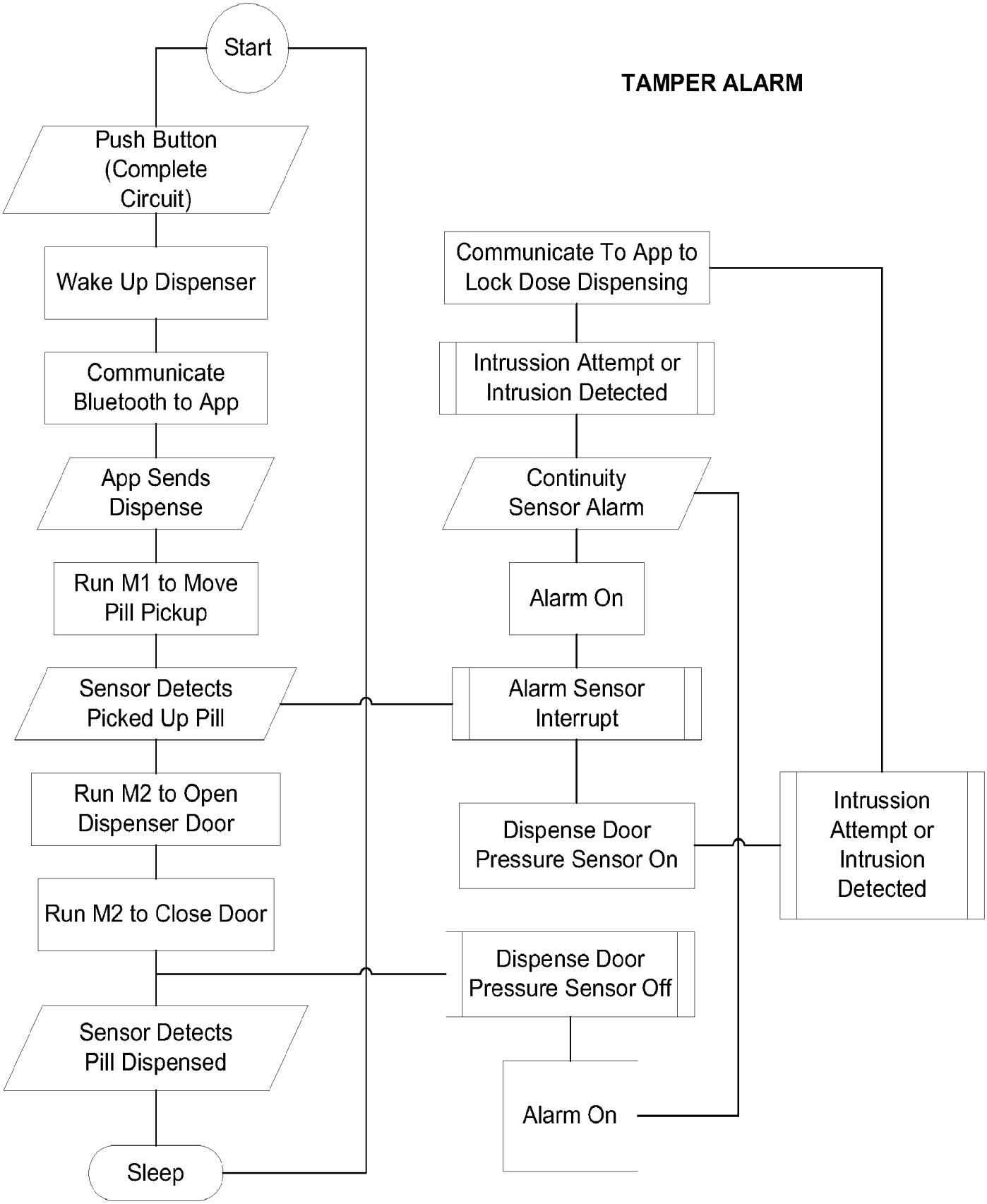
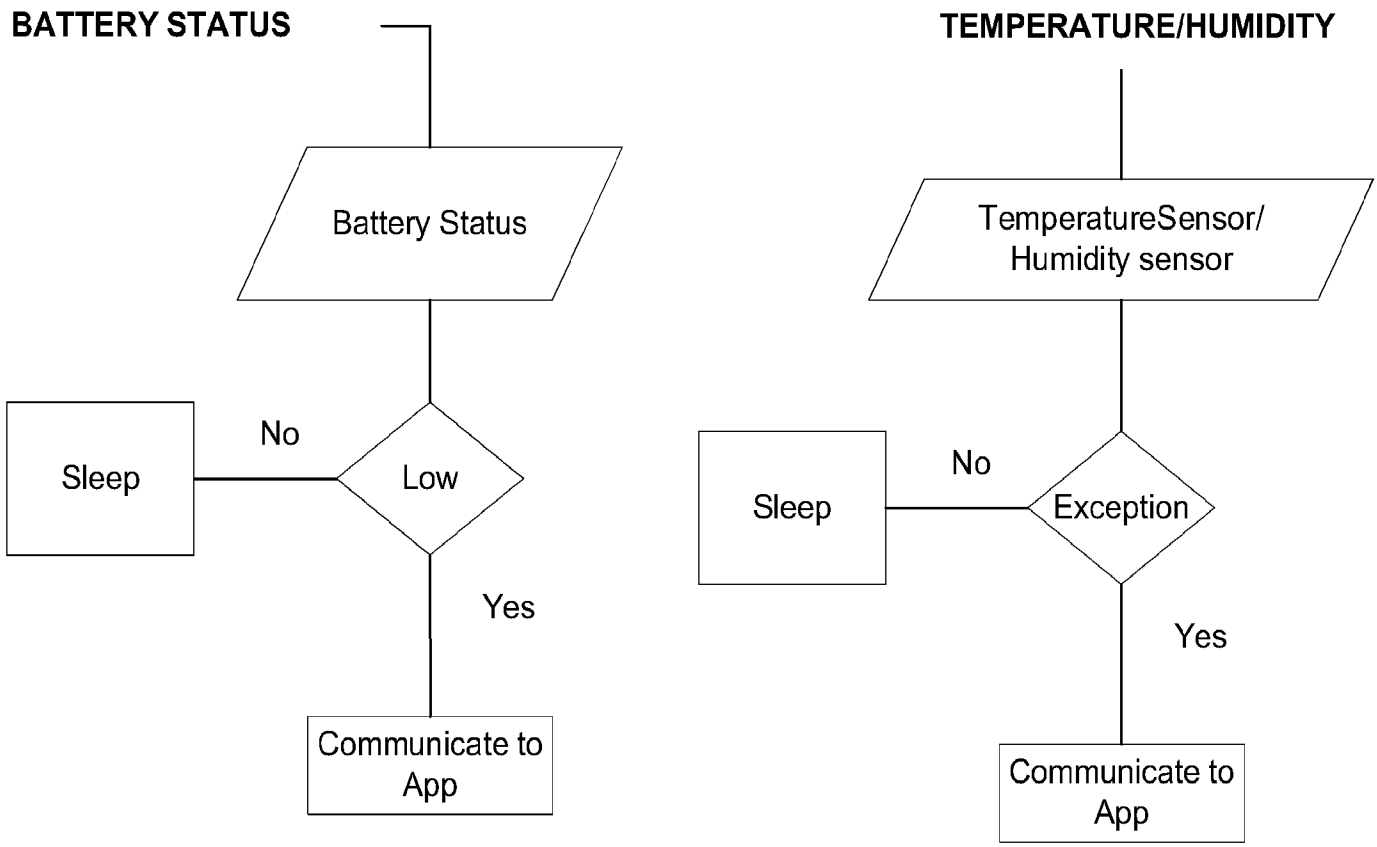



FIG. 12a


BATTERY STATUS
Battery Status
Low
No
Sleep
Yes
Communicate to App
TEMPERATURE/HUMIDITY
TemperatureSensor/ Humidity sensor
Exception
No
Sleep
Yes
Communicate to App

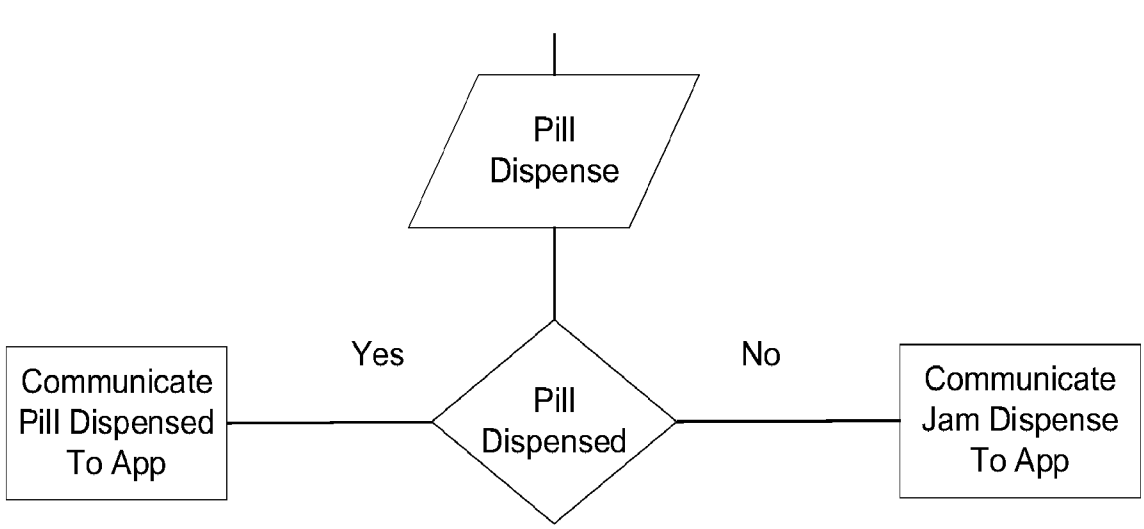

PILL DISPENSE
Pill Dispense
Pill Dispensed
Yes
No
Communicate Pill Dispensed To App
Communicate Jam Dispense To App

FIG. 12b

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/19141

A. CLASSIFICATION OF SUBJECT MATTER

IPC - B65D 75/36, A61J 1/03, B65D 83/04 (2020.01)

CPC - B65D 75/36, A61J 1/03, B65B 1/04, B65D 83/04, B65D 85/42, A61J 1/00, B65D 75/28, B65D 2575/3227, B65D 75/327, B65D 2215/04, B65D 2585/56

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 2006/0027480 A1 (Buss) 09 February 2006 (09.02.2006), entire document, especially Fig. 1, 5; para[0021]; | 1-4 |
| X<br>---<br>Y | US 2012/0145739 A1 (Doyle et al.) 14 June 2012 (14.06.2012), entire document, especially Fig. 6, 7, 8, 9, 28, 29; para[0064]; para[0092]; para[0067]; para[0057]; para[0073]; para[0068]; para[0077]; | 1, 5, 8-9<br>---<br>6-7 |
| X | US 7,946,449 B2 (Benktzon et al.) 24 May 2011 (24.05.2011), entire document, especially Fig. 3a, 3b; col 4, ln 33-60; col 5, ln 44-62; | 1, 10 |
| X<br>---<br>Y | US 7,401,702 B2 (Hession) 22 July 2008 (22.07.2008), entire document, especially Fig. 3, 4, 7, 8, 9; col 6, ln 10-19; col 6, ln 20-37; | 1<br>---<br>6-7 |
| A | US 2010/0102062 A1 (Jones et al.) 29 April 2010 (29.04.2010), entire document | 1-10 |
| A | US 5,339,960 A (Price) 23 August 1994 (23.08.1994), entire document | 1-10 |
| A | US 7,828,149 B2 (Kalvelage et al.) 09 November 2010 (09.11.2010), entire document | 1-10 |
| A | US 5,348,158 A (Honan et al.) 20 September 1994 (20.09.1994), entire document | 1-10 |
| A | US 5,046,618 A (Wood) 10 September 1991 (10.09.1991), entire document | 1-10 |

☒ 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
"D" document cited by the applicant in the international application
"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
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 15 June 2020 | 02 JUL 2020 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer<br>Lee Young<br>Telephone No. PCT Helpdesk: 571-272-4300 |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/19141

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 2016/0193152 A1 (OREXIGEN THERAPEUTICS, INC.) 07 July 2016 (07.07.2016), entire document | 1-10 |
| A | US 2009/0139893 A1 (McGonagle et al.) 04 June 2009 (04.06.2009), entire document | 1-10 |
| A | US 2009/0184023 A1 (Brollier et al.) 23 July 2009 (23.07.2009), entire document | 1-10 |
| A | US 2014/0252032 A1 (Eco.logic Brands Inc.) 11 September 2014 (11.09.2014), entire document | 1-10 |
| A | US 2013/0341232 A1 (Mikula) 26 December 2013 (26.12.2013), entire document | 1-10 |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/19141

**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:
This 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 searched, the appropriate additional search fees must be paid.

Group I: Claims 1-10 directed to a single use blister pack.

Group II: Claims 11-39 directed to an app controlled blister pack drug dispenser.
*Note: see Note below.

The inventions listed as Groups I-II 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 for the following reasons:

--- Continued in 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.:

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.:
1-10

**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.

**INTERNATIONAL SEARCH REPORT**
Information on patent family members

International application No.
PCT/US 20/19141

--- Continuation of Box No. III Observations where unity of invention is lacking ---

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a single use blister pack designed to be dispensed by a blister pack drug dispenser, not required by the claims of Group II.

The invention of Group II includes the special technical feature of an app controlled blister pack drug dispenser designed to control dose -by-dose dispensing and to capture sensor data to enable point of care pharmacy, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I and II share the common technical features of a blister pack (generally) capable of being dispensed (generally).

However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,348,158 A (Honan et al.), which discloses a blister pack (generally) capable of being dispensed (generally) (10, 14, 30, Fig. 1, 2, 4, 5, 6; col 2, ln 60-68, 'the dispenser pack (10) comprises a container (11) including a cover (12) and a base portion (13). Disposed within the base portion (13) is a disposable blister package (14)'; col 3, ln 35-43, 'in use, when it is desired to release a tablet (16) from a dispenser pack (10), the plunger (30) is positioned at a corner (18) in the double "S" shaped race (17) in the cover (12). As the plunger (30) is depressed, the button portion (32) of the plunger (30) contacts the blister (15) in the blister package whereby the blister (15) is ruptured and the tablet (16) drops through the opening (21) in the base portion (13), dropping into the space (37) underneath the container (11) where it can be retrieved').

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

*Note: Claims 1 and 11: Regarding claims 1 and 11, the body of the claims are inadvertently missing, and the terms "comprised of" have been interpreted as being removed from the claims, resulting in the claims being interpreted as being drafted without a transitional phrase. As such, the claims are defective since the scope of the claims are indefinite without a transitional phrase and the claim is merely a function limitation (ISPE Guidelines para 5.22+).