PATENT

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CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on June 13, 2025.

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AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the Office Action mailed March 14, 2025, the period of response for which runs through June 14, 2025, please amend the application.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 14 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1–20 (Canceled).

Claim 21 (Currently Amended): A system comprising:

a memory configured to store:

medication dispense transaction data indicating information corresponding to a plurality of medication dispense events; [[and]]

medication waste transaction data indicating information corresponding to a plurality of medication waste transactions; and

electronic health record data indicating information corresponding to a plurality of medication administration events; and

processing circuitry in communication with the memory, wherein the processing circuitry is configured to:

obtain at least one of medication dispense transaction data, medication waste transaction data, or electronic health record data, from at least one of a medical device, electronic health record system, or automated medication dispensing system (AMDS), over a data stream using a computational messaging format;

determine ~~identify~~, based on the medication dispense transaction data, the medication waste transaction data, and the electronic health record data, a ~~plurality of potential drug diversion events~~ set of comparisons, the set of comparisons comprising at least of a comparison of an expected wasted amount of the medication to an amount of medication administered to a patient;

~~identify one or more users of a plurality of users corresponding to each drug~~

~~diversion event of the plurality of potential drug diversion events, wherein the plurality of users comprise a set of peer groups;~~

determine a plurality of variances, wherein the plurality of variances includes a respective variance for each one of the comparisons of the set of comparisons when the respective comparison yields a difference that exceeds a respective threshold;

identify a plurality of users across a plurality of healthcare facilities, wherein each user of the plurality of users is associated with at least one of the medication dispense transaction data, the medication waste transaction data, or the electronic health record data, associated with at least one variance of the plurality of variances;

perform, for each user of the plurality of users, longitudinal analysis of one or more variances of the plurality of variances associated with the user;

identify, based on the longitudinal analysis, one or more variances patterns indicative of potential drug diversion events, wherein to identify the one or more variance patterns, the processing circuitry is configured to:

detect a first variance pattern based on a first set of variances detected during a first period of time for one of the plurality of users;

detect a second variance pattern based on a second set of variances detected during a second period of time for the one of the plurality of users, wherein the second period of time is subsequent to the first period of time;

determine that the second variance pattern is different than the first variance pattern; and

identify a potential drug diversion event corresponding to the one of the plurality of users based on the determining that the second variance pattern is different than the first variance pattern.

~~determine a baseline corresponding to each peer group of the set of peer groups; and~~

~~determine, based on the one or more users corresponding to each drug diversion event of the plurality of potential drug diversion events and the baseline corresponding to each~~

~~peer group of the set of peer groups, a probability that each user of the plurality of users is associated with drug diversion~~.

Claim 22. (Cancelled)

Claim 23. (Currently Amended): The system of claim 21, wherein to obtain medication dispense transaction data, the processing circuitry is ~~further~~ configured to:

~~receive~~ obtain the medication dispense transaction data from a plurality of automated medication dispensing stations (AMDS) over an HL7 data stream, wherein each AMDS of the plurality of AMDS is configured to perform one or more medication dispense events of the plurality of medication dispense events; and

save the medication dispense transaction data to the memory~~;~~

~~receive the electronic health record data from an electronic health record system over an HL7 data stream; and~~

~~save the electronic health record data to the memory~~.

Claim 24. (Currently Amended): The system of claim 21[[3]], wherein to obtain medication waste transaction data, the processing circuitry is ~~further~~ configured to:

receive medication waste transaction data from the plurality of AMDS over an HL7 data stream, the medication waste transaction data indicating information corresponding to a plurality of medication waste events, wherein each AMDS of the plurality of AMDS is configured to perform one or more medication waste events of the plurality of medication waste events; and

save the medication waste transaction data to the memory~~; and~~

~~identify the plurality of potential drug diversion events based on the medication dispense transaction data, the electronic health record data, and the medication waste transaction data~~.

Claim 25. (Currently Amended): The system of claim [[24]] 21, wherein to determine ~~identify~~ the set of comparisons, ~~plurality of potential drug diversion events based on the medication dispense transaction data, the electronic health record data, and the medication waste transaction data,~~ the processing circuitry is configured to:

compare medication dispense transaction data corresponding to each medication dispense event of the plurality of medication dispense events with electronic health record data corresponding to a medication administration event of the plurality of medication administration events associated with the medication dispense event; and

compare medication waste transaction data corresponding to each medication waste event of the plurality of medication waste events with electronic health record data corresponding to a medication administration event of the plurality of medication administration events associated with the medication dispense event.

Claim 26. (Cancelled)

Claim 27. (Currently Amended): The system of claim 21,

wherein the medication dispense transaction data indicates, for each medication dispense event of the plurality of medication dispense events:

a net amount of medication dispensed; and

a user of the plurality of users associated with the medication dispense event,

wherein the electronic health record data indicates, for each medication administration event of the plurality of medication administration events:

a net amount of medication administered; and

a user of the plurality of users associated with the medication administration event, and

wherein the set of comparisons further comprises ~~processing circuitry is configured to identify the plurality of potential drug diversion events based on~~ a comparison of the net amount of medication dispensed to ~~each medication dispense event of the plurality of medication dispense events, and wherein the processing circuitry is configured to identify the plurality of potential drug diversion events based on~~ the net amount of medication administered ~~and the user of the plurality of users corresponding to each medication administration event of the plurality of medication administration events~~.

Claim 28. (Cancelled)

Claim 29. (Cancelled)

Claim 30. (Cancelled)

Claim 31. (Currently Amended): A method comprising:

obtaining, by processing circuitry, information associated with at least one of a medication dispense transaction data indicating information corresponding to a plurality of medication dispense events, a medication waste transaction data indicating information corresponding to a plurality of medication waste transactions, or a electronic health record data indicating information corresponding to a plurality of medication administration events, from at least one of a medical device, electronic health record system, or medication dispensing system, over a data stream using a computational messaging format, wherein a memory in communication with the processing circuitry is configured to store the medication dispense transaction data, the medication waste transaction data, and the electronic health record data;

identifying, by the processing circuitry based on the medication dispense transaction data, the medication waste transaction data, and the electronic health record data, a ~~plurality of potential drug diversion events~~ set of comparisons, the set of comparisons comprising at least of a comparison of an expected wasted amount of the medication to an amount of medication administered to a patient;~~, wherein a memory in communication with the processing circuitry is configured to store: the medication dispense transaction data indicating information corresponding to a plurality of medication dispense events; and the electronic health record data indicating information corresponding to a plurality of medication administration events; and~~

~~identifying, by the processing circuitry, one or more users of a plurality of users corresponding to each drug diversion event of the plurality of potential drug diversion events, wherein the plurality of users comprise a set of peer groups;~~

~~determining, by the processing circuitry, a baseline corresponding to each peer group of the set of peer groups; and~~

~~determining, by the processing circuitry based on the one or more users corresponding to each drug diversion event of the plurality of potential drug diversion events and the baseline corresponding to each peer group of the set of peer groups, a probability that each user of the plurality of users is associated with drug diversion~~

determining, by the processing circuitry, a plurality of variances, wherein the plurality of variances includes a respective variance for each one of the comparisons of the set of comparisons when the respective comparison yields a difference that exceeds a respective threshold;

identifying, by the processing circuitry, a plurality of users across a plurality of healthcare facilities, wherein each user of the plurality of users is associated with at least one of the medication dispense transaction data, medication waste transaction data, or electronic health record data, used to determine at least one variance of the plurality of variances;

performing, by the processing circuitry and for each user of the plurality of users, longitudinal analysis of one or more variances of the plurality of variances associated with the user;

identifying, by the processing circuitry and based on the longitudinal analysis, one or more variances patterns indicative of potential drug diversion events, wherein to identify the one or more variance patterns, the processing circuitry is configured to:

detect a first variance pattern based on a first set of variances detected during a first period of time for one of the plurality of users;

detect a second variance pattern based on a second set of variances detected during a second period of time for the one of the plurality of users, wherein the second period of time is subsequent to the first period of time;

determine that the second variance pattern is different than the first variance pattern; and

identify a potential drug diversion event corresponding to the one of the plurality of users based on the determining that the second variance pattern is different than the first variance pattern.

Claim 32. (Cancelled)

Claim 33. (Currently Amended): The method of claim 31, wherein obtaining the medication dispense transaction data ~~further comprising~~ comprises:

obtaining ~~receiving~~, by the processing circuitry, the medication dispense transaction data from a plurality of automated medication dispensing stations (AMDS) over an HL7 data stream, wherein each AMDS of the plurality of AMDS is configured to perform one or more medication dispense events of the plurality of medication dispense events; and

saving, by the processing circuitry, the medication dispense transaction data to the memory~~;~~

~~receiving, by the processing circuitry, the electronic health record data from an electronic health record system; and~~

~~saving, by the processing circuitry, the electronic health record data to the memory~~.

Claim 34. (Currently Amended): The method of claim [[33]] 31, wherein obtaining the medication waste transaction data ~~further comprising~~ comprises:

receiving, by the processing circuitry, medication waste transaction data from the plurality of AMDS over an HL7 data stream, the medication waste transaction data indicating information corresponding to a plurality of medication waste events, wherein each AMDS of the plurality of AMDS is configured to perform one or more medication waste events of the plurality of medication waste events; and

saving, by the processing circuitry, the medication waste transaction data to the memory~~; and~~

~~identifying, by the processing circuitry, the plurality of potential drug diversion events based on the medication dispense transaction data, the electronic health record data, and the medication waste transaction data~~.

Claim 35. (Currently Amended): The method of claim [[34]] 31, wherein determining ~~identifying~~ the set of comparisons ~~plurality of potential drug diversion events based on the medication dispense transaction data, the electronic health record data, and the medication waste transaction data comprising~~ comprises:

comparing medication dispense transaction data corresponding to each medication dispense event of the plurality of medication dispense events with electronic health record data corresponding to a medication administration event of the plurality of medication administration events associated with the medication dispense event; and

comparing medication waste transaction data corresponding to each medication waste event of the plurality of medication waste events with electronic health record data corresponding to a medication administration event of the plurality of medication administration events associated with the medication dispense event.

Claim 36. (Cancelled)

Claim 37. (Currently Amended): The method of claim 31,

wherein the medication dispense transaction data indicates, for each medication dispense event of the plurality of medication dispense events:

a net amount of medication dispensed; and

a user of the plurality of users associated with the medication dispense event,

wherein the electronic health record data indicates, for each medication administration event of the plurality of medication administration events:

a net amount of medication administered; and

a user of the plurality of users associated with the medication administration event, and

wherein the set of comparisons further comprises a comparison of ~~method further comprises:~~

~~identifying, by the processing circuitry, the plurality of potential drug diversion events based on~~ the net amount of medication dispensed to ~~and the user of the plurality of users corresponding to each medication dispense event of the plurality of medication dispense events, and identifying, by the processing circuitry, the plurality of potential drug diversion events based on~~ the net amount of medication administered ~~and the user of the plurality of users corresponding to each medication administration event of the plurality of medication administration events~~.

Claim 38. (Cancelled)

Claim 39. (Cancelled)

Claim 40. (Currently Amended): A computer-readable medium storing instructions that, when applied by processing circuitry, causes the processing circuitry to:

~~identify, based on medication dispense transaction data and electronic health record data, a plurality of potential drug diversion events,~~ obtain at least one of medication dispense transaction data, medication waste transaction data, or electronic health record data, from at least one of a medical device, electronic health record system, or automated medication dispensing

system (AMDS), over a data stream using a computational messaging format, wherein a memory in communication with the processing circuitry is configured to store:

the medication dispense transaction data indicating information corresponding to a plurality of medication dispense events; [[and]]

the medication waste transaction data indicating information corresponding to a plurality of medication waste transactions; and

the electronic health record data indicating information corresponding to a plurality of medication administration events; and

determine ~~identify~~ based on the medication dispense transaction data, the medication waste transaction data, and the electronic health record data, ~~one or more users of a plurality of users corresponding to each drug diversion event of the plurality of potential drug diversion events, wherein the plurality of users comprise a set of peer groups;~~ a set of comparisons, the set of comparisons comprising at least of a comparison of an expected wasted amount of the medication to an amount of medication administered to a patient;

~~determine a baseline corresponding to each peer group of the set of peer groups; and~~

~~determine, based on the one or more users corresponding to each drug diversion event of the plurality of potential drug diversion events and the baseline corresponding to each peer group of the set of peer groups, a probability that each user of the plurality of users is associated with drug diversion~~

determine a plurality of variances, wherein the plurality of variances includes a respective variance for each one of the comparisons of the set of comparisons when the respective comparison yields a difference that exceeds a respective threshold;

identify a plurality of users across a plurality of healthcare facilities, wherein each user of the plurality of users is associated with at least one of the medication dispense transaction data, the medication waste transaction data, or the electronic health record data, associated with at least one variance of the plurality of variances;

perform, for each user of the plurality of users, longitudinal analysis of one or more variances of the plurality of variances associated with the user;

identify, based on the longitudinal analysis, one or more variances patterns indicative of potential drug diversion events, wherein to identify the one or more variance patterns, the

processing circuitry is configured to:

detect a first variance pattern based on a first set of variances detected during a first period of time for one of the plurality of users;

detect a second variance pattern based on a second set of variances detected during a second period of time for the one of the plurality of users, wherein the second period of time is subsequent to the first period of time;

determine that the second variance pattern is different than the first variance pattern; and

identify a potential drug diversion event corresponding to the one of the plurality of users based on the determining that the second variance pattern is different than the first variance pattern.

Claim 41. (New): The system of claim 21, wherein the computational messaging format is designed for the electronic exchange of health care data.

Claim 42. (New): The system of claim 41, wherein the computational messaging format is operated according to Health Level 7 (HL7) standards.

Claim 43. (New): The method of claim 31, wherein the computational messaging format is designed for the electronic exchange of health care data.

Claim 44. (New): The method of claim 43, wherein the computational messaging format is operated according to Health Level 7 (HL7) standards.

Claim 45. (New): The computer-readable medium of claim 40, wherein the computational messaging format is designed for the electronic exchange of health care data.

Claim 46. (New): The computer-readable medium of claim 45, wherein the computational messaging format is operated according to Health Level 7 (HL7) standards.

REMARKS

Applicant respectfully submits this Amendment in response to the Office Action dated March 14, 2025. Applicant has amended claims 21, 23-25, 27, 31, 33-35, 37, and 40. Applicant has cancelled claims 22, 26, 28-30, 32, 36, and 38-39. Applicant has submitted new claims 41-46. Claims 21, 23-25, 27, 31, 33-35, 37, and 40-46 are pending upon entry of this communication.

Interview Summary

Applicant thanks the Examiner for the telephonic interview conducted on Wednesday, May 14, 2025. Participating in the interview were Examiner Patel, Examiner Nguyen, and Applicant's representative, Hunter T. Berry (Reg. No. 82,969). During the interview, Applicant's representative discussed the rejection of claims 21-40 under § 101 and § 103, and proposed potential claim amendments, for example, to claim 21. Applicant's representative also presented arguments regarding the interpretation of the claims under § 112(f), and rejection of the claims under § 112(a). No agreements were reached during the interview. No exhibits were submitted, and no demonstrations were performed.

Claim Rejection Under 35 U.S.C. § 101

The Office Action rejected claims 21-40 under 35 U.S.C. § 101 based on an assertion that these claims are directed to non-statutory subject matter. Applicant respectfully traverses this rejection, at least to the extent the rejection can be applied to the claims as amended.

The 2019 Revised Patent Subject Matter Eligibility Guidance explains that, under Step 2A, abstract ideas can be grouped as, e.g., mathematical concepts, certain methods of organizing human activity, and mental processes. Second, this guidance explains that a patent claim or patent application claim that recites a judicial exception is not "directed to" the judicial exception if the judicial exception is integrated into a practical application of the judicial exception. A claim that recites a judicial exception, but is not integrated into a practical application, is directed to the judicial exception under Step 2A and must then be evaluated under Step 2B (inventive concept) to determine the subject matter eligibility of the claim.

The method recited in independent claim 21, for example, provides one or more technical advantages. For example, as described in Applicant's specification:

> "An example nursing auditing program may utilize the Health Level Seven (HL7) data stream from the electronic healthcare administration record (eHR). The program compares and analyzes clinical documentation to medication administration obtained from automated medication dispensing systems (AMDS)."[1]
>
> "An example procedural auditing application may be very similar to the anesthesia application. The procedural auditing application may utilize the HL7 data stream from the electronic healthcare administration record (eHR). The program compares and analyzes clinical documentation in procedural areas to medication administration obtained from electronic medication dispensing systems (AMDS) in a procedural setting. Medication dispensed in these areas is obtained from an AMDS that allow a user to remove any medication in the cabinet and the removal of the medication is not physically restricted."[2]
>
> "An example Patient Controlled Analgesia (PCA) and Epidural administration program may compare the HL7 clinical data of administration to the dispensing of medication including returns and waste and also to an electronic administration history from the pump administration."[3]
>
> "By tracking medication transaction history for multiple user's over time, the medication administration auditing system described herein may establish a baseline for each job role (e.g., nurse, physician, etc.) for each criterion (e.g., practice area/department, geographic location, dispensing location, patient, timeframe, etc.) to be reviewed. A user's medication transaction activity (e.g., removal and waste), both individually and over time, may then be compared against the appropriate baseline to identify potential diversion activity (582, 586, 588)."[4]
>
> "In some examples, the medication administration auditing systems and/or methods may allow for independent user disposition of a controlled substance. In other words, rather than requiring a "witness" to waste a controlled substance, the processes and procedures underlying the medication administration auditing system provide confirmation that a medication or other controlled substance was properly disposed of. This may simplify and increase efficiency of the medication waste process because a user need not find an administrator or other witness to verify their controlled substance waste. It may also increase the likelihood that users will properly deposit controlled substance waste in designated waste bins rather than dispose of controlled substances in sinks, toilets, or trash. It may further identify and/or prevent diversion by two colleagues working together."[5]

Claim 21, as amended, reflects an improvement in the technology or technical field of detection of drug diversion by "obtain[ing] at least one of medication dispense transaction data, medication waste transaction data, or electronic health record data, from at least one of a medical device, electronic health record system, or medication dispensing system over a data stream using a computational messaging format." Newly submitted claims 41 and 42 further specify that the computation messaging format may be designed for the electronic exchange of health care

[1] Specification, ¶ [0057].
[2] Specification, ¶ [0061].
[3] Specification, ¶ [0063].
[4] Specification, ¶ [0086].
[5] Specification, ¶ [0034].

data, such as according to the Health Level 7 (HL7) standards, a set of standards for the "exchange, integration, sharing, and retrieval of electronic health information."[6] That is, a data stream using a specialized computation messaging format, such as a data stream transmitting HL7 messages, may be used to exchange electronic health care and medical data between computing systems and may support "near real-time transmission of data."[7] Messages sent according to specialized computation messaging format may be structured messages designed for readability and use by computing devices. For instance, an example HL7 message, provided by HL7 International, the organization responsible for the creation and management of the HL7 standards, and reads as:

> MSH|^~\&#|NIST EHR^2.16.840.1.113883.3.72.5.22^ISO|NIST EHR
> Facility^2.16.840.1.113883.3.72.5.23^ISO|NIST Test Lab
> APP^2.16.840.1.113883.3.72.5.20^ISO|NIST Lab
> Facility^2.16.840.1.113883.3.72.5.21^ISO|20130211184101-0500||OML^O21^OML_O21|NIST-LOI_3.0_1.1-GU|T|2.5.1|||AL|AL|||||LOI_Common_Component^LOI Base Profile^2.16.840.1.113883.9.66^ISO~LOI_GU_Component^LOI GU Profile^2.16.840.1.113883.9.78^ISO~LAB_PRU_Component^LOI PRU Profile^2.16.840.1.113883.9.82^ISO
> PID|1||PATID1234^^^NIST
> MPI&2.16.840.1.113883.3.72.5.30.2&ISO^MR||Jones^William^A^JR^^^L||19610615|M||2106-3^White^HL70005|2100 Kennwood Ave^Apt 41^Los Angeles^CA^90067^^H
> ORC|NW|ORD777888^^2.16.840.1.113883.3.72.5.24^ISO||GORD874244^^2.16.840.1.113883.3.72.5.24^ISO|||||20120628070100|||5742200012^Radon^Nicholas^^^^^^NPI&2.16.840.1.113883.4.6&ISO^L^^^NPI|||||||2^Patient has been informed of responsibility, and agrees to pay for service^HL70339
> OBR|1|ORD777888^^2.16.840.1.113883.3.72.5.24^ISO||400.1^Lipid Panel - direct LDL^99USL^57698-3^Lipid panel with direct LDL - Serum or Plasma^LN^20130421^^Lipid Panel - direct LDL|||20110531123551-0800|||||||||5742200012^Radon^Nicholas^^^^^^NPI&2.16.840.1.113883.4.6&ISO^L^^^NPI||||||||||||10092000194^Hamlin^Pafford^^^^^^NPI&2.16.840.1.113883.4.6&ISO^L^^^NPI
> PRT|1^NIST EHR^2.16.840.1.113883.3.72.5.22^ISO|AD||RCT^Result Copies To^HL70912^^^^^^Send blind carbon copies to|10092000194^Hamlin^Pafford^^^^^^NPI&2.16.840.1.113883.4.6&ISO^L^^^NPI|||||||||^^FX^^^323^5555555
> DG1|1||Z82.49^Family history of ischemic heart disease and other diseases of the circulatory system^I10C^^^^^^family history of heart diease NOS|||W|||||||2
> DG1|2||R00.2^Palpitations^I10C^^^^^^Palpitations|||W|||||||1
> OBX|1|CWE|49541-6^Fasting status^LN^1902^Fasting Status^99USL||Y^Yes^HL70136|||||O|||20110531|||||||||||||SCI

[6] Introduction to HL7 Standards, HEALTH LEVEL 7 INTERNATIONAL, https://www.hl7.org/implement/standards/index.cfm?ref=nav (last visited May 22, 2025).
[7] Claire Broome & J. Loonsk, Public Health Practice Public Health Information Network --- improving early detection by using a standards-based approach to connecting Public Health and Clinical Medicine (2004), CENTER FOR DISEASE CONTROL, https://www.cdc.gov/mmwr/preview/mmwrhtml/su5301a36.htm (last visited May 22, 2025).

SPM|1|S-666555&NIST EHR&2.16.840.1.113883.3.72.5.24&ISO||119297000^Blood Specimen^SCT^^^^^^Blood||||||||||||20110531123551-0800[8]

Studies have shown that the use of HL7 messaging may increase accuracy in data collection, analysis, and reporting, when compared to traditional mechanisms, such as paper reporting.[9] With these factors in mind, the use of the a data stream operating according to a computation messaging format designed for health care communications, such as the HL7 data stream, improves the field of drug diversion detection by enabling the computing system to receive, in near real-time, the "dispense transaction data, medication waste transaction data, or electronic health record data" from one or more devices and/or systems (e.g., an automated from across a plurality of healthcare facilities (e.g., clinics, hospitals, etc.). By obtaining the information in near real-time, the auditing system may more quickly detect potential diversion events the traditional systems involving the use of paper reporting and monitoring, enabling healthcare administrators to more quickly react to and investigate any events identified as potential diversion events.

Additionally, claim 21, as amended, reflects an improvement in the technology or technical field of detection of drug diversion by analyzing users and health record data from "across a plurality of healthcare facilities." That is, the claimed techniques enable the auditing and diversion identification system to aggregate data from across multiple geographically disparate sites. This, in turn, enables the system to more quickly identify potential diversion events when compared to traditional methods that may involve the manual gathering of information and physical records from across a plurality of different facilities in order to determine a baseline (e.g., for the same department across multiple facilities) or detect variances (e.g., for an individual, such as a travel nurse or a travel doctor, that may work and be associated with electronic health records generated across multiple different medical facilities). Further, by

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[8] OML_Lipid Panel-GU-ExampleMessage.txt (July 21, 2021), HEALTH LEVEL 7 INTERNATIONAL, https://confluence.hl7.org/download/attachments/49644116/OML_Lipid%20Panel-GU-ExampleMessage.txt?api=v2.

[9] *See generally* Update on Progress in Electronic Reporting of Laboratory Results to Public Health Agencies — United States, 2014 (2015), CENTER FOR DISEASE CONTROL, https://www.cdc.gov/Mmwr/preview/mmwrhtml/mm6412a5.htm (last visited May 22, 2025). "Electronic laboratory reporting (ELR) generally refers to the secure, automated messaging of laboratory reports, using HL7 or other formats, sent using one or more electronic communication protocols… In North Carolina, use of ELR has decreased the time required for case processing by as much as 5 days (from when a case report is received by public health authorities to when it is submitted to CDC). Additionally, cases initiated via ELR are more accurately reported and require less follow-up than cases initiated through traditional mechanisms, such as paper reporting of laboratory results…"

aggregating data from across multiple disparate medical facilities, the claimed techniques enable the system to detect potential variances that single facility systems may miss (e.g., due to less-tuned baselines, lack of dispense transaction data, medication waste transaction data, or electronic health record data from another facility that may indicate a variance, etc.).

Furthermore, claim 21, when viewed as a whole, leads to additional technical improvements in the field of detecting drug diversion events. That is, by using the data stream to obtain electronic health data, the system may alleviate the need for "a 'witness' to waste a controlled substance," since the "processes and procedures underlying the medication administration auditing system provide confirmation that a medication or other controlled substance was properly disposed of."[10] By relieving a medical facility of the burden of having additional healthcare practitioners witness the disposal of a controlled substance (e.g., a medication), the claimed system assists the facility in reducing the need for human oversight and intervention, increasing the efficiency of the facility by increasing the availability of practitioners previously needed to act of witnesses. Additionally, by eliminating the use of a witness in the disposal process, the system may lead to the increased detection of diversion by two colleagues working together, as witness are no longer needed, preventing individuals from working together in the future (e.g., as a disposing practitioner and as a witness).[11] As yet another impact, this system may "increase the likelihood that users will properly deposit controlled substance waste in designated waste bins rather than dispose of controlled substances in sinks, toilets, or trash," due to practitioners' knowledge of the auditing system and ongoing investigations.

Additionally, Applicant submits that the Examiner is improperly characterizing claim 21 as reciting a mental process. Claims do not recite a mental process when they do not contain limitations that can practically be performed in the human mind, for instance when the human mind is not equipped to perform the claim limitations.[12] The Federal Circuit has routinely held that claims to specific data encryption methods for computer communications do not amount to mental processes.[13] For example, the Federal Circuit noted in *Synopsys, Inc. v. Mentor Graphics*

[10] Specification, ¶ [0034].
[11] *Id.*
[12] MPEP § 2106.04(a)(2)(III)(A).
[13] *Id.*, citing *Synopsys.,* 839 F.3d at 1148, 120 USPQ2d at 1481 (distinguishing the claims in *TQP Development, LLC v. Intuit Inc.,* 2014 WL 651935 (E.D. Tex. 2014)). "Examples of claims that do not recite mental processes because they cannot be practically performed in the human mind include: a claim to a specific data encryption method for computer communication involving a several-step manipulation of data."

Corp., that a specific data encryption method "involve[d] a several-step manipulation of data that, except in its most simplistic form, could not conceivably be performed in the human mind or with pencil and paper," and, as such, was eligible under § 101. Much like a human cannot mentally or manually "generate sequences of pseudo-random key values based on seed values,"[14] a human cannot mentally or manually "obtain at least one of medication dispense transaction data, medication waste transaction data, or electronic health record data, from at least one of a medical device, electronic health record system, or medication dispensing system, over a data stream using a computation messaging format" or detect variances for users "across a plurality of healthcare facilities." That is, claim 21 recites techniques for the use of a computation messaging format in obtaining a series of electronic records (e.g., medication dispense transaction data, medication waste transaction data, or electronic health record data) to detect a series of variances for users across a plurality of healthcare facilities. Claims 41 and 42 recite additional techniques that specify computation messaging format as one designed for the exchange of electronic health care data, such as a messaging format designed according to HL7 standards. As seen from the previously presented example data stream, an HL7 message may contain numerous unique delimiters, fields, and segments, that must be decoded for a receiver to properly interpret a message.[15] For example, the HL7 standard includes almost 200 unique segments that may be included in a message.[16] A human cannot mentally obtain the electronic health records over an data stream, such as a data stream operating according to the HL7 standards, and decipher the messages to obtain medication dispense transaction data, medication waste transaction data, or electronic health record data,

Additionally, according to Step 2B, the Examiner is required to determine whether any element, or combination of elements, in the claim is sufficient to ensure that the claim amounts to "significantly more" than the judicial exception. Even assuming Step 2A of the *Mayo* test were satisfied, to which Applicant does not acquiesce, the claims include additional elements that amount to "significantly more" than a judicial exception itself.

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[14] *TQP Development, LLC v. Intuit Inc.,* 2014 WL 651935 at 1 (E.D. Tex. 2014).
[15] *See generally* HL7 V2 Control, HEALTH LEVEL 7 INTERNATIONAL, https://v2plus.hl7.org/2021Jan/composition/Control.html#Control-6 (last visited June 11, 2025).
[16] *See generally* HL7 V2 18.8 Segments (99.3), HEALTH LEVEL 7 INTERNATIONAL, https://www.hl7.eu/refactored/seg.html (last visited June 11, 2025).

According to the PTO Eligibility Guidance, a claim that is directed to a judicial exception is patent-eligible if the claim includes additional features that ensure that the claim describes a process or product that applies the exception in a meaningful way, such that it is more than a drafting effort designed to monopolize the exception.[17]

The present claims do not "seek to tie up any judicial exception such that others cannot practice it."[18] Unlike the claims at issue in *Bilski*[19] and *Alice*,[20] in which the Supreme Court determined that claims at issue would effectively grant a monopoly over the abstract ideas of risk hedging and intermediate settlement, respectively, the claims of the present Application do not seek a monopoly over the alleged abstract idea of identifying potential drug diversion events.

Instead, the pending claims recite a **specific way** of determining whether a drug diversion event has occurred. For example, claim 21, as amended, expressly requires "detecting a first variance pattern based on a first set of variances detected during a first period of time for one of the plurality of user identifiers" and "a second variance pattern based on a second set of variances detected during a second period of time for the one of the plurality of user identifiers." Claim 21, as amended, is also limited to an auditing system as designed for a "multi-medical center system," such as a system involving multiple clinics, hospitals, outpatient centers, and other similar medical centers and facilities. As such, claim 21 does not seek a monopoly over the alleged abstract idea of determining potential drug diversion events, and in no manner seeks to "wholly pre-empt" all manners in which a computing system may identify such events. As set forth above, claim 21 requires a very specific technique. Indeed, the particular techniques recited in claim 21 does not pre-empt all other possible ways that drug diversion events may be identified, and therefore is patent eligible under Step 2B of the *Mayo* test.

Finally, the processes, alongside other claim features of claim 21, are preformed by the recited "processing circuity." While Applicant does not acquiesce that the claims recite abstract ideas and mental processes under Step 2A, Prong 1, as alleged by the Office Action,[21] Applicant submits that the use "processing circuity" of the amended claims is sufficient to integrate any alleged abstract ideas into a practical application. A judicial exception may be integrated into a

[17] PTO Eligibility Guidance, p. 74624.
[18] *Id.* at 74625.
[19] Bilski v. Kappos, 561 U.S. 593 (2010).
[20] Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 134 S. Ct. 2347 (2014).
[21] *See generally* Office Action, pgs. 7-11.

practical when the judicial exception is applied "with, or by use of, a particular machine," or when the judicial exception is applied in "some other meaningful way… linking the use of the judicial exception to a particular technological environment."[22] Applicant's specification notes that:

> The techniques described in this disclosure, including functions performed by a processor, controller, control unit, or control system, may be implemented within one or more of a general purpose microprocessor, digital signal processor (DSP), application specific integrated circuit (ASIC), field programmable gate array (FPGA), programmable logic devices (PLDs), or other equivalent logic devices. Accordingly, the terms "processor" "processing unit" or "controller," as used herein, may refer to any one or more of the foregoing structures or any other structure suitable for implementation of the techniques described herein.[23]

The claims, as amended, provide one or more hardware components that are incorporated into a practical application, because the claims, as amended, link any alleged judicial exceptions to the field of "automated auditing of medication administration," and apply any alleged judicial exceptions to particular hardware components and machines.

In view of at least the foregoing, independent claims 21 recites patentable subject matter under 35 U.S.C. § 101. Independent claims 31 and 40 recite similar features to those of amended claim 21, and thus, are patentable for the same reasons. Dependent claims 23-25 and 27 incorporate the features of independent claim 21 by virtue of their dependency, and dependent claims 33-35 and 37 incorporate the features of independent claim 31, by virtue of their dependency. Consequently, dependent claims 23-25, 27, 33-35, and 37 are patent eligible for at least the same reasons as independent claims 21 and 31. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Claim Interpretation Under 35 U.S.C. § 112(f)

The Examiner finds that claim 21-40 should be interpreted as a "means-plus-function" claim under 35 U.S.C. § 112, sixth paragraph, while pending claims 21, 23-25, 27, 31, 33-35, 37, and 40 should not. The Examiner notes that while claims 21-40 "include one or more claim limitations that do not use the word 'means,' claims 21-40 are nevertheless interpreted under 35 U.S.C. 112(f). With respect to the "processing circuitry configured to" limitations of claims 21-

[22] *Id.*, pg. 5.
[23] Specification, ¶ [0044].

34 and 36-40, the Examiner asserts the claim limitations "use a generic placeholder that is coupled with functional language without reciting sufficient structure to perform the recited function" and "the generic placeholder [are] not preceded by a structural modifier." Applicant respectfully disagrees, and believes that all of pending claims 21, 23-25, 27, 31, 33-35, 37, and 40 clearly do not satisfy the three-prong analysis set out by MPEP § 2181.

A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following three-prong analysis:

(A) the claim limitations must use the phrase "means for" or "step for;"

(B) the "means for" or "step for" must be modified by functional language; and

(C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.[24]

There can be no debate that the elements of claims 21-40 do not meet the first two prongs of this test, as neither the phrase "means for" nor "step for" are used. The Examiner, however, argues that the third prong is met because "the claims are not modified by sufficient structure, material, or acts for achieving the specified function." Applicant respectfully disagrees. Per MPEP § 2181:

> "[t]o determine whether a word, term, or phrase coupled with a function denotes structure, examiners may check whether: (1) the specification provides a description sufficient to inform one of ordinary skill in the art that the term denotes structure; (2) general and subject matter specific dictionaries provide evidence that the term has achieved recognition as a noun denoting structure; and/or (3) the prior art provides evidence that the term is an art-recognized structure to perform the claimed function."

Applicant's specification clearly describes structure corresponding to the claimed means for identifying potential drug diversion events. Applicant's specification that the claimed methods may be performed by a computing system (e.g., computing system 130 of FIG. 1). The computing system may include "storage media 133" and "one or more processors 132."[25] Applicant's specification notes that "[t]he techniques described in this disclosure, including functions performed by a processor, controller, control unit, or control system, may be implemented within one or more of a general purpose microprocessor, digital signal processor (DSP), application specific integrated circuit (ASIC), field programmable gate array (FPGA),

[24] MPEP § 2181.
[25] Specification, ¶ [0041].

programmable logic devices (PLDs), or other equivalent logic devices."[26] Additionally, as noted in MPEP § 2181.01(A), courts have previously found that the recitation of circuitry was sufficient to overcome being interpreted under § 112(f).[27]

Finally, the "processing circuitry" of the claims, as described by the specification, provides sufficient context for a personal of ordinary skill in the art to understand the structure. According to MPEP § 2181.01(A), "[i]f persons of ordinary skill in the art reading the specification understand the term to have a sufficiently definite meaning as the name for the structure that performs the function, even when the term covers a broad class of structures or identifies the structures by their function… 35 U.S.C. 112(f) will not apply." For at least these reasons, Applicant requests the withdrawal of the Examiner's decision to interpret the claim terms as "means-plus-function" claims under § 112(f).

Claim Rejection Under 35 U.S.C. § 112(a) and 112(b)

The Office Action rejected claims 21-40 under 35 U.S.C. § 112(a) or 35 U.S.C. § 112(pre-AIA), first paragraph, asserting that claims 21-40 are not supported by Applicant's specification. The Office Action further rejected claims 21-40 under 35 U.S.C. § 112(a) or 35 U.S.C. § 112(pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action stated that Applicant's specification does not contain "any support for structure that implements the processing circuitry functionality that demonstrates possession of the claimed invention."[28] Applicant submits that pending claims 21, 23-25, 27, 31, 33-35, 37, and 40 are supported by Applicant's specification, in accordance with 35 U.S.C. § 112(a) or 35 U.S.C. § 112(pre-AIA), first paragraph. Applicant respectfully requests withdrawal of these rejections.

Applicant submits that the specification provides sufficient support for the use of "processing circuity," as included in claims 21-40. That is, computing system 130 is described as possessing the ability to perform each of the techniques of the independent claims (e.g., claims

[26] Specification, ¶ [0138].
[27] *See* MPEP § 2181.01(A), citing Mass. Inst. of Tech., 462 F.3d at 1355-1356. "[T]he court found the recitation of "aesthetic correction circuitry" sufficient to avoid pre-AIA 35 U.S.C. 112, paragraph 6, treatment because the term circuit, combined with a description of the function of the circuit, connoted sufficient structure to one of ordinary skill in the art.
[28] Office Action, pg. 6.

21, 31, and 40).[29] Computing system 130 is further described, in ¶ [0041], as including "one or more processors 132." The specification notes that "[t]he techniques described in this disclosure, including functions performed by a processor, controller, control unit, or control system, may be implemented within one or more of a general purpose microprocessor, digital signal processor (DSP), application specific integrated circuit (ASIC), field programmable gate array (FPGA), programmable logic devices (PLDs), or other equivalent logic devices."[30] The specification further notes that the term 'processor' "may refer to any one or more of the [previous] structures or any other structure suitable for implementation of the techniques described herein."[31] Accordingly, the specification provides sufficient support for the use of "processing circuity" in implementing the techniques of the claims as a logic device for processing and controlling data flow. To the extent that the "means" may correspond to a general purpose processor such that an algorithm must be shown or demonstrated, Applicant attests that the flowcharts depicted by FIGS. 2, 3, 21, 22, 23, 24, and 25, and the associated prose of paragraphs [0047]-[0051], [0052]-[0066], [0083]-[0097], [0098]-[0102], [0103]-[0106], [0107]-[0110], and [0111]-[0117], respectively, describe such algorithms As such, Applicant requests the withdrawal of the § 112(a) and § 112(b) rejections.

Claim Rejection Under 35 U.S.C. § 103

The Office Action rejected claims 21-29 as allegedly being unpatentable over Bochenko et al., U.S. Patent No. 8,606,596 B1 (hereinafter, "Bochenko") in view of Miller et al., U.S. Publication No. 2011/0161108 A1 (hereinafter, "Miller").

Applicant respectfully traverses the rejections to the extent the rejections may be considered applicable to the claims as amended. The applied references, alone or in any combination, fail to disclose or suggest the features defined by Applicant's claims, and there would have been no apparent reason that would have caused one of ordinary skill in the art to modify the applied references to arrive at the claimed features.

Applicant submits that Bochenko, in view of Miller, would not have led a person skilled in the art to arrive at "perform[ing], for each user of the plurality of users, longitudinal analysis

[29] *See generally* Specification, ¶ ¶ [0041]-[0046].
[30] Specification, ¶ [0138].
[31] *Id.*

of one or more variances of the plurality of variances associated with the user; identify[ing], based on the longitudinal analysis, one or more variances patterns indicative of potential drug diversion events, wherein to identify the one or more variance patterns, the processing circuitry is configured to: detect a first variance pattern based on a first set of variances detected during a first period of time for one of the plurality of users; detect a second variance pattern based on a second set of variances detected during a second period of time for the one of the plurality of users, wherein the second period of time is subsequent to the first period of time; determine that the second variance pattern is different than the first variance pattern; and identify a potential drug diversion event corresponding to the one of the plurality of users based on the determining that the second variance pattern is different than the first variance pattern,"[32] as recited by amended independent claim 21.

For example, Miller discloses that "[t]o facilitate and simplify the identification of diversion activity, in some embodiments, a diversion score is determined for each user for each category of diversion activity considered. The diversion score reflects a relative severity of diversion activity with respect to other users. Thus, a high diversion score may indicate to an auditor that the particular user's behavior deviates greatly from the behavior of the user's peers, or that the user's behavior deviates from that of her peers in several categories of diversion activity."[33] In other words, Miller discloses techniques for determining a diversion score for a user by comparing the activity of the user with the activity of other users. Miller does not disclose identifying drug diversion corresponding to a user based on comparing a first set of variances with a second set of variances, where the first set of variances and the second set of variances both correspond to the same user but correspond to different periods of time. Furthermore, Miller discloses that "[i]n the case of the category Sole User Dispensing to Patients, the diversion score may be determined by first multiplying the user's raw score…by a weight value of 1/10. The weighted raw score is then added to a value indicative of the dispersion activity of the user's peers to obtain a diversion score."[34] This further confirms that Miller discloses determining dispersion activity by comparing a user's activity to the activity of other users, and Miller does not disclose determining drug diversion by comparing a first set of

[32] (emphasis added).
[33] Miller, paragraph [0048] (emphasis added).
[34] Miller, paragraph [0050]. (emphasis added).

variances and a second set of variances both corresponding to the same user. Bochenko fails to overcome the deficiencies of Miller with respect to claim 21.

For at least the reasons discussed above, independent claim 21 is patentable over Bochenko, in view of Miller. Independent claims 31 and 40, as amended, recite similar features to those of amended claim 21, and thus, are patentable over the cited references for similar reasons. Dependent claims 23-25 and 27 incorporate the features of independent claim 21 by virtue of their dependency, and dependent claims 33-35 and 37 incorporate the features of independent claim 31, by virtue of their dependency. The dependent claims are thus patentable over the cited references for at least the same reasons as the independent claim from which they depend. Accordingly, the cited references fail to establish a *prima facie* case for the non-patentability of pending claims 21, 23-25, 27, 31, 33-35, 37, and 40 under 35 U.S.C. § 103. Applicant, therefore, respectfully requests reconsideration and withdrawal of this rejection.

New Claims

Applicant has added claims 41-46 to the pending application. No new matter has been added. Support for the subject matter of claims 41-46 can be found at least at paragraph [0057], [0059], [0061], and [0063]. The cited references, alone or in combination, fail to disclose or suggest all features of claims 41-46 and would have provided no apparent reason for modification to arrive at the claimed features.

CONCLUSION

All claims in this application are in condition for allowance. Applicant does not necessarily acquiesce as to any assertion made in the Office Action, and Applicant's silence with respect to any such assertion in the Office Action should not be interpreted as Applicant's acquiescence thereto. Further, Applicant does not concede that the art cited in the record is relevant art. Applicant reserves the right to comment further with respect to the applied references and any pending claim in a future Amendment, Response, on appeal, in any other proceeding, or otherwise. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed representative to discuss this application.

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