UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CERNER CORPORATION, CERNER HEALTH SERVICES, INC., ALLSCRIPTS HEALTHCARE SOLUTIONS, INC., EPIC SYSTEMS CORPORATION, and EPIC HOSTING, LLC

Petitioners

V.

UNILOC LUXEMBOURG S.A.

Patent Owner

Patent No. 5,715,451

Filing Date: July 20, 1995

Issue Date: February 3, 1998

Title: METHOD AND SYSTEM FOR CONSTRUCTING FORMULAE FOR PROCESSING MEDICAL DATA

Inter Partes Review No.: To be Assigned

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1 – 2 AND 6 – 8 OF U.S. PATENT NO. 5,715,451 UNDER 35 U.S.C. §§ 311-319 AND C.F.R. § 42.100 *ET SEQ*.

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EXHIBITS

EXHIBIT NUMBER	DOCUMENT
1001	U.S. Patent No. 5,715,451
1002	Certificate of Service
1003	Power of Attorney
1004	Declaration of Dr. Bryan Bergeron
1005	Excerpt of '451 File History, Information Disclosure Statement (Feb. 7, 1996) (UNISMOK0000649-651)
1006	Excerpt of '451 File History, Office Action (Feb. 25, 1997) (UNISMOK0000662-672)
1007	Excerpt of '451 File History, Amendment (June 9, 1997) (UNISMOK0000700-708)
1008	Excerpt of '451 File History, Interview Summary (July 17, 1997) (UNISMOK0000711-712)
1009	Excerpt of '451 File History, Notice of Allowability (July 14, 1997) (UNISMOK0000713-722)
1010	U.S. Patent No. 5,447,164 ("Shaya")
1011	J. Barclay Adams, "Three Surveillance and Query Languages for Medical Care," <u>Clinical Computing</u> , vol. 3, no. 1, pp. 11- 19 (1986) ("Adams")
1012	Ute Gappa et al., <u>Graphical Knowledge Acquisition for</u> <u>Medical Diagnostic Expert Systems</u> (1993) ("Gappa")
1013	Mark A. Musen, <u>Automated Generation of Model-Based</u> <u>Knowledge-Acquisition Tools</u> , Pitman Publishing (1989) ("Musen")

Real parties-in-interest Cerner Corporation and Cerner Health Services, Inc. (together, "Cerner"); Allscripts Healthcare Solutions, Inc. ("Allscripts"); and Epic Systems Corporation and Epic Hosting, LLC, (together, "Epic")(collectively, "Petitioners") hereby petition for *inter partes* review under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et. seq.* of claims 1, 2, 6, 7, and 8 of U.S. Patent No. 5,715,451 ("the '451 Patent") (EX 1001) and assert there is a reasonable likelihood of prevailing with respect to the claims challenged in this Petition.

I MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(A)(1)

Real Parties-In-Interest under 37 C.F.R. § 42.8(b)(1). Cerner, Allscripts, and Epic are the real parties-in-interest for this Petition.

Related Matters under 37 C.F.R. § 42.8(b)(2). Uniloc Luxembourg S.A., the alleged owner by assignment of the '451 Patent, and Uniloc USA, Inc, the alleged exclusive licensee of the '451 Patent, have asserted the '451 Patent against Petitioners in multiple suits filed in the U.S. District Court for the Eastern District of Texas, on or around July 18, 2014. These various cases have been consolidated into a single case, styled Uniloc USA, Inc. et al., v. E-MDS, Inc. et al., Civil Action No. 6:14-cv-625 (Consolidated) (E.D. TEX). The cases that have been consolidated include Case Nos. 6:14-cv-626-RWS through 6:14-cv-633-RWS, sequentially, and Case No. 6:14-cv-00692-RWS.

The application that matured into the '451 Patent was filed concurrently with an application that matured into U.S. Patent No. 5,682,526 ("the '526 Patent"), which allegedly "contains subject matter related to" the '451 Patent. *See* '451 Patent at 1:5-11; 2:53-60. The '526 Patent was asserted in the cases listed above, and *inter partes* review of that patent is requested concurrently in a separate petition.

Designation of Lead and Back-Up Counsel under 37 C.F.R. § 42.8 (b)(3).

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Petitioners provide the following designation of counsel:

Grounds for Standing under 37 C.F.R. § 42.104(a). Petitioners certify that the '451 Patent is eligible for *inter partes* review and Petitioners are not barred or estopped from requesting this review challenging the '451 Patent claims on the identified grounds. Petitioners were served with a Complaint asserting the '451 Patent on or after July 25, 2014, and this petition is being filed on July 22, 2015. **Service Information under 37 C.F.R. § 42.8(b)(4).** As identified in the Certificate of Service (EX 1002), a copy of this Petition, in its entirety, is being served to the address of each attorney or agent of record.

II PAYMENT OF FEES – 37 C.F.R. § 42.103

This Petition for *inter partes* review requests review of claims 1, 2, 6, 7, and 8 of the '451 Patent and is accompanied by the required Petition fee. Thus, this Petition meets the fee requirements under 35 U.S.C. § 312(a)(1). Petitioners hereby authorize charging Deposit Account 19-2112 in the amount of the required Petition fee and further authorize any additional charges that may be necessary (or any credit of overpayment) to that account.

III IDENTIFICATION OF CHALLENGE UNDER 37 C.F.R. § 42.104(B) AND RELIEF REQUESTED

Petitioners request *inter partes* review of claims 1, 2, 6, 7, and 8 ("challenged claims") of the '451 Patent on the grounds set forth below and request that each of the claims be found unpatentable and cancelled. Petitioners' detailed statement of the reasons for relief requested is set forth in section VI, below.

Ground	Index of References	'451 Patent Claims
1	Shaya in view of Adams, as rendering the asserted	1, 2, 6, 7, 8
	claims obvious under 35 U.S.C. § 103(a)	
2	Shaya in view of Musen as rendering the asserted	1, 2, 7, 8
	claims obvious under 35 U.S.C. § 103(a)	
3	Adams in view of Gappa as rendering the asserted	1, 2, 6, 7, 8
	claims obvious under 35 U.S.C. § 103(a)	

Each prior art reference relied upon qualifies as prior art. Specifically, Shaya is a patent that has a filing date of November 8, 1993, and a publication date of September 5, 1995, which qualifies Shaya as prior art under at least 35 U.S.C. § 102(e)(2). Adams is an article that was published in January/February of 1986, and therefore qualifies as prior art under at least 35 U.S.C. § 102(b). Musen is a book that was published on January 15, 1989, and therefore qualifies as prior art under at least 35 U.S.C. § 102(b). Gappa is an article that was published in June 1993, and therefore qualifies as prior art under at least 35 U.S.C. § 102(b).

IV SUMMARY OF THE '451 PATENT

The '451 Patent was filed on July 20, 1995, and issued on February 3, 1998. It does not claim priority to any prior application or patent. The sole inventor of the '451 Patent is Tom Marlin, and the original assignee is SpaceLabs Medical, Inc.

The '451 Patent describes a method and system for a user to construct formulas for processing medical data, based on the display of certain information to a user and the receipt of various inputs from the user. EX 1001 at ABSTRACT; 1:41-43; 2:30-35. The '451 Patent discloses users constructing formulas by inputting (or selecting) the following items via a computer interface: (1) at least one variable with a plurality of values that are "time indexed," *i.e.*, a variable where each value is stored in conjunction with the time at which the value was recorded; (2) a time range of interest for the variable; (3) a pre-determined "aggregation function" or

"selection function" to apply to the values of the variable that occur within the specified time frame; and (4) a text string or conclusion that the formula will output based on the result of the aggregation or selection function. *Id.* at Abstract, 3:10-30 (time indexed variable); 3:43-4:13 (time range); 4:52-55; 4:65-5:5; 6:41-7:13 (functions); 7:28-43; 7:55-22 (text string); *see* EX 1004 ¶ 29.

The systems and methods of the '451 Patent are implemented on a "general purpose computer system" that includes a video monitor for displaying information. EX 1001 at 1:67-67; 2:61-3:9. An exemplary "visual interface" for constructing formulas is shown in Figure 4 of the patent, below.



This embodiment includes areas for entering the name and other information about a formula (410); listing variables on which a formula can be based (471, 472); entering a time frame for a selected variable (471); entering pre-defined aggregation functions (430, 438) or selection functions (430, 437); and displaying—via a window—the formula being constructed (420). *Id.* at 4:14-5:40; 7:28-33; Fig. 4. Formulas are constructed by inputting information via clicking buttons (*e.g.*, 430), selecting items from lists (*e.g.*, 470), typing on a keyboard, or by a combination thereof. *See, e.g., id.* at 4:45-49; Fig. 4; EX 1004 at ¶¶ 30-31.

Formulas are based on one or more medical variables, such as "temperature, heart rate, and cough assessment," which are used by health care personnel to evaluate and treat patients. *Id.* at 3:10-16. Each of these variables is "time-indexed," where the variable's value is its "measure or state" at a particular time. *Id.* at 3:10-30. Each instance of a variable is referred to as an "event." *Id.* at 3:10-30. The patent explains:

... if the patient's heart rate is measured as 35 beats per minutes at 10:40 a.m. and as 42 beats per minutes at 11:15 a.m., two events will be stored for the Heart Rate parameter: a first event having a value of 35 and a time of 10:40 a.m., and a second event having a value of 42 and a time of 11:15 am.

Id. at 3:10-30; *see also id.* Fig. 2; *see* EX 1004 ¶ 32.

The '451 Patent utilizes the construction of "Highest Recent Heart Rate" —a formula for the maximum heart rate of a patient—as an example of its claimed invention. EX 1001 at Figs. 2-10; 3:51-4:13; 5:50-51. This formula looks at a patient's heart rate over the last two hours, and returns a text string incorporating the time at which the maximum value occurred, namely,

"Highest recent heart rate in preceding two hours at <event time>,"

where "<event time>" is the time at which the heart rate variable had the highest value, over the last two hours. *Id.* at 7:33-43; EX 1004 ¶ 34.

To construct this formula, a user selects the variable named "Heart Rate" (EX 1001 at 471 of Fig. 7; 6:13-41), and indicates the interval of time over which this variable should be analyzed—in this case, two hours backwards from the time the formula is executed. *Id.* at 471 of Fig. 7; 3:51-4:13; 6:18-37. This results in the following text being entered in the formula window: **'vit! Heart Rate [-2 hours]**', as shown below. *Id.* at Fig. 8 (420, 422).



The user clicks on the "MAX" button to input a "selection function" that will find the maximum heart rate over the specified time interval (*id.* at 4:67-5:1-3; 6:41-65; Figs. 9 (437), clicks on the "Event time" button to input a function that returns the time at which a particular value (in this case, the maximum heart rate value) occurred (*id.* at Fig. 10 (439); 7:13-29), and "use[s] the keyboard to type an

introductory string" to combine with the result of the "Event time" function. *Id.* at Fig. 10, 7:33-43. This results in a formula that produces a text string ("Highest recent heart rate in preceding two hours at") concatenated ("+") with the time the value of the heart rate variable determined by the selection function to be the maximum value over the previous two hours occurred (event_time (max ('vit! Heart Rate [-2 hours]')). *Id.* at 7:33-43; Fig. 10 (420, 422); EX 1004 ¶¶ 34-36.

The '451 Patent provides a second example, wherein a user inputs a formula by selecting from lists, clicking on buttons, and entering text via the keyboard that determines if the last value of the heart rate variable over the last hour was less than 45 and if the last value for the cardiac rhythm variable over the last hour was "regular":

(last(Heart Rate[-1 hour]<45))&&(last(Cardiac Rhythm[-1 hour]=="regular") EX 1001 at 7:44-8:25; Fig. 11 (formula simplified for ease of review). The user then inputs two different text strings that "result" from the formula, based on the value generated by the statement above. *Id.* If the result of the above statement is "true", then a text string combined (red underlining, below) with the value of the last heart rate results; otherwise, a different text string results (blue underlining):

LA

422

([last/vit! Heart Rate [-1 hour]] < 45) && (last (vit!Cardiac Rhythm [-1 hour]) = = "regular")) ? ("Patient enhibits apparent Sinus Bradycardia, based on recent heart rate measurement of "+ (last(vit!Heart Rate [-1 hour]) + "coupled with regular rhythm. Cousider administration of a vagolytic agent such as Atropine.") : "Patient heart rate and cardiac rhythm do not indicate Sinus Bradycardia."

Id. at 8:1-25; Fig. 11 (excerpted and annotated); EX 1004 ¶ 37.

A '451 Patent Claims

The '451 Patent includes three challenged independent claims—claims 1, 6, and 7; and two challenged dependent claims—claims 2 and 8. As explained further *supra*, all of the challenged claims are directed towards methods or systems which allow a user to input or select information to include in a formula and—in effect—construct the formula with the aid of a computer system.

The requirements of these claims are similar, but not identical. Claim 1 is directed towards "a method . . . for constructing . . . a formula for producing a textual . . . string" in response to inputs from a user, where the inputs received by a computer system specify "a period of time during which the . . . time-indexed . . . variable is to be analyzed," a function to "aggregate the identified values into a single value," and "a manner of manipulating [the] single value to produce a textual string conveying patient information." EX 1001 at 9:31-67. Claim 2 further requires "displaying . . . the names" of the available time-indexed variables and "receiving . . . input" indicating a user's selection of a variable.

Claim 6 is similar to Claim 1, but—instead of requiring the receipt of an aggregation function to generate a single value—it requires the receipt of "a selection function" for selecting a single instance of a variable as well as a separate input "identifying a data component" of each instance of the variable, in order to "extract" a single value. Further, the claim requires that the formula is for

"deriving a medical conclusion," rather than "producing a textual ... string." See EX 1004 \P 40.

Claim 7 has limitations specifically requiring "a formula construction subsystem," "a display device," "an input device," and a memory, but otherwise differs very little in substance from claim 1. Claim 8 is the system claim version of claim 2, and is similar in scope, aside from the inclusion of a "display device." *Id*. \P 41

B Prosecution History Summary

The prosecution history of the challenged claims of the '451 Patent is particularly relevant to this Petition. The Examiner initially rejected claims 1-2 and 6-8 as being rendered obvious by U.S. Pat. No. 5,072,383 (Brimm) in view of U.S. Pat. No. 5,265,010 (Evans-Paganeli). EX 1006 at UNISMOK0000673. The Examiner found that Brimm disclosed all of the limitation of claim 1, except for the step requiring the input of a manner of manipulating the single value generated by the aggregation function "to produce a textual string." *Id.* at UNISMOK0000668-669. The Examiner found that Evans-Paganeli disclosed this limitation, and that it would have been obvious to combine these two references, as they "are both directed to a method for performing patient documentation and are both from the same field of endeavor." *Id.* at UNISMOK0000669. The Examiner made the same findings with respect to independent claims 6 and 7. *Id.* at

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UNISMOK0000670. With respect to dependent claims 2 and 8, the Examiner further noted that Brimm disclosed the "displaying" and "receiving" steps recited in these claims. *Id.* at UNISMOK0000669-670; EX 1004 ¶ 43.

In response, the Applicant proposed adding two primary amendments to independent claims 1, 6, and 7, to "distinguish the pending claims from the cited references," namely: (1) a "window-based user interface" requirement, and (2) a phrase stating that the formula "may be used" to generate and display "a textual string conveying patient information" [claim 1], or "a medical conclusion" [claim 6]. EX 1007 at UNISMOK0000701-703. Claim 1, below, is exemplary:



The Applicant argued that these amendments distinguished the invention of the '451 Patent over the cited prior art, and the Examiner agreed. EX 1008 at UNISMOK0000712; EX 1009 at UNISMOK0000714; EX 1004 ¶¶ 44-45. Thus,

the allegedly novel aspect of the claims is the ability for a user to construct a formula via a "window based user interface" that can produce "a textual string conveying patient information" or generate a medical "conclusion." *Id.*

As discussed below, the prior art cited herein clearly discloses these supposed points of novelty, as well as the other claimed limitations. Accordingly, claims 1, 2, 6, 7, and 8 should be found unpatentable as obvious. *Id.* \P 46.

V CLAIM TERMS

A claim subject to *inter partes* review ("IPR") is given its "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b); *In re Zletz*, 893 F.2d 319, 321-322 (Fed. Cir. 1989); *In re Cuozzo Speed Techs., LLC*, No. 2014-1301, 2015 WL 4097949, *5-*8 (Fed. Cir. July 8, 2015). This means that the words of the claim are to be given their plain meaning, as understood by a person of ordinary skill in the art ("POSITA"), consistent with the disclosures in the specification. *Id*.

1. "Window-based user interface." Claims 1, 2, 6, and 7 require the use of a "window-based user interface." The '451 Patent only refers to a "window" when describing the "formula window 422" in "formula area 420" of Figures 4, 8-11:



((last('vit! Heart Rate [-1 hour]') < 45) && (last ('vit!Cardiac Rhythm [-1 hour]') = = "regular")) ? ("Patient exhibits apparent Sinus Bradycardia, based on recent heart rate measurement of " + (last('vit!Heart Rate [-1 hour]') + "coupled with regular rhythm. Consider administration of a vagolytic agent such as Atropine.") : "Patient heart rate and cardiac rhythm do not indicate Sinus Bradycardia."



EX 1001 at Fig. 11 (excerpt); *see also id.* at Fig. 12; 8:33-66. According to the '451 Patent:

The formula area 420 contains a formula window 422 in which the formula is constructed and displayed ... The user may insert additional formula contents into the formula ... by typing them using the keyboard 107, or by using the buttons in the manipulator area 430 and the input parameter area 470 ...

Id. at 4:37-49, Fig. 4; *see also id.* at 5:40-50; 6:28-47; 7:13-43; 7:55-8:13; EX 1004 ¶ 48.

Based on the disclosure of the '451 Patent, a POSITA would understand the term "window-based user interface" to refer to any interface that permits a user to interact with the system via a keyboard or pointing device where one or more areas of the screen is designated by a rectangular frame (*i.e.*, a "window"). *See* EX 1004 ¶¶ 48-52. Thus the broadest reasonable interpretation of the term "window-based user interface" would be a least as broad as "an interface that allows a user to interface with the system via one or more areas of a screen, where an area is designated by a rectangular frame, and allows input by at least typing on a keyboard, the use of a pointing device, or both." *Id.* at ¶ 53.

2. "A medical conclusion." Claim 6 refers to the construction of a formula that may be used to derive and display "a medical conclusion." A POSITA would understand that "a medical conclusion" could encompass not only text strings, but

also the use of symbols or numbers as a means of conveying higher-level medical information. *See id.* ¶ 54. Notably, the '451 Patent does not define the term "medical conclusion" at all, and uses the term "conclusion" once, where it equates "inferential conclusions" to "higher-level patient information that provides a more useful basis for health care decisions" than raw patient data alone. EX 1001 at 1:28-37; 2:46-50. Thus a "conclusion" that a patient suffered a heart attack could, for example, may be indicated symbolically by a check mark on a screen, or a "plus" symbol on a chart, or a "tick-mark" on a time line. *See* EX 1004 ¶ 54. Accordingly, based on the disclosure of the specification and the knowledge of a POSITA, the broadest reasonable interpretation of the term "a medical conclusion" would be a least as broad as "higher-level medical information, such as a judgment or decision, based on patient data." *Id.*

3. "A manner of manipulating a single value to produce a textual string"/ "manipulating the single value ... to produce a textual string." Claims 1 and 7 require the "manipulation" of a "single value" to produce a text string, where the "single value" being referred to is generated by an aggregation function. The specification does not define the phrase "manipulating a single value," and it does not have a specialized meaning in computer science or medical informatics. A POSITA would, therefore, understand the phrase "manipulating a ... value" the same way any person would understand a phrase involving the manipulation of any object—that is, "handling" or "using" the object (*e.g.*, manipulating scissors, a doctor manipulating tissue) or value. *See id.* ¶¶ 55-56. Further, this plain and ordinary meaning is consistent with the specification's disclosure of manipulating a single value to produce a textual output. *See, e.g., id.* at Fig. 10 (using the "+" button to combine a text string with result of the "event-time" function); Fig. 11 (text string output based on the result of an arithmetic/ logic statement); *see also* EX 1004 ¶ 55. Accordingly, the broadest reasonable interpretation of the term "manipulating a [the] single value to produce a textual string" would be a least as broad as "handling or using [the] single value to produce a textual string." *Id.* ¶ 56.

VI. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '451 PATENT IS UNPATENTABLE

As detailed below, all of the limitations of claims 1, 2, 6, 7, and 8 of the '451 Patent were well-known in the prior art. None of the references relied upon in this Petition were considered by the Examiner during prosecution of the '451 Patent; accordingly, none of the 103(a) obviousness combinations presented as grounds of rejection were considered during prosecution of the '451 Patent.

A Ground 1: Claims 1, 2, 6, 7, and 8 are rendered obvious under 35 U.S.C. § 103(a) by Shaya in view of Adams

Shaya is a patent that was filed over a year and a half prior to the date the application for the '451 Patent was filed. It describes a system and method that allows a user to construct formulas ("event type definitions") that identify when

certain medical circumstances ("events") have occurred over a period of time, and then display each occurrence of an event on a timeline via a "tick-mark," along with information pertinent to each occurrence. EX 1010 at ABSTRACT; 1:5-15; 2:5-56; 3:24-58; 10:36-46; EX 1004 ¶ 57. In Shaya, a formula consists of "a combination of relations and conditions of stored patient information" (EX 1010 at 4:20-35; 10:35-52), which can include aggregation and/or selection functions. *Id.* at Figs. 8, 9; 11:34-36; 12:62-13:5; 14:16-59; Appendix A; EX 1004 ¶ 94. Shaya discloses a "graphical user interface to facilitate the entry" of such formulas. EX 1010 at 10:43-46; EX 1004 ¶ 59. Although Shaya discloses that information displayed with regards to a particular occurrence of an events can include text Shaya does not explicitly disclose that this text is included in the formula ("event type definition") itself (claims 1, 7). EX 1004 ¶ 94. Further, although Shaya discloses variables with multiple data components (data and time), Shaya does not explicitly disclose instructions for selecting a particular data component of a variable (claim 6). *Id.*

Adams, an article published almost a decade prior the '451 Patent's filing, describes three systems in existence (and in use) at that time that were designed to allow users to construct queries "to help analyze data in a patient's record," including "examin[ing] a patient's data and decid[ing] whether a specified set of conditions is met by that data, and if so, ... produc[ing] a specified output." EX

1011 at 11, cols. 1-3; 12 col. 1; 13 col. 2; 14, col. 1; 18, cols. 2-3; EX 1004 ¶ 64. Thus, the "queries" in Adams correspond to the "formulas" of the '451 Patent and the "event type definitions" in Shaya. EX 1004 ¶ 95. These queries, like the corresponding features in the '451 Patent and Shaya, are based on variables (id. at 15, col. 1), and may contain temporal relationships (id. at 14, col. 3) and aggregation and/or selection functions. EX 1010 at 14, col. 3-15, col 1; 15, col. 3; 16, cols. 3-17, col. 1; EX 1004 ¶ 95. Adams further describes allowing a user to input textual strings into queries that can later be displayed based on the result of statements within the queries—for example, a textual output could be displayed based on the value produced by an aggregation function. See, e.g., EX 1011 at 15, col. 1-17, col. 2; Figs. 2-4; EX 1004 ¶ 95. Further, Adams discloses the use of multiple data components for each variable, and the use of instructions that identify a particular data component or element of that variable. EX 1011 at 15, col. 1; Figs. 2-4; EX 1004 ¶ 95.

As discussed below, Shaya, in view of Adams, discloses all of the limitations of the challenged claims. Further, it would have been obvious to a POSITA to combine the text string input/output feature of Adams with the disclosure of Shaya, so that the system and method of Shaya allowed for the inclusion of a text string within a formula ("event type definition"), and the generation of said text string as a result of the formula. EX 1004 ¶ 96. This combination would have improved the

system and method of Shaya by allowing for the provision of additional useful information to users of the Shaya system regarding certain "events." *Id.* Further, it would have been obvious to incorporate instructions for identifying individual data components into Shaya, so that the system and method disclosed therein allowed user to specifically and clearly indicate which component of a variable a formula referenced. *Id.* ¶ 97. This would have made the system easier to use, as it would have provided greater clarity to the user. *Id.*

1. Claim 1: "A method ... for constructing, in response to input from a user using a window-based user interface, a formula for producing a textual patient information string from a selected time-indexed medical data variable having a value for each of a plurality of times"

Shaya describes a system and method that allows a user to **construct formulas** ("event types" or "event type definitions") that identify when certain medical circumstances ("events") have occurred over a period of time, and then display each occurrence of an event along with information pertinent to that event. EX 1010 at ABSTRACT; 1:5-15; 3:24-58. These formulas are based on **variables** ("parameters"), whose **values** ("data") are either stored in a real-time "temporal database" using "implicit time stamping" or "explicit time stamps" for data, and are therefore **time-indexed**. *Id.* at 5:10-26; EX 1004 ¶ 99.

An "Event Definition Language Application ('EDL') provides the user with the ability to define events as a combination of relations and conditions of stored patient information." EX 1010 at 4:20-35; 10:35-52; EX 1004 ¶ 101. A window-

based graphical **user interface** facilitates the input of such definition by a user, and allows for the creation of **formulas** ("event type definitions") based on the receipt of **user input**. EX 1010 at Figs. 8-9; 10:43-46; 10:53-11:43; EX 1004 ¶¶ 100-101. It displays "a list of all condition parameters that can be used in an event definition," and allows user to **select a variable** ("parameter") on which to base a **formula** ("event type definition"). EX 1010 at 10:53-11:12; 114 of Fig. 8; 201 of Fig. 9 (listing all available parameters on which an event can be based); 214 of Fig. 9 (displaying a "list of existing variables"). Each formula results in the **production** and display **of patient information** (an "event") indicated by a "tickmark" on a time scale, and each "event" or "tick-mark" may have additional **text** associated with it. *Id.* at 33 and 52 of Fig. 4, 6:33-62; 8:8-21; EX 1004 ¶ 99.

Shaya does not explicitly describe formulas that produce "a textual information string" from a selected variable. EX 1004 ¶ 102. However, Adams discloses three systems for constructing **formulas** ("queries") that **produce textual patient information strings** that for, example, summarize findings regarding a patient, draw a conclusion, or alerts a user to the existence of a condition, based on a **variable**. EX 1011 at 15, col. 1-17, col. 2; Figs. 2-4; EX 1004 ¶ 102. As discussed above, a POSITA would have been motivated to combine this feature of Adams with Shaya to increase the functionality of Shaya's systems and methods—*e.g.*, instead of just a "tick-mark" indicating the occurrence of an event for a particular

patient, Shaya could also output a "text-string" conveying information about that event. *See supra* at § VI.A; EX 1004 ¶ 102.

(a) Claim 1[a]: "receiving input via the window-based user interface specifying a period of time during which the...variable is to be analyzed"

In Shaya, **formulas** ("events types" or "event type definitions") are constructed in response to **user input** via a **window-based** "graphical **user interface**." EX 1010 at 10:43-46; Figs 8-9. Figure 9 illustrates one embodiment of such a graphical user interface that permits the user to specify a **period of time** over which the values of a **variable** ("parameter") should be analyzed using a "powerful set of operators" to specify "timing relationships," such as AFTER, BEFORE, DURING, and SINCE in conjunction with a parameter name in a single event definition. *Id.* at 11:12-43; 13:25-67; Appendix A; 215 of Fig. 9; EX 1004 ¶ 103. An example of such an event type definition could be "HR \leq 60 <u>AFTER Set. 29</u>, <u>1990 10:00 PM</u>," which would indicate that the system should only consider the values of the variable ("parameter") "HR" between 10:00 PM on September 29, 1990 and the present. EX 1010 at 13:25-67; EX 1004 ¶ 103.

(b) Claim 1[b, c]: "displaying via the …interface names of a plurality of functions capable of aggregating a plurality of values into a single value;" "receiving input via the…interface indicating that the user selected the name of a selected function from the displayed …names"

Area 215 of Figure 9 of Shaya displays an exemplary set of operators that can be utilized to define a **formula** ("event type definition"). EX 1010 at 11:20-39.

These operators include **functions capable of aggregating a plurality of values** into a single value, such as COUNT, RUN, RATE, and EXIST. *Id.* at 11:29-31; 12:61-13:5; 14:1-5 (describing "language constructs" that operate on "a set of values"); 14:38-59; Appendix A; EX 1004 ¶ 104. An example of an event definition including an aggregation function could be <u>COUNT</u> (HR \leq 60 AFTER Set. 29, 1990 10:00 PM), which would indicate that system should count the number of instances between 10:00 PM on September 29, 1990 and the present where the value of the variable ("parameter") HR was less than or equal to 60. EX 1010 at 12:51-13:5; 13:61-67; EX 1004 ¶ 104. Shaya also discloses a windows-based user interface that displays the names of these functions and receives a user's selection of a function via the click of a button. EX 1010 at Figs. 8, 9; 10:43-46; EX 1004 ¶ 104.

(c) Claim 1[d]:"receiving input ...specifying a manner of manipulating a...value to produce a textual string conveying information"

As discussed above, Shaya discloses a **window-based** graphical **user interface** that facilitates user input. *Supra* at §§ VI.A-A.1(a). Shaya further discloses **a manner of manipulating a single value** to produce a result that **conveys patient information**. Namely, Shaya discloses that the output of the **formula** ("event type definition")—a single value—results in the display of a "tick-mark" on a time line, indicating that a certain "event" has occurred. EX 1010 at 4:35-42; 5:30-40; 6:8-8:36; Fig. 4 at 33; EX 1004 ¶ 105. Shaya also discloses that information, which

may include **text**, can be displayed with each event occurrence. EX 1010 at 6:61-62; 7:33-50; 8:8-21; Fig. 4 at 52 (showing a line for displaying a strip comment); EX 1004 ¶ 105.

Shaya does not explicitly disclose the receipt of inputs defining a manner of manipulating the single value to produce a "text string." Adams, however, does disclose the receipt of such input. EX 1004 ¶¶ 105-106. Adams discloses systems that-like Shaya-allow users to build queries that determine whether certain conditions have been met based on user input. Id. Further, the systems in Adams all allow for the input specifying a text string conveying patient information, by, for example, summarizes findings regarding a patient, drawing a conclusion, or alerting a user to the existence of a condition. See, e.g. EX 1011 at 15, col. 1-17, col. 2; Figs. 2-4; EX 1004 ¶ 106. Critically, each system allows for input specifying a manner of manipulating a single value to produce such a text string. Id. For example, Figures 2-4 in Adams shows a similar query implemented in each language. Generally, each query determines whether the value of the last measurement of a variable named potassium is lower than a certain value and—if the result of the inquiry is "true"—generates the following message, or some similar variant thereof:

SERUM POTASSIUM OF <value> **MEQ/L IS BELOW CRITICAL LEVEL**, where <value> represents the value of the last measurement of the potassium variable. EX 1011 at Figs. 2-4; EX 1004 ¶ 106. Thus Figures 2-4 describe user input specifying how values should be manipulated to produce a text string. *See* EX 1011 at 15, col. 3 (referring to the "data manipulation" and a query's ability to "summarize data"); EX 1004 ¶ 106.

As discussed above, a POSITA would have been motivated to combine this feature of Adams with the disclosure of Shaya, so that instead of just a "tick-mark" indicating the occurrence of an event for a particular patient, Shaya could also output a "text-string" conveying information about that event. *See supra* at §§ VI.A.1-1(a); EX 1004 ¶ 107.

(d) Claim 1[e]: "based upon the receiving steps, creating a formula that specifies: identifying values of the selected ... variable having times within the specified period of time; applying the selected function to the identified values of the ... variable to aggregate the ... values into a single value, and manipulating the single value ... to produce a textual string conveying patient information based on the values of the selected ... variable,"

As described above, in Shaya describes **creating formulas** from **information received from a user** through a graphical user interface. EX 1010 at 35 of Fig. 4; 71 of Fig. 5; 112 of Fig. 8; 212 of Fig. 9; 10:53-11:43; *see supra* at §§ VI.A.1-1(c). For example, areas 112 of Figure 8 and 212 of Figure 9 show a **formula** ("definition for [an] event" or "event type definition") as it is created in response to information received through a user interface. EX 1010 at 10:53-11:12; EX 1004 ¶ 108. The system of Shaya receives all the inputs described in the previous claim limitations and creates a formula based upon these inputs. *See supra at* §§ VI.A.1-1(c).

As described above, a user could easily create the formula COUNT (HR \leq 60 AFTER Set. 29, 1990 10:00 PM), which **identifies values of the selected time-indexed medical data variable** ("HR") **having times within the specified period of time** ("AFTER Set. 29, 1990 10:00 PM"), and **applies the selected function** ("COUNT") **to the identified values of the selected time-indexed medical data variable to aggregate the identified values into a single value**. *See supra*, at §§ VI.A.1-1(c); EX 1004 ¶ 109; EX 1010 at 11:29-34; 12:51-13:5; 13:25-67; 14:38-50; 14:51-59; Appendix A.

As discussed above, Adams discloses creating a formula that "specifies ... manipulating the single value ... to produce a textual string conveying patient information," and it would have been obvious to a POSITA to incorporate this feature into Shaya. *See supra* §§ VI.A.1-1(c); EX 1004 ¶ 110.

(e) Claim 1[f]: "such that the formula may be used to generate and display a textual string conveying patient information based on the values of the selected time-indexed medical data variable."

In Shaya, a particular **formula** ("event type definition") may be selected for implementation, in which case an "event generator … monitors the patient information in accordance with a time period selected by the user and in accordance with the set of event type definitions … selected by a user." EX 1010 at 4:62-64; 5:30-40. If occurrences of events are detected, these events are **displayed to the user**. *Id.* at 4:35-42; 5:30-40; 6:8-8:36; Fig. 4; EX 1004 ¶ 111.

Area 32 of Figure 4 shows the "event names" that have been selected for display—in this case, six different "events" are being monitored. EX 1010 at 6:33-38. The occurrences of each event over the selected time frame are shown via tick marks in area 33, where the tick marks in line (horizontally) with an event name indicate an occurrence of that event. Id. at 6:39-52; EX 1004 ¶ 112. These "tickmarks" are generated using the formula and indicate that the values of selected variables ("parameters") have met certain conditions, over a particular period of time. As a result, the tick marks constitute patient information based on the values of the selected time-indexed medical data variable. EX 1004 ¶ 112. Further, each "tick-mark" may have additional information associated with it, which may be displayed as text. EX 1010 at 6:61-62; 7:33-50; 8:8-21 ("... information region 57 is used to display text ... for the selected event or the selected event occurrence."); Fig. 4 at 52 (line for displaying a strip comment); EX 1004 ¶ 112.

As discussed above, it would have been obvious to a POSITA to modify Shaya to allow for the output of textual strings in conjunction with the event "tick-marks" to provide additional patient information, based on the disclosure of Adams. *See*

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supra §§ VI.A.1-1(c); EX 1004 ¶ 113. Accordingly, Shaya—in view of the disclosures of Adams—renders claim 1 obvious.

2. Claim 2: "The method of claim 1 ... further including the steps of: [a] displaying via the window-based user interface the names of the plurality of ... variables; and [b] receiving via the window-based user interface input indicating that the user selected the name of the selected ... variable from the displayed variable names."

As discussed above, Shaya discloses **displaying the names of the variables** ("parameters") that can be included in a formula ("event type definition") using a **window-based** graphical **user interface**. *See supra*, at §§ VI.A & VI.A.1; *see also* EX 1010 at 114 of Fig. 8 ("a list of all condition parameters that can be used in an event definition"); 10:53-11:12; 201 of Fig. 9 (listing parameters) and 214 (displaying a "list of existing variables"). The **user selects a variable** on which to base the formula via the graphical user interface, resulting in the **receipt** of this information by the system. EX 1010 at Figs. 8, 9; EX 1004 ¶ 114. Accordingly, Shaya—in view of Adams—renders claim 2 obvious.

3. Claim 6: "A method ... for constructing, in response to ... a user using a window-based user interface, a formula for deriving a medical conclusion from one of a plurality of time-indexed medical data inputs, the ... inputs each having events, the events each having multiple data components including a time ... "

As discussed above, Shaya describes a system and method that allows **a user to construct formulas** ("event type definitions") that identify when certain medical circumstances ("events") have occurred and then display each occurrence of an event as a "tick-mark" on a timeline. See supra, at §§ VI.A., VI.A.1 & VI.A.1(c)-

(e). These formulas use **medical data inputs** ("parameters") which have a plurality of **events**, wherein each event **consists of at least two** data **components**: data and time. EX 1010 at 5:10-26. Accordingly, each "tick-mark" derived and generated by a **formula** constitutes a **medical conclusion derived from one of a**

plurality of time-indexed medical data inputs. EX 1004 ¶ 115.

(a) Claim 6[a, b]: "receiving input via the window-based user interface identifying a ... input upon which the formula is to be based"; "receiving via the window-based user interface an instruction identifying a time interval qualifying the events of the identified ... input"

Claims 6[a] and 6[b] are substantively identical to the claims 2[b] and 1[a], respectively. Accordingly, Shaya discloses the limitations of claims 6[a] and [b] for the reasons discussed above. *See supra*, §§ VI.A.1(a) & VI.A.2.

(b) Claim 6[c]: "receiving via the window-based user interface an instruction identifying a selection function for selecting one event from the events of the ... input qualified by the identified time interval"

In Shaya, **formulas** ("event type definitions") are constructed by a user via a **window-based** "graphical **user interface."** EX 1010 at 10:43-46; Figs 8-9; EX 1004 ¶ 117. Figure 9 illustrates one example of such an interface that includes **selection functions** such as MINIMUM (MIN) and MAXIMUM (MAX) that determine "the extreme values for numeric or ordinal values." EX 1010 at 11:34-36; 14:1-5 (describing "language constructs" that operate on "a set of values"); 14:16-34; Appendix A; EX 1004 ¶ 117. These functions can operate on a subset of

events (data and time pairings) for a **medical data input** ("parameter") over an identified time interval, and **select the event** (data and time pairing) with the largest or the smallest data value. EX 1010 at 11:34-36; 13:61-37; 14:1-15:7; Appendix A; EX 1004 ¶ 117.

For example, the formula MAX (HR AFTER Set. 29, 1990 10:00 PM), would determine which **event** of the **medical data input** HR (*i.e.*, particular data/time instance) had the highest data value, and then indicate the occurrence of that event via a "tick-mark". *See id.; see also* EX 1010 at Fig. 4; 6:39-52. Selecting that "tick-mark" would result in the display of event information, including the data and time. EX 1010 at 7:33-50; 6:61-62; 8:8-21; Fig. 4; EX 1004 ¶ 117.

(c) Claim 6[d]: "receiving via the window-based user interface an instruction identifying a data component of each event of the ... input ..."

As discussed above, Shaya describes a method and system in which users identify particular **time-indexed medical data inputs** ("parameters") to include in a formula by selecting them from a **window-based** graphical **user interface**. *See supra*, at §§ VI.A.1–1(d) & VI.A.2, 3-3(b). These **instructions** (selections) are received by the system, and the identified **medical data inputs** are incorporated into the formula. *Id*. The selection functions described in claim 6[c] (*e.g.*, "MAX" and "MIN") inherently **identify** and operate on the **data components** of these parameters and return the highest data value, along with the time that value occurred. EX 1010 at 6:39-52; 11:34-36; 13:61-37; 14:1-15:7; Appendix A; Fig.

4; EX 1004 ¶ 118. Thus, the receipt of a particular parameter combined with a selection function constitutes "an instruction identifying a data component of each event of the time-indexed medical data input." EX 1004 ¶ 118.

However, claim 6[d] requires the <u>additional step</u> of receiving "an instruction . . . identifying a data component," which is <u>separate</u> from the steps of receiving "input ... identifying a time-indexed medical data" and "an instruction identifying a selection function," as recited in claims 6[a] and 6[c]. *Id.* ¶ 119. It is implicit that the system in Shaya distinguishes the data components of a medical data input ("parameter") from the time component since functions such as COUNT and MAX select and process the data (rather than the time) component of each parameter. *Id.* However, Shaya does not explicitly disclose the receipt of an instruction, separate from the instruction identifying a medical data input ("parameter") that identifies the data component of each input ("parameter"). *Id.*

Adams discloses **time-indexed medical data inputs** ("variables") that have events with multiple **data components** ("data elements—for example, one that indicates whether an item exists, one that indicates the value of an item, and one that gives the date the item was recorded"), and explicitly discloses receiving **instructions identifying a** particular **data component of each data input.** EX 1011 at 15, col. 1; EX 1004 ¶ 120. For example, in Figure 4 of Adams, the "K+"{VALUE}" syntax in the formula refers to the value component for the variable "K+." EX 1011 at Fig. 4; EX 1004 ¶ 120. Similarly, the "LAST VALUE" syntax in Figure 2, and the "VALUE" syntax in Figure 3 refers to the value of the variable "POTASSIUM." EX 1011 at Figs. 2, 3; EX 1004 ¶ 120.

As discussed above, it would have been obvious to a POSITA to modify Shaya to include instructions that enable a user to identify a particular data component of a variable, as disclosed in Adams, so that a user could clearly and explicitly indicate the data component of a referenced variable. *See supra* at § VI.A; EX 1004 ¶ 121.

(d) Claim 6[e, f]: "storing a formula for applying the identified selection function to events of the identified ... input whose effective times are within the identified time interval in order to select one of the events, and for extracting the identified data component of the selected event"; "such that the formula may be used to derive and display a medical conclusion from the identified ... input."

As described *supra*, **formulas** ("event type definitions") in Shaya are created via the receipt of information from a user through a graphical user interface. *See supra* at §§ VI.A.1-1(e) & VI.A.3-3(c). Once a **formula** has been created, it is **stored** in a database. EX 1010 at Figs. 10-11; 4:29-35; 14:64-15:5; *see also id.* at 11:6-11: 14:64-15:5; Fig. 8 (selecting the "OK" button (119) will result in the formula being stored in a database); Figs. 10-11; EX 1004 ¶ 122. For example, the formula MAX (HR AFTER Set. 29, 1990 10:00 PM) would **apply the identified selection function** ("MAX") **to events of the medical data input** ("HR") **whose times are within the identified time interval** (AFTER Set. 29, 1990 10:00 PM")

to select one of the events and extract the identified data component of that event. EX 1004 \P 122.

Once a **formula** has been stored, it can be selected for implementation and display. *Id.* at Figs. 10-11; 4:29-35; 14:64-15:5. At this point, an "event generator . . . monitors the patient information in accordance with a time period selected by the user and in accordance with the set of event type definitions . . . selected by a user." EX 1010 at 4:62-64, 5:30-40; Fig. 4; EX 1004 ¶ 123. The formula could be used to **derive and display a medical conclusion** from the identified time-indexed medical data input—*i.e.*, a "tick-mark" indicating that an "event" or certain set of circumstances had occurred at a particular time, based on the data for a selected parameter. EX 1004 ¶ 123.

Accordingly, Shaya—in view of Adams—renders claim 6 obvious. Id. ¶ 124.

4. Claim 7: "An apparatus for constructing, in response to input from a user using a window-based user interface, a formula for producing a textual patient information string from a selected time-indexed ... variable having a value for each of a plurality of times ... "

Claims 7 is essentially claim 1 rewritten in system claim format. EX 1004 ¶ 125. Accordingly, the discussion regarding the disclosures of Shaya and Adams for claim 1, *supra* at §§ VI.A.1–1(e), are incorporated herein for claim 7, and only the additional system-specific limitations of claim 7 will be addressed below.

(a) Claim 7[a]: "<u>a formula construction subsystem for constructing a formula</u> for producing a displayable textual patient information string from a selected ... variable"

Shaya discloses a **formula construction subsystem** in the form of an "Event Definition Language Application ("EDL")" operating on a "workstation," accompanied by and operating in conjunction with a graphical user interface. EX 1010 at 4:3-54; Figs. 2, 3, 10; EX 1004 ¶ 126. The EDL "provides the user with the ability to define events as a combination of relations and conditions of stored patient information," (EX 1010 at 4:20-55; 10:35-52), and a "graphical user interface to facilitate the entry of [such] definitions." Id. at 10:43-46; Fig. 8; EX 1004 ¶ 126. As described above, it would have been obvious to modify Shaya, in light of the teaching of Adams, so that the **formulas** ("event type definitions") produce textual patient information strings in addition to conclusions (e.g., "tick-marks" indicating occurrences of an "event" on a timeline), based on a selected time-indexed medical variable ("parameter"). See supra §§ VI.A.1(c)-(e); *see also supra*, at VI.A.2; EX 1004 ¶ 126.

(b)Claim 7[b]: "<u>a display device coupled to the formula construction</u> <u>subsystem</u> to display via the window-based user interface names of a plurality of functions capable of aggregating a plurality of values into a single value"

Shaya discloses a **display device** ("monitor") **coupled to the formula construction subsystem** ("EDL Application" that is being run on a "workstation"). EX 1010 at 3:58-4:55; Figs. 2-3; EX 1004 ¶ 127; *see also supra* at claim 7[a]. The device uses a window-based "graphical user interface" to display the names functions—such as COUNT, RATE, RUN, EXIST—capable of aggregating a plurality of values into a single value, as described *supra*, at § VI.A.1(b); EX 1004 ¶ 127.

(c) Claim 7[c]: "<u>an input device coupled to convey to the formula</u> <u>construction subsystem from the user</u>: input specifying a period of time during which the ... variable is to be analyzed, input indicating that the user selected the name of a selected function from the displayed function names, an input specifying a manner of manipulating a single value to produce a textual string ..."

Shaya discloses an input device (mouse and/or keyboard) to convey input from

the user **to the formula construction subsystem** ("EDL Application" being run on a "workstation"). EX 1010 at 3:58-4:55; Figs. 2-3; EX 1004 ¶ 128. These inputs include "a period of time," the selection of a "name of a selected function," and "a manner of manipulating a ... value to produce a textual string", as described *supra*, at §§ VI.A.1-1(c); EX 1004 ¶ 128.

(d) Claim 7[d]: "<u>a memory coupled to the formula construction subsystem to</u> <u>store a formula</u> that specifies: identifying values of the selected ... variable having times within the specified period of time, applying the selected function to the identified values of the selected ... variable to aggregate the ... values into a single value, and manipulating the single value ... to produce a textual string conveying patient information ..."

Shaya discloses **memory** ("databases" and "disk systems") **coupled to the formula construction subsystem** ("EDL Application" being run on a "workstation") **to store a formula** ("event type" or "event type definition"). EX 1010 at 3:58-5:5; Figs 2, 3, 10-11; EX 1004 ¶ 129. As described above, Shaya discloses that a formula can specify "values of the selected ... variable within the specified period of time" and "apply[] the selected [aggregation] function" to those values. *See supra* at VI.A.1(d)-(e). Further, it would have been obvious to a POSITA to modify Shaya in view of Adams so that the formula can also specify "manipulating the value ... to produce a textual string." *See supra* §§ VI.A.1, VI.A.1(c) & VI.A.2; EX 1004 ¶ 129.

5. Claim 8: "The apparatus of claim 7 wherein the selected ... variable is one of a plurality of ... variables each having a name, and [a] wherein the display device is also coupled to display the names of the plurality of ... variables, and [b] wherein the input device is also coupled to convey input indicating that the user selected the name of the selected ... variable from the displayed variable names."

Claim 8 is essentially claim 2 rewritten in system claim format. In combination with the system disclosures cited in the discussion of claim 7[b], the prior art disclosures cited in claim 2 disclose all of the claim limitations of claim 8. *See supra* §§ VI.A.2, 4(b; EX 1004 ¶ 130.

B Ground 2: Claims 1, 2, 7, and 8 are rendered obvious under 35 U.S.C. § 103(a) by Shaya in view of Musen

As discussed above, Shaya discloses all of the limitations of claims 1, 2, 7, and 8 except that it does not explicitly disclose the inclusion of "a manner of manipulating a single value to produce a textual string conveying patient information" in its formula ("event type definitions") as required by certain limitations of claims 1 and 7. *See supra* at §§ VI.A-A.5; EX 1004 ¶ 133.

Musen describes a graphical "knowledge acquisition" tool to "facilitate knowledge acquisition for advice systems" such as creating treatment models and treatment plans for cancer patients, along with methodologies for using this tool. EX 1013 at xvii, ¶ 1-xviii, ¶ 1; 5, ¶ 3- 12, ¶ 2; EX 1004 ¶ 134. The system described in Musen allows users to define protocols for determining, based on patient data, whether a particular patient should be provided with additional dosages of a chemotherapy drug, or whether their drug regimen should be changed in some way (e.g., dose, different drug, delayed drug administration of drug, etc.). EX 1013 at 5, ¶ 4 – 7, ¶ 4; 122, ¶ 2; Fig. 1.2; 92, ¶ 2; Fig. 4.1; Figures 6.5, 6.6; EX 1004 ¶ 134. In Musen, physicians first fill out "special purpose graphical forms" by "[making] selections from pop-up menus to fill in the various pre-defined blanks," as shown in Figures 6.5 and 6.6. EX 1013 at 9, ¶ 2-10, ¶ 1; EX 1004 ¶ 134. When physicians enter "time-oriented data concerning individual patients (Figure 1.2)," the system uses these protocols "in conjunction with the patient data entered ... to arrive at a recommendation for treatment." EX 1013 at 5, $\P 4 - 7$, $\P 4$; EX 1004 ¶ 134. These "protocols" or "task actions" of Musen constitute formulas based on patient-specific time-oriented data that result in textual conclusions or "recommendations" regarding treatment. EX 1013 at 275 (Appendix A, "Rule-Conclusion"), Figs. 1.2, 4.1, 6.5, 6.6; EX 1004 ¶ 134.

Thus, like Shaya, Musen discloses a system for creating formulas (e.g., "rules", "task-actions", "protocols") based on values of "time-oriented data concerning individual patients" via inputs received through window-based graphical user interfaces ("graphical forms" with "pop-up menus"). EX 1004 ¶ 135. However, Musen also discloses the receipt of input indicting how to manipulate a single value in order to generate a textual result and creating a formula that is capable of generating a medical conclusion in a text format (a "recommendation") from a single value, *e.g.*, "TREAT" or DELAY". EX 1013 at 5, ¶ 4 − 7, ¶ 4; 122, ¶ 2; Fig. 1.2; 92, ¶ 2; Fig. 4.1; Figures 6.5, 6.6; 275 (Appendix A); EX 1004 ¶ 135. For example, in Figure 6.5, "the user is about to specify that, when a patient's whiteblood-cell (WBC) count is greater than or equal to 3500 and the platelet count is between 75,000 and 100,000, treatment should be delayed." EX 1013 at Fig. 6.5. So, if the expression (WBC \geq 3500) AND (75,000 < PLATELETS < 100,000) return a single value of "true," then text-string "DELAY" will be displayed. In this case, "WBC" and "platelet" constitute time-indexed variables, with multiple values, and the formula specifies that if the result of a function applied to these values is "true," then a text-string ("DELAY") should be displayed. Id. at Fig. 1.2; 5, ¶ 4 – 7; 92, ¶ 2; Fig. 4.1; EX 1004 ¶ 135.

Accordingly, modifying Shaya in accordance with the teachings of Musen would result in a system and method for constructing a formula "for producing a textual patient information string from a selected time-indexed medical data variable having a value for each of a plurality of times," wherein the formula specifies "a manner of manipulating a single value to produce a textual string conveying patient information," so that the formula may be used to generate and display a textual string conveying patient information based on the values of the selected time-indexed medical data variable." *See* §§ VI.A-A.5; ; EX 1004 ¶ 136.

It would have been obvious to a person of skill in the art to combine the text input and output feature of Musen with Shaya so that the system and method of Shaya included a text string within the "event type definition," and generated the text string as a result of the application of this definition. EX 1004 ¶ 137. This would have provided additional useful information to users who later used the "event type definitions" regarding the "events" flagged as a result of the definitions. *Id.* Given the similarities in the systems, the inclusion of such a feature would not have involved any undue experimentation by a POSITA. Moreover, this combination would have yielded a predictable result—namely, an event query system that generated text output associated with occurrence of a particular event. *Id.*

C Ground 3: Claims 1, 2, 6, 7, and 8 are rendered obvious under 35 U.S.C. § 103(a) by Adams in view of Gappa

As described above in Ground 1, Adams describes systems designed to allow users to construct queries "to help analyze data in a patient's record." *See supra* at § VI.A; EX 1011 at 11, cols. 1-2; 12 col. 1; 13, col. 2; EX 1004 ¶ 139. The systems allow users to construct formulas ("queries") to "examine a patient's data and decide whether a specified set of conditions is met by that data, and if so, ... produce a specified output." EX 1011 at 11, col. 3. These queries are based on variables, such as "patient information" (*id.* at 15, col. 1), and may contain temporal relationships (*id.* at 14, col. 3) and aggregation and/or selection functions ("primitives"). *Id.* at 14, col. 3-15, col 1; 15, col. 3; 16, col. 3-17, col. 1; EX 1004 ¶ 139. Adams further describes allowing a user to input textual strings into queries that can later be displayed based on the result of statements within the queries. *See, e.g.*, EX 1011 at 15, col. 1-17, col. 2; Figs. 2-4; EX 1004 ¶ 139.

In all three systems, the inputs are received via a text-based user interface. EX 1011 at Figs. 2-4; 17, col. 2-18, col. 1; EX 1004 ¶ 139. As a result, Adams does not explicitly disclose the use of a "window-based" user interface (claims 1, 2, 6, 7) for inputting and/or receiving input, nor does it explicitly disclose "displaying [the] names of a plurality of functions" or "variables" for selection or input by the user (claims 1, 2, 7, 8); EX 1004 ¶ 139. Gappa, however, describes a "graphical knowledge acquisition tool" designed to create formulas ("rules" and "tables") to identify medical diagnoses based on the values of various variables (patient data). EX 1012, Gappa, at Abstract; 187, ¶ 2; 188, ¶ 3 – 189, ¶ 2; Figs. 4, 5, 6, 8, 9; EX 1004 ¶ 140. In Gappa, variables include "symptoms" or "conditions" (*e.g.*,

"dactylitis", "result-of-skin-examination") (*id.* at Figs. 5, 6), as well as other general patient attributes such as sex, height, and weight. EX 1012 at Figs. 4, 5; *see also id.* at 193, ¶ 3; EX 1004 ¶ 140.

The formulas of Gappa are created, in part, by inputting functions that operate on the values of selected variables. EX 1012 at Fig. 4 (disclosing selection functions such as "MAX" and "MIN"); EX 1004 ¶ 140. Formulas further include inputs in the form of textual strings ("diagnoses") that maybe displayed as the result of the formula. EX 1012 at Fig. 2 (description); EX 1004 ¶ 140. Gappa further discloses the use of these formulas to generate a single value from which a textual conclusion ("diagnoses") may be produced and displayed. Ex 1012 at Fig. 2 (description); *id.* at 199, ¶¶ 3-6; *see also id.* at 187, ¶ 4; EX 1004 ¶ 140. For example, a diagnosis of "psoriatic arthritis" may result from the table in Figure 5 (see top row) and/or the table of Figure 6 (see bottom row), based on the values for the "symptoms" and "conditions" for a patient, and could be displayed as shown in Figures 8 ("established diagnoses") and 9 ("Justification of Psoriatic-arthritis"). See, e.g., EX 1012 at 193, ¶ 4 – 195, ¶ 4; Figs. 5-6; *id.* at 199, ¶ 4-6; Figs. 8-9; EX 1004 ¶ 140.

Thus, like Adams, Gappa describes a querying system that allows a user to construct formulas to analyze certain portions of patient data and generate and display textual conclusions as a result of these queries. EX 1004 ¶ 141. However,

Gappa, unlike Adams, also discloses receiving inputs into the system via a user interface utilizing windows and "pop-up" windows. EX 1012 at Figs. 4-6; 195, ¶ 2; EX 1004 ¶ 141. Gappa also discloses the display of function names (*e.g.*, EX 1012 at Fig. 4, "MAX" and "MIN") and variable names (*e.g.*, *id.* at Figs. 4-6, "symptoms" or "conditions") for user selection. EX 1004 ¶ 141.

Accordingly, modifying Adams in accordance with the teachings of Gappa would result in a system and method for constructing a formula ("query") that receives inputs and/or instructions "via [a] window-based user interface," and displays "via the window-based user interface the names of ... variables" and "functions." EX 1004 ¶ 142. It would have been obvious to a person of skill in the art to combine the graphical window-based user interface with the analytical features of Adams, since the replacement of a "text-only" or line-entry system with a graphical user interface would have enabled user to more easily enter information, and required users to memorize fewer pieces of information. *See* EX 1004 ¶ 142.

1. Claim 1: "A method ... for constructing, in response to input from a user using a window-based user interface, a formula for producing a textual patient information string from a selected time-indexed medical data variable having a value for each of a plurality of times"

Adams describes systems and methods that allow a user to **construct formulas** ("queries") **from selected medical data variables** ("variables") **in response to user input**. EX 1011 at 11, cols. 1-2; 12 col. 1; 13 col. 2-14, col. 1; 14, col. 3; 15,

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col. 1; EX 1004 ¶ 143. Adams also discloses that **times** may also be associated with various **values of a variable** (*see, e.g.* functions such as "time of first value, last value and time of last value." EX 1011 at 14 col. 1; 14, col. 3-15, col. 1; EX 1004 ¶ 143. In each system, **formulas** determine "whether a specified set of conditions is met by [a patient's] data, and if so, they produce a specified output," such as **a text string** summarizing findings, drawing a conclusion, or alerting a user to the existence of a condition for a particular patient. EX 1011 at 11, col. 3; 15, col. 1-17, col. 2; Figs. 2-4; EX 1004 ¶ 143. For example, Figures 2-4 show a similar **formula** (constructed in each language) that determines whether the **value** of the last measurement of a **variable** named potassium is lower than a certain value and, if so, generates the following text-based message, or some similar variant thereof:

SERUM POTASSIUM OF <value> **MEQ/L IS BELOW CRITICAL LEVEL**, where <value> represents the value of the last measurement of the variable. EX 1011 at Figs. 2-4; EX 1004 ¶ 143.

As described above, it would have been obvious to a POSITA to replace the text-based **user interface** of Adams with Gappa's windows-based user interface. *See supra* at §§ VI.C-C.1; EX 1004 ¶ 144.

(a) Claim 1[a]: "receiving input via the window-based user interface specifying a period of time during which the ... variable is to be analyzed"

Adams describes systems that allow users to input "temporal relationships using such terms as *before, after,* and *between,*" that **specify a period of time during which a variable is to be analyzed**. EX 1011 at 14, col. 3; EX 1004 ¶ 145. Adams discloses that one system "handles the set of all values of a code found within a specified time range." EX 1011 at 14, col. 3-15, col 1; EX 1004 ¶ 145. A formula in that system "can return the average of all blood sugar measurements for the last three days." EX 1011 at 15, col. 3; EX 1004 ¶ 145. Another system can operate on a set of values of a variable "defined … by time boundaries." EX 1011 at 15, col. 1; EX 1004 ¶ 145. Although the systems receive inputs via text-based user interfaces, it would have been obvious to a POSITA to modify Adams to receive inputs via a window-based user interface, in light of Gappa. *See supra* at §§ VI.C-C.1; EX 1004 ¶ 145.

(b) Claim 1[b, c]: "displaying via the window-based user interface names of a plurality of functions capable of aggregating a plurality of values into a single value;" "receiving input via the window-based user interface indicating that the user selected the name of a selected function from the displayed function names"

The systems described by Adams "offer useful primitives [functions] for analyzing properties of sets." EX 1011 at 14, col. 3; EX 1004 ¶ 146. They include **a plurality of functions capable of aggregating a plurality of values into a single value**, such as the "primitives that select the … average, trend, number of elements found" (EX 1011 at 14, col. 3-15, col 1; 15, col. 3) and that calculate the "sum of elements ... and number of elements in a set." *Id.* at 15, col. 1; 16, col. 3-17, col. 1; EX 1004 ¶ 146. As discussed above, the systems in Adams **receive inputs via a** text-based **user interface and** do not display the names of aggregation functions, and therefore a user cannot select a displayed function name. *See supra* at §§ VI.C–C.1(a); EX 1004 ¶ 146. For the reasons discussed, above, however, it would have been obvious to a POSITA to modify the systems in Adams to utilize Gappa's **window-based** user interfaces to **display the names** of the plurality of aggregation functions and to **receive input indicating the user selected one of these displayed names**. *See supra at* §§ VI.C–C.1(a); EX 1012 at Figs. 4-6; *id.* at 195 ¶ 2; EX 1004 ¶ 146.

(c) Claim 1[d]: "receiving input via the window-based user interface specifying a manner of manipulating a single value to produce a textual string conveying patient information"

As discussed above, all three systems described by Adams can receive input specifying a textual string that should be output when certain conditions have been met—such as when a certain value results from an aggregation function. *See supra* at §§ VI.A–A.1, A.1(c)-(e), VI.C–C.1; EX 1011 at 15, col. 1-17, col. 2; Figs. 2-4; EX 1004 ¶ 147. Figures 2-4 of Adams show a similar formula ("query") that determines whether a value of a variable is lower than a certain number and, if so, generates the following message, or some similar variant thereof: SERUM POTASSIUM OF <value> MEQ/L IS BELOW CRITICAL LEVEL, where

<value> represents the value of the last measurement of the variable. EX 1011 at Figs. 2-4. Adams therefore describes a manner of manipulating a single value (*i.e.*, the last measurement of the variable) to produce a textual string conveying patient information. EX 1004 ¶ 147.

As discussed *supra*, Adams teaches **receive inputs**—including a manner of manipulating a single value to produce a text string—via a text-based user interface. *See supra* at §§ VI.C–C.1(c); EX 1011 at Figs. 2-4, 17, col. 2 – 18, col. 1. However, it would have been obvious to a POSITA to modify the systems in Adams to utilize window-based user interfaces taught by Gappa and receive such inputs via a window-based user interface. EX 1012 at Figs. 4-6, 195, ¶ 2; EX 1004 ¶ 148.

(d) Claim 1[e, f]: "based upon the receiving steps, creating a formula that specifies: identifying values of the selected ... variable having times within the specified period of time; applying the selected function to the identified values of the selected ... variable to aggregate the ... values into a single value, and manipulating the single value ... to produce a textual string ... based on the values of the selected time-indexed medical data variable," "such that the formula may be used to generate and display a textual string ... based on the values of the selected ... variable."

As discussed above, all three systems described by Adams **create formulas** ("queries") **based upon the receipt of input from a user via a user interface.** *See* §§ VI.C-C.1; EX 1011 at Figs. 2-4. These formulas "examine a patient's data and decide whether a specified set of conditions is met by that data, and if so, they produce a specified output—in the case of surveillance, a reminder to the attending physician; in the case of a query, a data summary." EX 1011 at 11, col. 3; *see also* 11, col. 2; 12; 14, col. 1. Further, a POSITA could easily create a formula using these systems that, for example, **identifies the values of a variable** named "Heart Rate" **over a particular time period, applies a selected aggregation function** ("primitive") named "average" **to these values**, and **manipulates the resulting value,** if the average is higher than a certain number, to **produce the text string** "Patient is having a heart attack, average heart rate is <value>" (where <value> is the result of the aggregation function). *See supra* at §§ VI.C-C.1(c); EX 1011 at 11, col. 2; 15, col. 1 -17, col. 2; Figs. 2-4; EX 1004 ¶ 149. **The formula** could therefore be **used to generate and display a textual string conveying patient information based on the values of the selected ...variable. EX 1004 ¶ 149.**

Accordingly, Adams—in view of Gappa—renders claim 1 obvious. EX 1004 ¶ 150.

2. Claim 2: "The method of claim 1 ... further including the steps of: [a] displaying via the window-based user interface the names of the plurality of ... variables; and [b] receiving via the window-based user interface input indicating that the user selected the name of the selected ... variable from the displayed variable names."

As discussed above, the systems in Adams all include **a plurality of timeindexed variables** which are referred to by **names** (EX 1011 at p. 15, col. 1; Figs 2-4); and **receive input indicating a user selected a** particular **variable** for inclusion in a formula (*id.*), **via a** text-based **user-interface**. *See supra* §§VI.C-C.1 & VI.C.1(b); EX 1011 at Figs. 2-4; 15, col. 1; 17, col. 2-18, col. 1. However, the systems in Adams do not utilize a window-based interface, nor do they display the names of those variables and—as a result—a user cannot select a displayed variable name. EX 1004 ¶ 151. As discussed above, however, it would have been obvious to a POSITA to modify the systems in Adams to utilize the **window-based** user interfaces taught by Gappa to **display the names** of the plurality of variables and to receive input indicating the user selected one of these displayed names. *See* §§ VI.C–C.1 & VI.C.1(b); EX 1012 at Figs. 4-6; *id.* at 195, ¶ 2; EX 1004 ¶ 152.

3. Claim 6: "A method ... for constructing, in response to user interface interactions by a user using a window-based user interface, a formula for deriving a medical conclusion from one of a plurality of time-indexed medical data inputs, the ... inputs each having events, the events each having multiple data components including a time ... "

As discussed above, Adams describes systems and methods for **constructing formulas** ("queries") **from selected time-indexed medical data inputs** ("variables") that may have **events** with a multitude of **data components including a time**. *See supra* §§VI.A.3(c), VI.C-C.1& VI.C.1(c)-(d). Adams further discloses the use of **instructions identifying a** particular **data component of each data input**. EX 1011; *id.* at 11, cols. 1-2; 12, col. 1; 13, col. 2; 14, col. 1;

14, col. 3-15, col. 1; Figs. 2-4; EX 1004 ¶ 153. In each system, formulas ("queries") determine "whether a specified set of conditions is met by [a patient's] data, and if so, they produce a specified output," such as a medical conclusion. EX 1011 at 11, col. 3; 15, col. 1–16, col 1, Fig. 2; *id.* at 16, col. 2–17, col. 1, Fig. 3; *id.* at 17, cols. 1-2, Fig. 4; EX 1004 ¶ 153. This conclusion can be derived from one of one of the plurality of medical data inputs ("variables"). EX 1011 at 14, col. 3-15, col 1; 16, col. 3-17, col. 1; EX 1004 ¶ 153.

As discussed above, Adams discloses the use of a text-based user interface. However, Gappa discloses a similar system utilizing a window-based user interface to construct formulas and output text strings (EX 1012 at Figs. 4, 5, 6, 195, \P 2), and it would have been obvious to a POSITA to modify Adams to utilize the window-based user interface described in Gappa. *See supra* at §§ VI.C-C.1. Thus Adams, in combination with Gappa, discloses constructing formulas **in response to user interface interactions by a user using a windows-based user interface**. *See* EX 1004 ¶¶ 154-55.

(a) Claim 6[a]: "receiving input via the window-based user interface identifying a time-indexed medical data input upon which the formula is to be based"; claim 6[b]: "receiving via the window-based user interface an instruction identifying a time interval qualifying the events of the identified time-indexed medical data input"

As discussed above, claims 6[a] and 6[b] are substantively identical to the claims 2[b] and 2[a], respectively. *See supra* at §§ VI.A.3-A.3(a). Accordingly,

Adams combined with Gappa discloses the limitations of Claim 6[a] and [b] for the reasons discussed above. *See supra* at §§ VI.C.1(a), VI.C.2; EX 1004 ¶ 156.

(b) Claim 6[c]: "receiving via the window-based user interface an instruction identifying a selection function for selecting one event from the events of the time-indexed medical data input qualified by the identified time interval"

All three systems described in Adams "offer useful primitives for analyzing properties of sets" that can be incorporated into a formula ("query"). Id. at 14, col. 3. These "primitives" include selection functions, such as "primitives that select the maximum, minimum, median, mode ... first value ... last value ... and value nearest to a specified time" than can select one event from the events of the time-indexed medical data input ("variable") from a defined time interval. *Id.* at 14, col. 3-15, col 1; see also id. at 16, col. 3-17, col. 1.; EX 1004 ¶ 157. As Adams teaches receiving instructions identifying a selection function ("primitives" such as "minimum" or "maximum") via a text-based user interface (EX 1011 at Figs. 2-4; 17, col. 2 - 18, col. 1), it would have been obvious to a POSITA to modify Adams to utilize the **window-based** user interfaces described in Gappa to **receive** an instruction identifying a selection function. indicating the user selected one of these displayed names. See supra, at §§ VI.C–C.1, VI.C.1(b); EX 1012 at Figs. 4, 5, 6, 195, ¶ 2; EX 1004 ¶ 157.

(c) Claim 6[d]: "receiving via the window-based user interface an instruction identifying a data component of each event of the time-indexed medical data input ..."

As discussed above, at §§ VI.A.3, 3(c), Adams discloses **time-indexed medical data inputs** ("variables") that have events with a multitude of **data components** ("data elements," well as the use of **instructions identifying a** particular **data component of each data input.** EX 1011 at 15, col. 1; Figs. 2 ("LAST VALUE"), 3 ("VALUE"), 4 (K+{VALUE}); EX 1004 ¶ 158.

As discussed *supra*, at §§ VI.C.1–3, although the systems in Adams receive instructions—including those identifying a data component--via a text-based **user interface** (EX 1011 at Figs. 2-4; 17, col. 2-18, col. 1), it would have been obvious to modify these systems in Adams to include the window-based user interfaces disclosed in Gappa (EX 1012 at Figs. 4-6, 195, ¶ 2), and thus to receive such instructions via a **windows-based user interface**, as described above. *See, e.g., supra* at §§ VI.C-C.1; EX 1004 ¶ 159.

(d) Claim 6[e]: "storing a formula for applying the identified selection function to events of the identified time-indexed medical data input whose effective times are within the identified time interval in order to select one of the events, and for extracting the identified data component of the selected event"; Claim 6[f]: "such that the formula may be used to derive and display a medical conclusion from the identified time-indexed medical data input."

Each of the systems described in Adams creates and stores formulas ("queries") based on the instructions received from the user. EX 1011 at 12, col. 1-13, col. 2 and 17, col. 2- 18, col. 3 (describing real-world implementations of each of the systems, utilizing various types of storage); 13, col. 3-14, col. 2

(describing compilation of queries into machine language); Figs. 2-4. As discussed *supra*, at § VI.C.3-3(c), these **formulas** ("queries") can **apply the identified selection function** (*e.g.*, a "primitive[] that select the maximum [or] minimum" of a set) **to select one of the events of a medical data input** (an instance of a "variable") **whose times are within a specified time frame**, and **extract the identified data component** ("value" or "data element") from that event. Further, as discussed *supra* at §§ VI.C.1(c)-(d) the formulas may be used to **derive and display a medical conclusion** (*e.g.*, "output messages, reports, or data ... to a specified destination") (*id.* at 14, col. 1); EX 1004 ¶ 160.

Accordingly, Adams—in view of Gappa—renders claim 6 obvious. EX 1004 ¶ 161.

4. Claim 7: "An apparatus for constructing, in response to input from a user using a window-based user interface, a formula for producing a textual patient information string from a selected time-indexed medical data variable having a value for each of a plurality of times ..."

Claim 7 generally contains the same limitations as claim 1, rewritten in a system claim format. Accordingly, the arguments for claim1 are incorporated herein, and only the additional system-specific limitations of claim 7 will be addressed below. *See supra* at §§ VI.C–C.1(d).

(a) Claim 7[a]: "<u>a formula construction subsystem for constructing a formula</u> for producing a displayable textual patient information string from a selected time-indexed medical data variable"

Adams discloses **formula construction subsystems** in the form of "query languages" that access data stored on databases and are executed by processors. EX 1011 at 11, cols. 1-2; 12, col. 1-14, col. 2; Fig. 1. These "query languages"— namely, "HCOM," "MQL," and "CARE,"–are used to construct **formulas** ("queries") for producing **textual strings** (*e.g.*, "output messages, reports, or data") (*id.* at 14, col. 1). *Id.* at 15, col. 1-17, col. 1; Figs. 2-4; EX 1004 ¶ 163; *see also supra* §§ VI.C.1(c)–(d). These formulas ("queries") can be based on a **selected time-indexed variable**. *See supra* §§ VI.C–C.2; EX 1004 ¶ 163.

(b)Claim 7[b]: "<u>a display device coupled to the formula construction</u> <u>subsystem</u> to display via the window-based user interface names of a plurality of functions capable of aggregating a plurality of values into a single value"

The systems in Adams display information and receive inputs **via a user interface**. EX 1011 at Figs. 2-4; 17, col. 2–18, col. 1. The disclosure of a user interference inherently discloses a **display device** ("terminal" or "monitor") **coupled to the formula construction subsystem** (a "query language" being executed by processors and accessing data stored on databases) to display information to the user. *Id.* at 11, cols. 1-2; 12, col. 1-14, col. 2; Figs. 2-4; EX 1004 ¶ 164. As described *supra* at § VI.C.1(b). Adams also discloses **aggregation functions** ("primitives that select the … average, trend, number of elements found" (EX 1011 at 14, col. 3-15, col 1; 15, col. 3); that calculate the "sum of elements … and number of elements in a set," (*id.* at 15, col. 1); or that generate "statistics about data sets" means, standard deviations, and standard errors" (id. at 16, col. 3-

p. 17, col. 1)); see also EX 1004 ¶ 164.

As discussed *supra*, it would have been obvious to a POSITA to modify the systems in Adams to utilize **window-based** user interfaces, as taught by Gappa, to **display the names** of the plurality of aggregation functions and to receive input indicating the user selected one of these displayed names. *See supra* § VI.C.1(b); EX 1012 at Figs. 4, 5, 6, 195, ¶ 2; EX 1004 ¶ 165.

(c) Claim 7[c]: "<u>an input device coupled to convey to the formula</u> <u>construction subsystem from the user</u>: [c][1] input specifying a period of time during which the medical data variable is to be analyzed, [c][2] input indicating that the user selected the name of a selected function from the displayed function names, and [c][3] input specifying a manner of manipulating a single value to produce a textual string conveying patient information ..."

The systems in Adams display information and receive inputs via a user interface. EX 1011 at Figs. 2-4; 17, col. 2–18, col. 1. It is implicit that each user-interface includes an input device (*e.g.*, a keyboard) coupled to the formula construction subsystem (processors executing a "query language" that accesses data stored on databases) to convey inputs from the user to the formula construction subsystem. *See id.* at 11, cols. 1-2; 12, col. 1-13, col. 2; 13, col. 3-14, col. 2; Figs. 2-4; EX 1004 ¶ 166. As discussed *supra* at sections VI.C.1(a)-(c), these inputs include a "period of time," the name of an aggregation function, and

"a manner of manipulating a ... value to produce a textual string." See EX 1004 ¶ 166.

As discussed *supra*, Adams does not disclose the display of the names of aggregations functions, and the selection of one of the displayed names. However, it would have been obvious to a POSITA to modify the systems in Adams to utilize **window-based** user interfaces, as taught by Gappa, to **display the names** of the plurality of aggregation functions and to receive input indicating the user selected one of these displayed names. *See supra* at §§ VI.C.1(b) & VI.C.4(b); *see also* EX 1012 at Figs. 4, 5, 6, 195, ¶ 2; EX 1004 ¶ 167.

(d) Claim 7[d]: "<u>a memory coupled to the formula construction subsystem to</u> <u>store a formula</u> that specifies: identifying values of the selected ...variable having times within the specified period of time, applying the selected function to the identified values of the selected ... variable to aggregate the ... values into a single value, and manipulating the single value ... to produce a textual string conveying patient information based on the values of the selected ... variable."

It is inherent that the systems disclosed in Adams contain **memory** (*e.g.*, "1500 megabytes of storage," a "database") **coupled to the formula construction subsystem**. ("EDL Application" that is being run on a "workstation") **to store** the **formulas** ("queries") created in response to user inputs. EX 1011 at 11, cols. 1-2; 12, col. 1-13, col. 2; 13, col. 3- 14, col. 2; Figs. 2-4; EX 1004 ¶ 168. As discussed *supra*, Adams discloses that a **formula** ("query") can specify "values of the selected … variable within the specified period of time," "applying the selected

[aggregation] function" to those values, and "manipulating the value ... to produce a textual string." *See supra*, at §§ VI.C.1(c)-(d); EX 1004 ¶ 168.

5. Claim 8

Claim 8 is essentially claim 2 rewritten in system claim format. Thus, Adams and Gappa therefore render obvious claim 8 for the reasons set forth above in

connection with claims 2 and 7[b]. See supra at §§ VI.C.2 & VI.C.4(b); see also

EX 1004 ¶ 169.

D Claim Chart for Grounds 1-3

The chart below provides a list of citations that support the disclosure of each of the claimed limitations by the cited prior art references, and the combinations thereof asserted in Grounds 1-3. *See also supra* at § VI; EX 1004 at Apdx. B-E.

'451 Claim Language	Prior Art Disclosures
1. A method in a computer system	Shaya (Grounds 1 & 2): 1:35-59; 2:5-56; 2:59-
for constructing, in response to	3:22; 3:24-58; 4:20-42; 4:42-57; 4:62-64;
input from a user using a	5:10-26; 5:30-40; 6:8-8:36; 9:10-31; 10:36-
window-based user interface, a	11:8; 11:12-48; Figs. 3, 5-7; Appendix A
formula for producing a textual patient information string from a selected time-indexed medical data variable having a value for	Adams (Grounds 1 & 3): 11, cl. 1-3; 12, cl. 1; 13, cl. 3; 14, cl. 2-3; 15, cl. 1-3; 16, cl. 1-3; 17, cl 1-3; 18, cl. 1; 19, cl. 1; Figs. 2, 3; Table 1
each of a plurality of times, the	<u>Musen (Ground 2)</u> : xvii ¶ 1-xviii ¶ 1; 5 ¶ 3-12,
method comprising the steps of:	1 2 ; 14-16; 92-94; 100; 109-10; 122-23; 158;
	263; Figs. 1.2, 1.3, 1.6, 1.9, 4.1, 5.1, 5.6, 6.5,
	6.6, 7.1.
	<u>Gappa (Ground 3)</u> : Abstract, 187 ¶¶ 2, 4; 189 ¶¶ 5 6: 190 ¶ 1: 193 ¶ 3: 208 ¶ 2: Figs 2, 4-9
[a] receiving input via the	Shava (Grounds 1 & 2): claim 1[preamble]:
window-based user interface	1:35-59; 2:5-3:58; 4:20-35; 4:42-63; 5:31-37;

specifying a period of time during	9:10-31; 10:36-11:48; 13:25-67; Figs. 2-3, 5-9;
which the medical data variable is	Appendix A
to be analyzed;	Adams (Grounds 1 & 3): claim 1 [preamble];
	$14, \operatorname{col} 3 - 15, \operatorname{col} 1; 15, \operatorname{col} 3; 16, \operatorname{col} 2; 17, 1$
	col. 2-18, col. 1; Figs. 2-4
	Gappa (Ground 3): claim 1 [preamble]
[b] displaying via the window-	Shaya (Grounds 1 & 2): claim 1[preamble];
based user interface names of a	2:5-3:58; 4:42-57; 9:10-31; 10:36-11:48;
plurality of functions capable of	12:51-13:5; 14:1-15; 14:38-50; 14:51-59; Figs.
aggregating a plurality of values	2-3, 5-9; Appendix A
into a single value;	Adams (Grounds 1 & 3): claim 1 [preamble];
	14, cl 3-15, cl 3; 16, cl 3-18, col. 1; Figs. 2-4
	Gappa (Ground 3): claim 1 [preamble]
[c] receiving input via the	Shava (Grounds 1 & 2): claim 1[preamble]:
window-based user interface	claim 1[h]: 2.5-3.58: 4.42-57: 9:10-31: 10:36-
indicating that the user selected	11.48. Figs 2.3 5.9
the name of a selected function	$11.70, 1120, 2^{-5}, 5^{-5}$
from the displayed function	Adams (Grounds 1 & 3): claim 1 [preamble,
namec.	b]; 17, cl. 2-18, cl. 1; Figs. 2-4
numes,	Copps (Ground 3): claim 1 [preamble]
[d] receiving input via the	<u>Gappa (Grounde 1</u> & 2); claim 1[preamble];
[0] receiving input via une	<u>Silaya (Grounds 1 & 2).</u> claim r[preamore], 2.5 2.59. 1.25 57. 5.20 10. 6.28 15. 7.22 50.
window-based user interface	2.5 - 5.56, 4.55 - 57, 5.50 - 40, 0.56 - 45, 7.55 - 50, 7.50, 0.20, 0.00, 120, 0.12, 210, 0.10, 210, 10.26
specifying a manner of	7:39-8:2; 8:8-12; 8:13-21; 9:10-31; 10:30-11:49; Eige 2.2, 5.0
manipulating a single value to	11:46; Figs. 2-5, 5-9
produce a textual string	Adams (Grounds 1 & 3): claim 1 [preamble,
conveying patient information,	b]; 13, cl. 3; 15, cl 1-2; 16, cl. 1; 17, cl. 1-18,
	cl. 1; Figs. 2-4
	$M_{\text{Mason}} (Crownd 2) \in \{2, 7, 14, 17, 02, 04, 111\}$
	<u>Musen (Ground 2):</u> 0; 7; 14-17; 93; 94; 111; 122, 22; 158; 101; Eig. 1.2; Eig. 1.0; Eig. 4.1;
	122-25; 156 ; 191 ; $FIg. 1.2$; $FIg. 1.9$; $FIg. 4.1$;
	FIg. 0.3, Fig. 0.0, Fig. 7.11, Fig. 0.3.
	<u>Gappa (Ground 3)</u> : claim 1 [preamble]
[e] based upon the receiving	Shaya (Grounds 1 & 2): claim 1[preamble];
steps, creating a formula that	ABSTRACT; 2:5-56, 3:24-58; 4:20-35; 4:43-
specifies:	53; 4:62-64; 5:30-40; 6:8-8:36; 10:36-11:8;
	11:12-43; Figs. 3,4, 8-11.
	-

	Adams (Grounds 1 & 3): claim 1 [preamble]	
[e][1] identifying values of the	Shava (Grounds 1 & 2): claim 1[preamble, a.	
selected time-indexed medical	e]	
data variable having times	-1	
within the specified period of	Adams (Grounds 1 & 3): claim 1[preamble, a]	
time.		
[e][2] applying the selected	Shava (Grounds 1 & 2): claim 1[preamble, b.	
function to the identified	c. e]	
values of the selected time-	•, •]	
indexed medical data variable	Adams (Grounds 1 & 3): claim 1[preamble, b,	
to aggregate the identified	c]	
values into a single value, and		
[e][3] manipulating the single	Shava (Grounds 1 & 2): claim 1[preamble, d.	
value in the specified manner	e]	
to produce a textual string	-1	
conveying patient information	Adams (Grounds 1 & 3): claim 1[preamble, d]	
based on the values of the	Gappa (Ground 3): claim 1 [preamble]	
selected time-indexed medical	<u>Suppu (Ground 5)</u> . chann i [preamore]	
data variable,		
[f] such that the formula may be	Shaya (Grounds 1 & 2): claim 1[preamble, d,	
used to generate and display a	e]	
textual string conveying patient		
information based on the values	Adams (Grounds 1 & 3): claim 1[preamble, d,	
of the selected time-indexed	e	
medical data variable.		
2451 Claim Language	Prior Art Diselesures	
2 The method of claim 1 where	n See claims 2[a] and [b]	
the selected time-indexed medic	al	
data variable is one of a plurality		
time indexed medical data variable		
and having a name furth		
including the steps of:		
fal displaying via the window base	d Shave (Grounds 1 & 2): claim 1[proomble]:	
user interface the names of the	$\frac{516}{2} = \frac{516}{2} + 51$	
plurality of time-indexed medic	2.5-5.56, 4.42-57, 5.10-51, 10.50	
data variables and	$[11, 10, 1150, 2, 5, 5^{-}]$	
	Adams (Grounds 1 & 3): claim 1[preamble];	
	Figs. 2-4; 15, cl. 1; 17, cl. 2-18, cl. 1	
	Gappa (Ground 3): claim 1 [preamble]	

[b] receiving via the window-based user interface input indicating that the user selected the name of the selected time-indexed medical data variable from the displayed variable names.	Shaya (Grounds 1 & 2): claim 1[preamble]; claim 2[a]; 1:66-3:58; 4:42-57; 9:10-31; 10:36-11:48; Figs. 2-3, 5-9 Adams (Grounds 1 & 3): claim 1[preamble]; Figs. 2-4; 15, cl. 1; 17, cl. 2-18, cl. 1 Gappa (Ground 3): claim 1 [preamble]
'451 Claim Language	Prior Art Disclosures
 6. A method in a computer system for constructing, in response to user interface interactions by a user using a window-based user interface, a formula for deriving a medical conclusion from one of a plurality of time-indexed medical data inputs, the time-indexed medical data inputs each having events, the events each having multiple data components including a time, the method comprising the steps of: [a] receiving input via the window-based user interface identifying a 	<u>Shaya (Grounds 1 & 2):</u> ABSTRACT; 1:35- 59; 2:5-56; 2:59-3:22; 3:24-58; 4:20-57; 4:62-64; 5:10-26; 5:30-40; 6:8-8:36; 9:10- 31; 10:36-11:8; 11:12-48; Figs. 3; 5-7; Appendix A <u>Adams (Grounds 1 & 3):</u> 11, cl. 1-3; 12, cl. 1; 13, cl. 3; 14, cl. 2-3; 15, cl. 1-3; 16, cl. 1- 3; 17, cl 1-3; 18, cl. 1; 19, cl. 1; Figs. 2, 3; Table 1 <u>Gappa (Ground 3)</u> : claim 1 [preamble] <i>See</i> claim 2[b].
upon which the formula is to be based;	
[b] receiving via the window-based user interface an instruction identifying a time interval qualifying the events of the identified time-indexed medical data input;	<i>See</i> claim 1[a].
[c] receiving via the window-based user interface an instruction identifying a selection function for selecting one event from the events of the time-indexed medical data input qualified by the identified time interval;	Shaya (Grounds 1 & 2): claim 6[preamble]; 2:5-3:58; 4:42-57; 9:10-31; 10:36-11:48; 14:16-41; Figs. 2-3; 5-9; Appendix A Adams (Grounds 1 & 3): claim 6 [preamble]; 14, cl 3-15, cl 1; 16, cl 3; 17, cl. 2-18, col. 1; Figs. 2-4 Gappa (Ground 3): claim 1 [preamble]

[d] receiving via the window-based user interface an instruction identifying a data component of each event of the time-indexed medical data input; and	Shaya (Grounds 1 & 2): claim 1[b]; claim 2[b,c]; claim 6[preamble]; claim 6[c]2:5- 3:58; 4:42-57; 9:10-31; 10:36-11:48; Figs. 2-3, 5-9 Adams (Grounds 1 & 3): claim 6 [preamble]; 14, cl 3-15, cl 1; 16, cl 3; 17, cl. 2-18, col. 1; Figs. 2-4
	<u>Gappa (Ground 3)</u> : claim 1 [preamble]
[e] storing a formula for applying the identified selection function to events of the identified time-indexed medical data input whose effective times are within the identified time interval in order to select one of the events, and for extracting the identified data component of the selected event,	Shaya (Grounds 1 & 2): claim 1[e]; claim 6[preamble, a-d]; 3:24-38; 4:23-42; 4:43-53; 4:54-68; 5:30-40; 5:50-60; 8:59-66; 11:5- 12; 14:64-15:5. Adams (Grounds 1 & 3): claim 1[e]; claim 6 [preamble, a ,b, c, d]; 14, col 3; 15, col 1; 17, col. 2-18, col. 1; Figs. 2-4
[f] such that the formula may be used to derive and display a medical conclusion from the identified time- indexed medical data input.	<u>Shaya (Grounds 1 & 2):</u> claim 1[e-f]; claim 6[e]; 3:24-45; 6:39-44; 7:33-50 <u>Adams (Grounds 1 & 3):</u> claim 1[e-f]; claim 6 [e]

'451 Claim Language	Prior Art Disclosures
7. An apparatus for constructing, in response to input	See claim 1[preamble].
from a user using a window-based user interface, a	
formula for producing a textual patient information	
string from a selected time-indexed medical data	
variable having a value for each of a plurality of times.	
[sic] the method [sic] comprising the steps of:	
[a] a formula construction subsystem for constructing	Shaya (Grounds 1 & 2):
a formula for producing a displayable textual patient	ABSTRACT; claim
information string from a selected time-indexed	1[preamble, d-f]; claim
medical data variable;	2[b]; 2:9-13; 3:59-61;
	4:3-57; 4:62-64; 10:36-
	53; Figs. 5-9
	A dama (Crosseda 1 8 2)
	Adams (Grounds 1 & 3):
	claim I[preamble, d-f],
	claim 2[b], 11, cl. 1-2; 12,

	cl 1-14 cl 2. Fig 1
[b] a display device coupled to the formula construction subsystem to display via the window- based user interface names of a plurality of functions capable of aggregating a plurality of values into a single value;	Shaya (Grounds 1 & 2): claim 1[b]; claim 6 [preamble]; 3:55-4:20 Adams (Grounds 1 & 3): claim 1[b]; claim 6 [preamble]; 13, cl. 1-3, 14, cl. 1-2; 17, cl 3, Figs. 2-4
[c] an input device coupled to convey to the formula construction subsystem from the user:	<u>Shaya (Grounds 1 & 2):</u> 3:55-4:3; 9:10-38; Figs. 5-9
	Adams (Grounds 1 & 3): claim 1 [preamble],_14, cl. 1-2, 17, cl. 2-18, cl. 1; Figs. 2-4
[c][1] input specifying a period of time during which the medical data variable is to be analyzed,	See claim 1[a].
[c][2] input indicating that the user selected the name of a selected function from the displayed function names, and	See claim 1[c].
[c][3] input specifying a manner of manipulating a single value to produce a textual string conveying patient information; and	See claim 1[d].
[d] a memory coupled to the formula construction subsystem to store a formula that specifies:	Shaya (Grounds 1 & 2): claim 1[e,f]; claim 6[e]; 4:3-10; Figs 2, 3, 10-11
	Adams (Grounds 1 & 3): claim 1 [e, f] and 6[e].
[d][1] identifying values of the selected time- indexed medical data variable having times within the specified period of time,	<i>See</i> claim 1[a, e].
[d][2] applying the selected function to the identified values of the selected time-indexed medical data variable to aggregate the identified values into a single value, and	See claim 1[c, e]

[d][3] manipulating the single value in the specified	<i>See</i> claim 1[d, e, f]
manner to produce a textual string conveying	
patient information based on the values of the	
selected time-indexed medical data variable.	

'451 Claim Language	Prior Art Disclosures
8. The apparatus of claim 7 wherein the selected time-	See claim 2
indexed medical data variable is one of a plurality of	[preamble], claim 7
time-indexed medical data variables each having a name,	[preamble]
and	
[a] wherein the display device is also coupled to display	See claim 2[a] and
the names of the plurality of time-indexed medical data	claim 7[a, b].
variables, and	
[b] wherein the input device is also coupled to convey	See claim 2[b] and
input indicating that the user selected the name of the	7[b].
selected time-indexed medical data variable from the	
displayed variable names.	

VII CONCLUSION

The prior art references identified in this Petition provide new, non-cumulative technological teachings not previously considered, and they establish a reasonable likelihood of success as to Petitioners' assertions that claims 1, 2, 6, 7, and 8 of the '451 Patent are not patent eligible. Petitioners respectfully request institution of *inter partes* review for claims 1, 2, 6, 7, and 8 of the '451 Patent.

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Respectfully submitted,

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