UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ALLSCRIPTS HEALTHCARE SOLUTIONS, INC.;
CERNER CORP.;
CERNER HEALTH SERVICES, INC.;
EPIC HOSTING, LLC AND
EPIC SYSTEMS CORP.

Petitioners
v.

UNILOC LUXEMBOURG S.A.,

Patent Owner

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CASE IPR: UNASSIGNED

_____

PETITION FOR INTER PARTES REVIEW OF

U.S. PATENT NO. 5,682,526

CLAIMS 1-7, 10-19, AND 25

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.1-.80, 42.100-.123

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TABLE OF ABBREVIATIONS

Abbreviation	Explanation
’526 patent	U.S. Patent No. 5,682,526
’801 application	File history of U.S. Patent Application No. 08/504,801
Norden-Paul	U.S. Patent No. 4,878,175
Potter	U.S. Patent No. 4,733,354
Brimm	U.S. Patent No. 5,072,383
Musen	Mark A. Musen, Automated Generation of Model-Based Knowledge-Acquisition Tools, Pitman Publishing (1989)
Costar	COSTAR User Manual (March 1981)
Nolan	U.S. Patent No. 5,253,362
Salas	U.S. Patent No. 5,317,686
Petitioners	Allscripts Healthcare Solutions, Inc.; Epic Systems, Inc.; Cerner
Patent Owner	Uniloc Luxembourg S.A.
Office	United States Patent and Trademark Office
Exh. __	This refers to the indicated exhibit
__:__	This refers to the indicated column or page and lines of the patent or patent publication
EMR	Electronic Medical Record

EXHIBIT LIST

Exhibit Number	Exhibit
1001	U.S. Patent No. 5,682,526
1002	Excerpt of file history of U.S. Patent Application No. 08/504,801, File Wrapper Jacket
1003	Excerpt of file history of U.S. Patent Application No. 08/504,801, Notice of Allowability, March 14, 1997
1004	Excerpt of file history of U.S. Patent Application No. 08/504,801, Resp. to Office Action, August 15, 1996
1005	Excerpt of file history of U.S. Patent Application No. 08/504,801, Amendment and Reply, March 10, 1997
1006	Excerpt of file history of U.S. Patent Application No. 08/504,801, Office Action, June 6, 1996
1007	Excerpt of file history of U.S. Patent Application No. 08/504,801, Office Action Summary, October 26, 1996
1008	Excerpt of file history of U.S. Patent Application No. 08/504,801, Response to Office Action, February 5, 1997
1009	U.S. Patent No. 4,878,175 to Norden-Paul, et al.
1010	Mark A. Musen, Automated Generation of Model-Based Knowledge-Acquisition Tools, Pitman Publishing (1989)
1011	COSTAR User Manual (March 1981)
1012	U.S. Patent No. 5,253,362 to Nolan, et al.
1013	U.S. Patent No. 5,317,686 to Salas, et al.
1014	U.S. Patent No. 5,715,451
1015	U.S. Patent No. 4,733,354 to Potter, et al.

1016	U.S. Patent No. 5,072,383 to Brimm, et al.
1017	Declaration of Dr. Bryan Bergeron, M.D.
1018	Dr. Bryan Bergeron, M.D. *curriculum vitae*
1019	Claim charts
1020	Claim Construction Order, *Uniloc Luxembourg S.A. v. Compulink Business Systems, Inc.*, Case No. CV-11-10122 (C.D. Cal. Feb. 28, 2013)(Dkt. 96)
1021	Declaration of Mark R. Dambro, *Uniloc v. eClinicalWorks*, Case No. 2:13-cv-03244-MWF (C.D. Cal.)(Dkt. 78)
1022	Fiddleman, "Proliferation of COSTAR—A Status Report," The Mitre Corporation
1023	Certificate of Service

RULE 42.8 MANDATORY NOTICES

Real Parties-In-Interest (37 C.F.R. § 42.8(b)(1)): The real parties-in-interest are Allscripts Healthcare Solutions, Inc. ("Allscripts"); Epic Systems Corp., Epic Hosting LLC (collectively "Epic"); Cerner Corp., and Cerner Health Services, Inc. (collectively, "Cerner" and, together with Epic and Allscripts, "Petitioners"). Petitioners are not barred by operation of estoppel to submit this petition for *inter partes* review.

Related Matters (37 C.F.R. § 42.8(b)(2)): Uniloc Luxembourg S.A., the alleged owner by assignment of the '526 patent, asserts the '526 patent against Petitioners, and many other entities neither in privity with, nor real parties-in-interest to the 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-00626-RWS through 6:14-cv-00633-RWS, sequentially,[1] and Case No. 6:14-cv-00692-RWS.

The application that matured into the '526 patent was filed concurrently with an application that matured into U.S. Patent No. 5,715,451 ("the '451 patent"),

[1] Case No. 6:14-cv-00626-RWS, Case No. 6:14-cv-00627-RWS, Case No. 6:14-cv-00628-RWS, Case No. 6:14-cv-00629-RWS, Case No. 6:14-cv-00630-RWS, Case No. 6:14-cv-00631-RWS, Case No. 6:14-cv-00632-RWS, Case No. 6:14-cv-00633-RWS.

which allegedly "contains subject matter related to" the '526 patent. (Exh. 1014 at 1:5-11; 2:53-60.) The '451 patent was asserted in all of the cases listed above. *Inter partes* review of the '451 patent is requested concurrently herewith by way of a separate petition.

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

Petitioners provide the following designation of counsel:

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Grounds for Standing (37 C.F.R. § 42.104(a)): Petitioners hereby certify that the patent for which review is sought is available for *inter partes* review and that Petitioners are not barred or estopped from requesting *inter partes* review challenging the patent claims on the grounds identified in the petition. Petitioners were each served with a complaint asserting the '526 patent no earlier than July 25, 2014, and this petition is being filed on July 23, 2015.

Service Information (37 C.F.R. § 42.8(b)(4)): As identified in the attached Certificate of Service (Exh. 1023), a copy of the present Petition, in its entirety, is being served to the address of each attorney or agent of record.

I. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. § 42.22(A))

Petitioners request *inter partes* review and cancellation of independent claims 1, 4, 10, 11, and 14-15, and dependent claims 2-3, 5-7, 12-13, 16-19, and 25 of the '526 patent (Exh. 1001) based on one or more of the grounds under 35 U.S.C. §§ 102 or 103 set forth herein. Petitioners' detailed statement of the reasons for relief requested is set forth in §V, below.

II. THE '526 PATENT

A. The Technology

Methods of medical recordkeeping are as old as the medical profession itself. Electronic recordkeeping evolved as the use of computer technology

advanced in the 1980s, and maintenance of patient information databases were well-known before the early 1990s. (Exh. 1001 at 1:39-42.) For example, the COSTAR system is a medical charting system that was installed in over 50 medical sites before 1982. (Exh. 1022 at p. 176.)

The ’526 patent is concerned with just such methods for electronic recordkeeping; more specifically, to “methods for organizing, recording, and displaying patient information.” (Exh. 1001 at 1:66-2:1, and 3:14-15.) At its core, the ’526 patent claims methods for setting up an electronic table of patient medical observations (*e.g.*, blood pressure, heart rate) and/or medications (*e.g.*, Tylenol®) and allowing a clinician to input values for those observations and medications (*e.g.*, 120/80 or 80 beats/min; and 120 mg). (Exh. 1001 at 4:60-5:24, and 12:41-13:2.) These pieces of patient data are called “parameters.” Related observations and medications are logically grouped into categories or “hierarchies.” (Exh. 1001 at 2:9-15, 3:31-34, and 4:28-36.) For example, blood pressure is with heart rate and pulse oxidation because these are all vital signs. And the tables, having parameters along one axis and a time progression of values across another, are called, “flowsheets.” (Exh. 1001 at 1:19-28 and 8:37-55.)

Paper-based flowsheets having parameters logically grouped together had existed long before the ’526 patent’s July 1995 filing date. (Exh. 1001 at 1:19-21.) The invention of the ’526 patent seeks to solve problems with paper-based

flowsheets by putting these flowsheets into electronic form for electronic data entry via a general purpose computer. (Exh. 1001 at 1:30-38.) No particular hardware, software, or programming is necessary. Thus, while the ’526 patent purports to concern itself with the field of patient information, there is nothing patentably distinct about this type of information over any other type of data. Further, the methods employed in the ’526 patent were well-known in the art before the priority date of the ’526 patent.

B. Claims

The ’526 patent, entitled “Method and System for Flexibly Organizing, Recording, and Displaying Medical Patient Care Information Using Fields in a Flowsheet,” issued on October 28, 1997, from U.S. Application No. 08/504,801 (the “’801 application”) filed on July 20, 1995.

Independent claim 1 of the ’526 patent recites a method for organizing data in a hierarchy according to the user’s preferences. The method of claim 1 includes steps of (a) receiving an instruction from a user to create a parameter, (b) creating that parameter, (c) receiving an instruction to specify a result value for the parameter, (d) specifying that result value, (e) receiving an instruction from a user to link a desired result value with the parameter, and (f) linking the result value with the parameter.

Independent claim 4 is directed to a similar method of creating a patient information hierarchy, but the method specifically contemplates "result parameters" and "encapsulating parameters," rather than "linked-from" and "linked-to" parameters. The '526 patent explains that encapsulating parameters can group related parameters, for example, "encapsulating parameter 320 (Demerol) encapsulates encapsulated parameters 321, 322, 323, and 331 (dose, dose units, route, and site)." (Exh. 1001 at 5:20–23.)

Thus, claim 4 is directed at nothing more than a logical grouping of data (*e.g.*, putting blood pressure and heart rate under "vital signs"). Independent claim 10 is also a method of designing a patient information hierarchy, but the method of claim 10 further involves "maintaining" the contents of such a hierarchy, and also requires the data to be associated with one or more flowsheets, or information management forms. Independent claims 11, 14, and 15 are also directed to methods for designing and maintaining the contents of a patient information hierarchy and are just minor variations of claims 1, 4, and 10.

As discussed in greater detail below, dependent claims 2-3, 5-7, 12-13, 16-19, and 25 are minor variations of the independent claims discussed above, and do not reflect independently patentable subject matter.

C. Priority Date

The ’526 patent issued from the ’801 application (Exh. 1002), filed on July 20, 1995. The ’801 application does not include any priority claim to another application. Therefore, the effective filing date for the asserted claims of the ’526 patent is July 20, 1995.

D. Prosecution History

During prosecution, the Office rejected all of the claims of the ’526 patent as anticipated by United States Patent No. 4,878,175 (“Norden-Paul”) (Exh. 1009). In an attempt to overcome the rejection, the Patentee argued that the claimed “linking” of parameters was not the same as that described by the prior art. (*See, e.g.* Exh. 1002 at pp. 7-8). However, as discussed below, the Examiner failed to consider all the variations of “linking” taught by Norden-Paul.

Further, the Patentee added additional claim limitations in an effort to re-center the claims around a “flowsheet” model, and in some embodiments further limited the flowsheet to include particular fields for user notes, and amended the title to reflect the re-centering . (Exh. 1008 at pp. 2-4, and Exh. 1003 at p. 2.) The prosecution history thus reflects that the other record management steps claimed in the ’526 patent were already known in the art, and only the addition of the “flowsheet” functionality was considered patentably distinct from the prior art.

As Petitioners' expert, Dr. Bryan Bergeron, describes in his declaration (Exh. 1017),[2] the prior art discloses the same record management, organization, recording and display functions that the Office previously found to be known in the art, as well as the flowsheet functionality.

In view of the foregoing and for the reasons discussed herein, *inter partes* review of the claims of the '526 patent is warranted to give the Office an opportunity to consider the validity of these claims in view of the prior art references discussed below.

III. A PERSON OF ORDINARY SKILL IN THE ART

As confirmed in Dr. Bergeron's declaration, the art of the '526 patent relates generally to electronic records management. A person of ordinary skill in this art would have an advanced degree in computer science or medical informatics, as well as several years of experience designing or using electronic record management systems. (Exh. 1017 at ¶¶ 18, and 19.)

IV. CLAIM CONSTRUCTION

Pursuant to 37 C.F.R. § 42.100(b), a challenged claim must be given its broadest reasonable construction in light of the specification of the '526 patent. Claim construction issues related to the '526 patent were previously addressed by

[2] In support of this petition, Petitioners file herewith the declaration of technical expert Dr. Bryan Bergeron, M.D., Fellow of the American College of Medical Informatics. ("Bergeron Dec.") (Exh. 1017.)

the U.S. District Court for the Central District of California in *Uniloc v. Compulink Business Systems, Inc.* (2:11-cv-10122; 2:13-cv-03246; 2:13-cv-03244) (Exh. 1020.) In the *Compulink* litigation, the court defined (or declined to define) the following terms:

Claim Term	Court Construction
"patient information hierarchy"	An organization of information related to a patient that is arranged into categories and one or more subcategories
"parameter"	Piece of patient information
"local parameter"	A parameter where each instance of the parameter is independent from one another and where each instance of the parameter can have different values for a given patient
"represent them together at a higher conceptual level	Group together parameters
"encapsulating parameter"	No construction necessary
"encapsulated parameter"	No construction necessary
"result parameter"	A parameter that may contain a result value for a particular patient at a particular time
"create a new parameter"	No construction necessary
"parameter identifier"	No construction necessary
"result value"	Data relating to a patient
"user"	No construction necessary
"author name field"	No construction necessary
"time field"	A field that holds a time and may also hold a date

The broadest reasonable construction is at least as broad as the *Compulink* court's constructions. While Petitioners do not believe that one of ordinary skill in the art would construe these terms exactly as the *Compulink* court did, Petitioners

assert that, even taking the constructions in their entirety as set forth by the *Compulink* court, one of ordinary skill in the art would still find the '526 patent claims to be invalid. For the purposes of this petition, Petitioners have used the constructions as dictated by the *Compulink* court.[3]

V. IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(B))

Inter partes review of claims 1-7, 10-19, and 25 of the '526 patent is requested based on the following grounds for invalidity. Pursuant to 37 C.F.R. § 42.6(d), copies of the references are filed herewith.

Ground 1: Claims 1-3, 10, and 25 are anticipated by United States Patent No. 4,878,175 ("Norden-Paul") (Exh. 1009).

Ground 2: Claims 1-3 are obvious over Norden-Paul in view of U.S. Patent No. 4,733,354 ("Potter") (Exh. 1015).

Ground 3: Claims 10 and 25 are obvious over Norden-Paul in view of U.S. Patent No. 5,072,383 ("Brimm") (Exh. 1016).

Ground 4: Claims 4-7 are anticipated by Mark A. Musen, Automated Generation of Model-Based Knowledge-Acquisition Tools, Pitman Publishing (1989) ("Musen") (Exh. 1010).

Ground 5: Claims 4-7 are obvious over Musen in view of Norden-Paul.

[3] Petitioners reserve the right to address other possible constructions or provide further information supporting alternative constructions in the event that the Patentee argues that different constructions should apply at this stage.

Ground 6: Claims 11-13 are anticipated by the COSTAR User Manual ("COSTAR") (Exh. 1011).

Ground 7: Claims 11-13 are obvious over COSTAR in view of Norden-Paul.

Ground 8: Claim 14 is anticipated by U.S. Patent No. 5,253,362 ("Nolan") (Exh. 1012).

Ground 9: Claim 14 is obvious over Nolan in view of Norden-Paul.

Ground 10: Claims 15-19 are obvious over Norden-Paul in view of U.S. Patent No. 5,317,686 ("Salas") (Exh. 1013).

A. Ground 1: Claims 1-3, 10, and 25 are Anticipated by Norden-Paul

Claims 1-3, 10 and 25 are anticipated by Norden-Paul (Exh. 1009). As discussed above in Section II.C., the priority date for the '526 patent claims is July 20, 1995. Norden-Paul issued on October 31, 1989 from an application filed on November 3, 1987. Accordingly, Norden-Paul is prior art under 35 U.S.C. § 102(b). In addition to the discussion below, the anticipating disclosures of the prior art relied upon here are summarized in a claim chart found in Section V.J.

1. Claims 1-3

a. The Patentee Did Not Contest Norden-Paul's Teaching of Any Element of Claims 1-3 Except "Linking"

During prosecution of the ’526 patent, the Office found that Norden-Paul teaches each and every element of claims 1-3. (Exh. 1005 at pp. 2-3, and Exh. 1007 at pp. 2-4, and 12.) Specifically, the Office found that Norden-Paul teaches user-controlled functionality and content, hierarchical data arrangement and encapsulation, determining possible result values for a parameter, linking parameters, default values, flowsheets, flowsheet subsets, flowsheet cells with multiple data types, and display options. (Exh. 1007 at p. 3.) As shown more particularly in the claim chart in Section V.J, *infra*, Norden-Paul, in fact, provides multiple disclosures of each of these elements.

The Patentee itself did not contest the presence of any element of claims 1-3 in Norden-Paul except element (f) of claim 1, which requires “linking the indicated linked-from possible result value to the indicated linked-to parameters.” (Exh. 1004 at pp. 7-8.) In accepting the Patentee’s argument, the Examiner failed to consider all the variations disclosed in the prior art, and the fact that the “linking” function is expressly taught by Norden-Paul.

b. Norden-Paul Teaches The Claimed “Linking” Functionality

“Linking” functionality is the most basic building block of any organizational system, whether computerized or manual, and merely involves associating one piece of data (“parameter”) with another. (Exh. 1017 at ¶ 31.) For example, as the ’526 patent indicates the parameter “cough” may be linked with

the parameter "endotracheal tube," such that a nurse taking a patient history for someone who has a cough may note the presence of an endotracheal tube. (Exh. 1001 at 5:55-61.)

During prosecution, the Office rejected the '801 application on the grounds that "linking" as claimed in claims 1-3 was taught by Norden-Paul. (Exh. 1006 at p. 2) (citing Norden-Paul col. 8, lines 41-44). In its response, the Patentee argued that the linking function described by the cited passages of Norden-Paul was different than the claimed linking step. (Exh. 1004 at pp. 7-8.) The Examiner's rejection and the Patentee's argument, however, failed to address the most explicit discussions of linking parameters disclosed in Norden-Paul.

Looking at the specific requirements of claim 1, Norden-Paul discloses a "HOSPITAL UNIT" parameter (*i.e.*, "the new parameter") with values such as "CARDIAC" and "9NBURN" (*i.e.*, "the possible result values of the new parameter"), and it also discloses the "CO" parameter (*i.e.*, "one or more indicated linked-to parameters contained within the patient information hierarchy"). (Exh. 1009 at Fig. 8.) As shown in Figure 8, the user tells the system to connect the "CARDIAC" and/or "9NBURN" result values with the "CO" parameter by entering them in fields 290–293 of the "CO" parameter's Vital Signs Parameters Table (*i.e.*, "receiving an instruction from the user to link [a linked-from result

value] to [a linked-to parameter] and in response [linking the linked-from result value to the linked-to parameter]"). (*Id*.)

Furthermore, Norden-Paul states, "…if the indication in field 289 had been 'Yes' and the "CARDIAC UNIT" had been indicated in field 290, then ***the 'CO' parameter would automatically appear in every Vital Signs Form*** for each patient admitted to the Cardiac Unit." (Exh. 1003 at 13:57-14:6, emphasis added.) In other words, as a consequence of adding "CARDIAC UNIT" to field 289 of the "CO" parameter's Vital Signs Parameters Table (*i.e.*, the claimed "instruction from the user to link…"), whenever "CARDIAC UNIT" is shown as the value of the "HOSPITAL UNIT" parameter on the flowsheet *(i.e.*, "when the new parameter is displayed for a particular patient, if the new parameter has the linked-from possible result value"), the "CO" parameter will also be displayed on the flowsheet (*i.e*., the linked-to parameters are displayed in conjunction with the new parameter). (Exh. 1017 at ¶¶ 33, and 34.)

2. Claim 10

Independent claim 10, as the patentee stated during prosecution, is directed to "setting all of the parameters in a flowsheet group to preselected values, such as their normal result values, in response to a single instruction from the user." (Exh. 1004 at p. 9.)

This is precisely what Norden-Paul teaches. With regard to default values, Norden-Paul teaches, for example, that "[t]he source list fields 281-284 are used to provide a set of names of patient device data channels which *can be used to default the value of the parameter* when the user is charting it." (Exh. 1009 at 13:42-45; emphasis added.) The source list is used to generate the candidate list of sources 173 (FIG. 5) presented to the system user when the system user is adding a parameter." (Exh. 1009 at 13:42-47.) With regard to the instruction from the user, Norden-Paul teaches, as the Office noted during prosecution, that "[t]he instruction from the user to set the normal result values for the specified patient of the displayed parameters specified by the selected flowsheet group of the selected flowsheet is made by specifying a "Yes" in the "Pre-printed" value, which causes the default result values to be placed on the forms associated with the specified patient." (Exh. 1007 at p. 15.)

The Patentee argued in response to the Office's rejection on these grounds only that the "pre-printed" values taught by Norden-Paul are not specifically described to be "stored for the parameter" as required by the claim language. (Exh. 1008 at p. 7.) The storing of result values, however, is inherent in the Norden-Paul system—a system with the sole purpose of recording medical information, which necessarily requires storage. (Exh. 1017 at ¶ 48.)

The fact that the patentee recognized that such storage in fact took place in earlier systems and included such an element in the ’526 claims is insufficient to impart patentability. *See In re Swinehart*, 439 F.2d 210, 212-13 (CCPA 1971) (“[T]he mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.”) Claim 10 is accordingly anticipated by Norden-Paul.

3. Claim 25

Claim 25, which depends from claim 10, is similarly anticipated by Norden-Paul. Claim 25 further limits claim 10 by specifying that the “associating step associates with the plurality of the parameters specified by the selected flowsheet group of the selected flowsheet normal result values for these parameters.” (Exh. 1001 at 20:5-8.) Norden-Paul teaches that “[t]he pre-printed field 289 is used to indicate whether the parameter is to be pre-printed (*i.e.,* default filled) on the Form when the patient is first admitted to the system.” (Exh. 1009 at 13:57-59.) This is precisely the scenario contemplated by claim 25—a patient arrives at the hospital, and the system user has the option to, with a single command, populate the fields of a flowsheet with “default” or “normal” values. By Patentee’s own admission during prosecution, this is the very situation the claim was designed to cover. Since Norden-Paul teaches this very solution, it necessarily anticipates the claim.

Based on the foregoing, because each element of claims 1-3, 10 and 25 is taught by Norden-Paul, there is a reasonable likelihood that these claims will be found to be anticipated by Norden-Paul, and Petitioners respectfully request the institution of review under 35 U.S.C. §314(a).

B. Ground 2: Claims 1-3 are obvious over Norden-Paul in view of Potter

Even in the event that the Office finds that the claimed linking is not taught by Norden-Paul, it was taught by numerous other prior art references at the time of filing of the '801 application, and a person of ordinary skill in the art would have had a reason to incorporate it into the method of Norden-Paul. For example, Potter, which was filed on November 23, 1984 (and is thus prior art under 35 U.S.C. 102(b)), expressly teaches that a user may use a computer system to construct a patient information hierarchy by entering text describing symptoms or medical data and *linking* each symptom to other parts of the hierarchy using field codes at the beginning of the data file. (Exh. 1015 at Figs. 3, and 7a-7e.) Potter discloses a system where the user is asked a series of questions—that is, asked to assign values to a list of parameters—wherein each of the parameters (*e.g.*, epidermal) has multiple possible result values (*e.g.*, lam. hyper, ker.fol. plug). (*Id.*) Each of these possible result values is *linked* to a second set of parameters, which are the linked-to parameters. (*Id.*)

An example of Potter's method is shown in Fig. 3, which shows "a decision tree hierarchical arrangement" and Figs. 7a through 7e, which "are reproductions of data displayed on a terminal according to the present invention in which one diagnosis in dermal pathology is made." (Ex. 1015 at 3:26–28.) Figure 3 shows the hierarchy designed by the user wherein a second parameter is connected to the result value of a first parameter (*i.e.*, "receiving an instruction from the user to link…"). Putting the hierarchy into action, Fig. 7a shows that the user is presented with three possible values for a first parameter, including "1 EPIDERMAL" and "2 DERMAL" (*i.e.*, each a "linked-from possible result value"). (*Id*. at Fig. 7a.) Having selected "CHOICE 2" ("DERMAL"), the user is then presented with another parameter (*i.e.*, the "linked-to" parameter) with its own set of possible result values, including "1 EPITHELIAL PROLIFERATION" (*i.e.*, "if the new parameter has the linked from possible result value, the linked-to parameters are displayed in conjunction with the new parameter). (*Id*. at Fig. 7b.)

One of ordinary skill in the art would have been motivated to combine the flowsheet model of Norden-Paul with the linking of Potter because both references teach medical data management systems and the manipulation of patient data to process information using a user interface. (Exh. 1015 at Abstract; Exh. 1017 at ¶ 52.) A skilled artisan would thus have been motivated to combine these

references, and the combination would have represented a set of predictable combinations using known functions to yield expected results. (Exh. 1017 at ¶ 54.)

C. Ground 3: Claims 10 and 25 are Obvious over Norden-Paul in view of Brimm

Even in the event that the Office finds that the use of default values by Norden-Paul does not disclose receiving an instruction from the user to set a parameter's result value to a predetermined (Claim 10)—including a normal (claim 25)—result value, claims 10 and 25 are nonetheless obvious over Norden-Paul in view of U.S. Patent No. 5,072,383 to Brimm et al. ("Brimm"), which issued on Dec. 10, 1991 (and, thus, is prior art under 35 U.S.C. 102(b).) Brimm is highly related to Norden-Paul, as it has the same assignee, its inventors include all of Norden-Paul's inventors, and it explicitly identifies Norden-Paul as a Related Invention. (Exh.1016 at [73], [75], and 1:10–15.)

For example, Brimm discloses that, in the "Orders" section of the medical-records system, a user can create an order for a particular medication by, among other steps, selecting its name from a pop-up menu. (Exh. 1016 at Fig. 5.) The act of clicking on the medication's name results in an instruction to populate the drug's name on the order form and, as a result, to populate a number of related fields with predetermined, normal values for those fields: "The physician then selects from list 265 which medication (*e.g.* Valium) is to be prescribed by placing cursor 200 over the designation 'Valium Tablet' and selecting with the pointing

device… The system may default certain entry fields, such as 'Route', 'Dose', and 'Frequency' to values conforming to hospital protocol for a given order." (Exh. 1016 at 9:16–35.)

One of ordinary skill in the art would have been motivated to combine the flowsheet model of Norden-Paul with Brimm's use of a user instruction to apply predetermined, normal values because both references teach components of the same—or at least a very similar—medical data management systems and the manipulation of patient data to process information using a user interface. (Exh. 1017 at ¶ 56.) Furthermore, one of ordinary skill would have had reason to combine Brimm with Norden-Paul because the use of Brimm's predetermined default values would have reduced the amount of data entry, which directly furthers Norden-Paul's goal of "maximize[ing] the productivity of hospital staff." (Ex. 1009 at 2:24; Exh. 1017 at ¶ 58.) A skilled artisan would thus have been motivated to combine these references, and the combination would have represented a set of predictable combinations using known functions to yield expected results. (Exh. 1017 at ¶ 58.)

D. Ground 4: Claims 4-7 are Anticipated by Musen

Claims 4-7 are anticipated by Musen (Exh. 1010). As discussed above in Section II.C., the priority date for the '526 patent claims is July 20, 1995. Musen was published in 1989, and is therefore prior art under 35 U.S.C. § 102(b).

1. Claim 4—Musen Teaches "Encapsulating Parameters"

The Patentee described the method of claim 4 during prosecution as centered around the concept of "encapsulating parameters." (Exh. 1004 at p. 8.)

"Encapsulating" parameters are simply "heading" parameters that encompass related points of data. For example, the '526 patent provides that the drug "Demerol" is an encapsulating parameter, which encapsulates data comprising the dose, dose units, route, and administration site for the drug. (Exh. 1001 at 5:20-25.)

Such encapsulating parameters were well known in the art before the priority date of the '526 patent. For example, Musen teaches the creation of a new data "class," which is an encapsulating parameter for data items. The data class taught by Musen is identified by a parameter name and a list of encapsulated parameters, which are added to a hierarchy via the "data items" form. A user can create a data class including first and second result parameters. (Exh. 1010 at pp. 15, and 174-175.) One of ordinary skill in the art would understand the data classes of Musen to be encapsulating parameters, in that they are groupings of patient information represented together under a common heading or class. (Exh. 1017 at ¶ 62.)

As one example, Figure 1.8 of Musen shows the method of claim 4 as applied to cancer therapy. (Exh. 1010 at p. 15.) In Figure 1.8, the user has previously specified that clinical trials have a class of input data called "chemistry

data." The form in Figure 1.8 shows the data items that the user has determined are relevant in the chemistry data class—laboratory tests that measure the concentration of various substances in the blood such as glucose, sodium, potassium, etc. (Exh. 1010 at pp. 14-15.) Those blood content parameters are encapsulated into the level of "chemistry data," which can be displayed as a list of blood chemistry tests. (Exh. 1010 at p. 15.) This is precisely the scenario contemplated by claim 4 of the '526 patent and described by the Patentee as the only novel feature of claim 4—*i.e.*, the creation of an encapsulating parameter. (Exh. 1017 at ¶ 63.) Such encapsulating parameters and their encapsulated parameters are displayed together on a flowsheet, such as those shown for the "Hematology" encapsulating parameter in Figure 1.2.

Furthermore, each other element of claim 4 is similarly taught by Musen. Musen teaches a user-defined patient hierarchy using prior art systems OPAL, PROTÉGÉ, and ONCOCIN. (Ex. 1017 at ¶ 65.) The user can add a plurality of parameters, such as data items that have result values and that may be displayed in a flowsheet. The hierarchy also, as discussed above, includes encapsulating parameters that identify the result parameters and represent them in a higher conceptual level. The conceptual levels are shown both in the forms used to create the hierarchy and the flowsheets that are output from the hierarchy. (Exh. 1017 at ¶ 65.)

Based on the foregoing, because each element of claim 4 is taught by Musen, there is a reasonable likelihood that at least claim 4 will be found to be anticipated by Musen, and Petitioners respectfully request the institution of review under 35 U.S.C. §314(a).

2. Claim 5

a. Musen Discloses Receiving an Instruction to Expand the First Encapsulating Parameter

Dependent claims 5-7 add further limitations to claim 4. Claim 5 adds the step of "receiving an instruction from the user to expand the first encapsulating parameter." (Exh. 1001 at 14:6-7.) Musen teaches this step. More particularly, Musen teaches that encapsulating parameters may be enlarged by selecting a particular data class which is then expanded, such as the "radiotherapy" header in Figure 1.2. (Exh. 1010 at 6, and 93.) One of ordinary skill in the art would understand that the selection and expansion of the "radiotherapy" header to show the encapsulated patient information to be "receiving an instruction from the user to expand the first encapsulating parameter." (Exh. 1017 at ¶ 69.) Thus, Musen teaches this limitation of claim 5.

b. Musen Teaches Displaying Both the Encapsulated Parameters and the First Encapsulating Parameter

Claim 5 further adds the limitation that "in response to step (i), displaying the encapsulated parameters of the first encapsulating parameter, including the first result parameter, in conjunction with the first encapsulating parameter." As

discussed above, Musen teaches displaying the encapsulated parameters by selecting a particular data class, such as "radiotherapy" in Figure 1.2, to display all of the data items. (Exh. 1010 at 6.) Furthermore, Musen teaches the inclusion of a "first result parameter," as that term was construed by the District Court for the Central District of California. In that case, the Court construed "result parameter" to mean a "parameter that may contain a result value for a particular patient at a particular time." (Exh. 1020 at 10-11.) Musen teaches the display of a flowsheet that a user uses to enter time-oriented data concerning individual patients. (Exh. 1010 at 5.) One of ordinary skill in the art would understand that Musen teaches that the encapsulated patient data is displayed in response to user input, and it can include a result parameter display in a flowsheet. (Exh. 1017 at ¶ 70.) Thus, Musen teaches this limitation of claim 5.

3. Claim 6—Musen Teaches Collapsing the First Encapsulating Parameter

Claim 6 further limits claim 5 by requiring receipt of an instruction to collapse the first encapsulating parameter, followed by a display without the encapsulating parameters, including the first result parameter. (Exh. 1001 at 14:15-22.) Musen also teaches this limitation. In particular, Musen discloses the presence of an icon— —that when clicked, condenses the data types by collapsing the encapsulated parameters, resulting in a display of only the

encapsulating parameters. (Exh. 1010 at pp. 6 and 93). Thus, Musen teaches this limitation of claim 6.

4. Claim 7—Musen Teaches Displaying the Result Value for the First Encapsulating Parameter

Claim 7 further limits claim 4 by requiring the receipt of an instruction to display a result value for a selected encapsulated parameter, and displaying the result value for the selected encapsulated parameter as the result value for the encapsulating parameter. (Exh. 1001 at 14:23-29.) Musen also teaches this limitation. For example, Musen discloses setting a "show always" parameter to "yes," making the data item—*i.e.*, the "result value"—appear in the flowsheet when other items do not. (Exh. 1010 at pp. 172-173) ("Although both static and dynamic data can be printed by the e-ONCOCIN Interviewer on the graphical flowsheet, PROTÉGÉ's model also assumes that display of a particular data item can be disabled optimally. Thus, if the "*Show Always?*" property is set to *NO*, the e-ONCOCIN Interviewer will not create a row in which to display the item if there are no data values to display. This property allows the knowledge engineer to distinguish between routine data items that should always appear on the flowsheet (whether any data have been recorded for these items or not) and less customary user entries.") Thus, Musen teaches this limitation of claim 7.

Based on the foregoing, because each element of claims 5-7 is taught by Musen, there is a reasonable likelihood that at least these claims will be found to

be anticipated by Musen, and Petitioners respectfully request the institution of review under 35 U.S.C. §314(a).

D. Ground 5: Claims 4-7 are Obvious Over Musen in view of Norden-Paul

Even in the event that the Office finds that each element of claims 4-7 is not taught expressly or inherently by Musen alone, despite the explanation above, claims 4-7 would have nevertheless been obvious over Musen, alone or in view of Norden-Paul. Norden-Paul expressly or inherently discloses arranging parameters of varying data types in an encapsulating-encapsulated format, and displaying parameters and their values in a flowsheet hierarchical display in a user-selected display format. More particularly, Norden-Paul teaches expansion of encapsulated parameters, stating: "The additional parameters . . . are not limited in number or type, but they may be expanded, modified, or deleted at the option of the system administrator." (Exh. 1009 at 11:9-13.) Norden-Paul also teaches that the display may be modified to show only the encapsulating parameter, or also the encapsulated parameters. For example, the encapsulating parameter "MEDS," can be displayed alone, or with its encapsulated parameters (for example, "Diazepam") by deselecting "MEDS" and selecting, for example, "VITALS"). (Exh. 1009 at Fig. 3.)

One of ordinary skill in the art would have been motivated to combine the Musen with Norden-Paul because both references teach medical data management systems and the manipulation of patient data to process information using a user interface. (Exh. 1017 at ¶ 75.) A skilled artisan would thus have been motivated to combine these references, and the combination would have represented a set of predictable combinations using known functions to yield expected results. (Exh. 1017 at ¶ 75.)

E. Ground 6: Claims 11-13 are Anticipated by COSTAR

Claims 11-13 would have been anticipated by COSTAR (Exh. 1011). As discussed above in Section II.C., the priority date for the '526 claims is July 20, 1995. COSTAR was published in March 1981, and is therefore prior art under 35 U.S.C. § 102(b). COSTAR was previously authenticated in the *eClinicalWorks* case, as set forth in the Declaration of Mark Dambro. (*See* Exh. 1021).

1. Claim 11

Claims 11-13 are directed to parameters—either "global" or "local"—that are located at different points in the patient information hierarchy but that have the same name or identifier. (Exh. 1004 at p. 9.) For example, the '526 patent provides that "route of administration" is a local parameter that may occur in different places of a hierarchy, such as once under Tylenol and once under Clonidine, with different values but the same identifier. (Exh. 1004 at p. 6.) More

particularly, "these claims recite creating global parameters at a first and second location in the patient information hierarchy that are both identified by a single first parameter identifier, and creating local parameters at a third and a fourth location in the patient information hierarchy that are identified by a second and third parameter identifier, respectively." (Exh. 1004 at 9.) As discussed in further detail below, each element of these claims is taught by COSTAR, which describes a system sold extensively over a decade before the priority date.

a. COSTAR Teaches a Hierarchy With a Plurality of Named Parameters Identified by Parameter Identifiers that May Contain Result Values for a Particular Patient

Claim 11 is directed to a method for designing and maintaining the contents of a patient information hierarchy containing a plurality of named parameters that have parameter identifiers that may contain result values for a patient. (Exh. 1001 at 15:10-38.) More particularly, COSTAR teaches a sample report wherein codes are used to identify parameters as described by Claim 11. (Exh. 1011at pp. A-1-A-3.) The codes operate as "parameter identifiers" for such conditions as "back pain," "drug allergy (penicillin)," "tension headache," or "tobacco addiction." (*Id*.) Furthermore, the codes contain result values, such as a value of "98.6" for the parameter "temperature (T)." (*Id*.) Thus, COSTAR teaches parameter identifiers as required by claim 11. (Exh. 1017 at ¶ 78.)

b. COSTAR Teaches Global and Local Parameters According to Claim Limitation 11(a)

Claim 11 further requires that a user must give instructions to create a parameter at a first (global) location in the hierarchy and a second (local) location in the hierarchy. (Exh. 1001 at 15:16-21.) COSTAR teaches both. More particularly, COSTAR discloses that the patient identification and header information are global parameters. The result values for these parameters never change despite whatever location they might have in the hierarchy or medical record. For example, date of birth is clearly a global parameter, and its result value never changes despite its location in the hierarchy or medical record. (Exh. 1011 at 3, 48, and 97.) Thus, COSTAR teaches this element of claim 11. (Exh. 1017 at ¶¶ 79, and 80.)

c. COSTAR Teaches that the Local and Global Parameters are Both Identified by a First Parameter Identifier

Claim 11 further requires that both the local and global parameters are identified by a single parameter identifier. (Exh. 1001 at 15:22-25.) The Patentee explained this concept during prosecution using the example of a "route of administration" parameter:

> Parameters with the same name occurring at different points in the patient information hierarchy may either be global parameters, which always contain the same values for a given patient, or local parameters, which can

> contain different values for the same patient. For example, the local parameter "route of administration" may occur once in the hierarchy for the drug Tylenol and once in the hierarchy for the drug Clonidine. The occurrence of this local parameter for the drug Tylenol can have the value "suppository," while the occurrence of this local parameter for the drug Clonidine may have a different value, such as "pro ora." A global parameter such as "blood pressure," on the other hand, has the same value at each point in the hierarchy at which it occurs.

(Exh. 1004 at p. 6.)

The COSTAR manual teaches the exact same parameters for blood pressure and for medication administration information. For example, COSTAR teaches a blood pressure parameter entry, which is a global parameter. (Exh. 1011 at pp. 34, and 37.) Further, COSTAR confirms that the parameters for medications are global parameters and the parameters for dose, route, frequency, directions, quantity, and refills are all local parameters, which nevertheless have the same identifier. (Exh. 1011 at pp. 14, 18, 43,44,61,68, 69, 102, 114, and A-3.) Thus, COSTAR teaches this element of claim 11. (Exh. 1017 at ¶¶ 81, and 82.)

d. Performing the Same Process Multiple Times Would Have Inherently Occurred in Performance of the COSTAR Method

Claim 11, elements (c) and (d) simply require the same steps that occurred in elements (a) and (b) to be reiterated with a third and fourth location and a second

identifier. (Exh. 1001 at 15:26-38.) The operation of the COSTAR system as described in the COSTAR user manual would necessarily dictate that the steps of identifying and displaying, as described in sections (b) and (c) immediately above, would be performed more than once. As explained by Dr. Bergeron, if there were not more than two parameters to be identified, there would be such little patient information that the hierarchy described by COSTAR would have no purpose. (Exh. 1017 at ¶¶ 83, 84, and 88.) Accordingly, the steps would have inherently been performed more than once, at a third and fourth location, in the use of the COSTAR software. (Exh. 1017 at ¶ 85.)

2. Claim 12

a. Receiving and Storing Functions are Taught by COSTAR

Claim 12 further limits claim 11 by requiring eight additional steps, directed to *receiving* and *storing* the result values for the parameters of claim 11. (Exh. 1001 at 15:39-67.) As explained below, the receiving, storing, retrieving, and displaying functions are expressly taught by COSTAR.

Receiving and storing results for a patient using identifiers is a principal function of the COSTAR system, and is taught throughout the COSTAR User Manual. For example, COSTAR teaches that "[w]hen you enter data from the Encounter Form, the preferred method is to enter the COSTAR code or code names for each principal term and modifier . . . Because it is more efficient for the

COSTAR system to use codes to store and retrieve information rather than long words or groups of words, a major function of the Directory is to identify the proper code assigned to a term." (Exh. 1011 at p. B-1.) Thus, COSTAR teaches the receipt and display of result values. Further, COSTAR discloses receiving a first result value for a parameter having the first name at the first location in the patient information hierarchy because COSTAR teaches a "flowchart format" where the flowsheets show parameters, each having more than one result value. (Exh. 1011 at pp. 112, 114, and 122.)

b. Iterations of Receiving and Storing Functions are Taught by COSTAR

Claim 12 further requires that the claimed receiving and storing functions discussed above be reiterated with respect to a third result value for a parameter at a third location, and a fourth result value for a parameter at a fourth location. (Exh. 1001 at 15:56-67.) This, too, is taught by COSTAR. In particular, COSTAR discloses a "List for the Medications Line Items," wherein the local parameters have separate result values. (Exh. 1011 at p. A-3.) COSTAR further discloses a fourth result value for the medication parameter in the "Display Medical Data Option > Interactive Flowchart" display. (Exh. 1011 at p. 114.) While one of ordinary skill in the art would understand the additional instances of receiving and storage to expressly teach the iterative elements of claim 12 (Exh. 1017 at ¶ 84), the iterations of the receiving and storage steps are inherently taught by COSTAR

for the reasons discussed above with regard to claim 11—*i.e.*, there would be such little patient information that the hierarchy described by COSTAR would have no purpose. (Exh. 1017 at ¶ 87.)

3. Claim 13

a. Retrieving and Displaying Functions are Taught By COSTAR

Claim 13 further limits claim 12 by adding an additional eight steps, directed to *retrieving* and *displaying* the values stored in claim 12. This, too, is an integral function of the COSTAR system. There would be no reason to create and store patient information in electronic databases or flowcharts as described by COSTAR unless such data could be retrieved and viewed (*i.e.*, displayed) by a user. (Exh. 1017 at ¶ 88.) More particularly, COSTAR expressly discloses the use of flowsheets for displaying parameters. (*See, e.g.*, Exh. 1011 at pp. 6, 7, 111-115, and 122.) In addition, COSTAR discloses retrieving data for display. For example, Section 4, entitled "Retrieving Medical Data," includes pages that show the display of various global and local parameters in several report format options, including flowsheets. (Exh. 1011 at p. 94.) Some of these display options teach global parameters because these pages show parameters with the same result value despite hierarchy location. (Exh. 1011 at pp. 112, 114, and 122.) For example, as discussed above with regard to claim 11, "date of birth" is taught as a global

parameter in that the result value does not change despite location in the hierarchy or medical record. (Exh. 1011 at pp. 3, 48, and 97.)

Based on the foregoing, because each and every element of claims 11-13 is taught by COSTAR, there is a reasonable likelihood that at least these claims will be found to be anticipated by COSTAR, and Petitioners respectfully request the institution of review under 35 U.S.C. §314(a).

F. Ground 7: Claims 11-13 are Obvious Over COSTAR in View of Norden-Paul

Even in the event that the Office finds that each element of claims 11-13 is not taught expressly or inherently by COSTAR alone, despite the explanation above, claims 11-13 would have nevertheless been obvious over COSTAR, alone or in view of Norden-Paul. Claim 11 adds local and global parameters to the methods of creating data hierarchies, and claims 12-13 add functionality associated with receiving, storing, retrieving, and displaying data. To the extent the Office finds that these are not taught by COSTAR, Norden-Paul teaches each. Norden-Paul teaches local parameters (such as "temperature" in the chart at Exh. 1012 at Fig. 4), and global parameters (patient name and unit number stay the same from place to place in the hierarchy, as shown in Exh. 1012, Figs. 3-4). Norden-Paul further teaches that the flowsheet receives and stores result values (for example, past blood pressure values are stored in Fig. 4), and retrieves and displays the patient data upon a user command (Exh. 1012 at 9:15-29).

Furthermore, a skilled artisan at the time of filing the ’526 patent would also have been motivated to combine COSTAR User Manual with Norden-Paul. Like COSTAR, Norden-Paul discloses a system and method for processing medical data with specific parameter creation capability along with flowsheet display and charting. (Exh. 1017 at ¶ 91.) Norden-Paul specifically discloses a system and method for a user to organize patient information into a hierarchy of interconnected parameters, soliciting values of those parameters for particular patients, and displaying some or all of those parameters and values for review or analysis. (Exh. 1017 at ¶ 91.) Accordingly, a skilled artisan would have been motivated to combine these references, and the combination would have represented a set of predictable combinations using known functions to yield expected results.

G. Ground 8: Claim 14 is Anticipated by Nolan

Claim 14 is anticipated by Nolan, entitled “Method for Storing, Retrieving, and Indicating a Plurality of Annotations in a Data Cell” (Exh. 1012). As previously discussed, the priority date for the ’526 claims is July 20, 1995. Nolan was filed on January 29, 1990, and issued on October 12, 1993, and is therefore prior art under 35 U.S.C. § 102(b).

Claim 14 is similar to claim 11, but differs in the following respects: Claim 14 requires designing and maintaining a patient information hierarchy that (i)

specifically associates the hierarchy with a flowsheet, (ii) specifies that a subset of parameters are displayed and modified, and (iii) has a field for a user to enter patient notes, including a result value comprising an author name field, a time field, and a note text field. (Exh. 1001 at 16:31-42.) Each of these elements is taught by Nolan.

Nolan is directed to "an automated records management system. Such an automated system has utility, for example, in a hospital based patient record keeping system. Patient record keeping systems are used for maintaining a wide variety of separate, often interrelated, types of medical records concerning patients." (Exh. 1012 at 1:58-63.) Nolan specifically teaches flowsheets as the vehicle for recordkeeping, (Exh. 1012 at 2:17-23); specifically teaches that a subset of parameters on the flowsheet may be displayed and modified (Exh. 1012 at 2:5-44); and specifically teaches a note function with a name, time, and note text field (Exh. 1006 at 5:20-22) ("FIG. 4, a nursing annotation window 480 is illustrated. Window 480 provides a parameter title 481, date 482, time 483, and a place for the nursing annotation 484.") One of ordinary skill in the art would understand the disclosures of Nolan, as set forth above and in the claim charts of Section V.J to teach precisely the method claimed in the '526 patent claim 14. (*See* Exh. 1017 at ¶¶ 99, and 100.)

Based on the foregoing, because each and every element of claim 14 is taught by Nolan, there is a reasonable likelihood that this claim is anticipated by Nolan, and Petitioners respectfully request the institution of review under 35 U.S.C. §314(a).

H. Ground 9: Claim 14 is Obvious Over Nolan in View of Norden-Paul

To the extent the Office finds that Nolan does not disclose each and every element of claim 14, claim 14 would nevertheless be obvious in view of Norden-Paul. Norden-Paul expressly teaches designing and maintaining a patient information hierarchy that (i) associates the hierarchy with a flowsheet, and (ii) has a subset of parameters are displayed and modified. (Exh. 1017 at ¶ 101.) It would have been an obvious modification to modify the flowsheets in the hierarchy taught by Norden-Paul to provide for specific note fields. (Exh. 1017 at ¶ 101.) The note fields required by claim 14—user name, time, and note text field—are pieces of information that would have been collected in any medical record setting, whether in paper or electronic format. (Exh. 1017 at ¶ 102.) There is nothing inventive about logging a nurse's name and time when he makes a note in a chart.

One of skill in the art at the time of filing of the '526 patent would also have been motivated to combine Nolan with Norden-Paul. Like Nolan, Norden-Paul discloses a system and method for processing medical data with specific parameter creation capability along with flowsheet display and charting. Norden-Paul

specifically discloses a system and method for a user to organize patient information into a hierarchy of interconnected parameters, soliciting values of those parameters for particular patients, and displaying some or all of those parameters and values for review or analysis. For example, Norden-Paul discloses creating, encapsulating, and linking medical parameters (when one selects a form, order or hospital unit, the system will display a flowsheet with pre-chosen (default) parameters) and allowing the user to control which, if any, of these linked parameters are displayed on medical reports. (Exh. 1017 at ¶ 103.)

Accordingly, a skilled artisan would have been motivated to combine these references, and the combination would have represented a set of predictable combinations using known functions to yield expected results.(Exh. 1017 at ¶ 104.)

I. Ground 10: Claims 15-19 are Obvious over Norden-Paul in View of Salas

Claims 15-19 are obvious over Norden-Paul (Exh. 1009) in view of Salas (Exh. 1013). Salas was filed on March 10, 1993, and issued on May 31, 1994, and therefore is prior art under 35 U.S.C. § 102(b).

A person of ordinary skill in the art at the time the ‘801 application was filed would have been motivated to combine Norden-Paul with Salas. Both Norden-Paul and Salas describe manipulating and organizing data via a user interface, where the data is stored in hierarchical form and displayed in a spreadsheet environment. Like Norden-Paul, Salas particularly discloses a system and method

for processing information data, which could be any data type, using a spreadsheet. A spreadsheet is functionally equivalent to a flowsheet for patient data and is explicitly known in the art to be similar (Exh. 1017 at ¶ 107.) Salas further discloses managing information in a spreadsheet under a user's control in which the user can create rules for processing data and manipulating the display of the spreadsheet. (Exh. 1013 at 1:61-2:6.) Salas includes a user interface for creating a hierarchical structure of patient data, including parameters having groups that encapsulate items of data within the groups, instructions for linking and displaying the data in various forms, and rules for linking the data together in the spreadsheet. (Exh. 1013 at 7:46-65; and 18:66-19:10.) To the extent Norden-Paul does not disclose or render obvious any one of the claim elements below, a person of ordinary skill in the art would have looked to Salas for those elements. (Exh. 1017 at ¶ 109.) Accordingly, a person of ordinary skill in the art would have been motivated to combine these references, and the combination would have represented a set of predictable combinations using known functions to yield expected results. (Exh. 1017 at ¶ 109.)

1. Claims 15-19

Claims 15-19 are directed to methods for designing and maintaining a patient hierarchy, wherein the hierarchy is associated with one or more flowsheets, and each flowsheet is comprised of one or more "flowsheet groups." (Exh. 1001 at

16:59-17:22.) As the Patentee explained during prosecution, "[c]laims 15-20 are directed to including a parameter placeholder in a flowsheet group, then replacing it with a parameter selected by the user. This feature of Applicants' invention enables the designer of a flowsheet group to remind users of the flowsheet that additional parameters may need to be added to the flowsheet group." (Exh. 1004 at p. 10.)

During prosecution, the Office found that each element of claims 15-20 was taught by Norden-Paul. The Patentee did not contest the Office's rejection, except to argue that "[t]he disclosed macro parameters differ from the placeholders recited in these claims . . . in that they are not replaced with a parameter selected by the user. Claims 15-20 are therefore patentable over Norden-Paul." (Exh. 1004 at p. 10.) To the extent that Norden-Paul does not teach the function of replacing or renaming a placeholder with a parameter, as required by claim 15, Salas discloses this limitation. (Exh. 1017 at ¶ 19.)

Salas discloses a hierarchy of information containing a plurality of parameters for a particular dimension (*e.g.*, Domestic, Sports, Units, US Made, Ford, Total) that contain result values (*e.g.*, in spreadsheet cells, such as, 81.9, 69.3, 151.2). (Exh. 1013 at Fig. 3b.) The information is associated with a particular spreadsheet, selected by the page dimension areas, which include flowsheet groups that specify parameters within the hierarchy (*e.g.*, Units, US

Made, Domestic). (Exh. 1013 at Fig. 3b.) Each of these groups may specify parameter placeholders that are not associated with any particular parameter. (Exh. 1013 at 2:17.) "Thus, a user is able to rearrange and/or relabel icons in the spreadsheet screen view to reformat the spreadsheet, and the supporting computer members provide display of the spreadsheet rearranged according to position of the icons without losing data of the items as held in respective intersections of the spreadsheet." (Exh. 1013 at Abstract; Exh. 1017 at ¶ 111.)

For the reasons above, it would have been obvious to one of ordinary skill in the art to combine the flowsheet groups of Norden-Paul with the auto-generated default parameters that can be renamed, as disclosed in Salas, to arrive at the claimed invention. (Exh. 1017 at ¶ 125.)

J. Claim Chart

The chart below cites the anticipating prior art disclosures discussed above.

'526 Claim Language	**Disclosure of Norden-Paul**
1. A method in a computer system for designing, under the control of a user, a patient information hierarchy, the hierarchy containing a plurality of parameters	"A hospital information system comprises a data processing system including a plurality of terminals having display means and data entry means." (Exh. 1009 at Abstract.) Figures 1 and 2 show a schematic for a computer system. (*See* Exh. 1009 at Figs. 1 and 2.) "Patient information is entered into the system via the terminal, is organized hierarchically in the system. . ." (Exh. 1009 at Abstract; *see also* Figures 3, 4, 6, 7, 8, and 6:48-7:47.)
including a linked-from	"The pre-printed field 289 is used to indicate

’526 Claim Language	Disclosure of Norden-Paul
parameter having a linked-from possible result value that is linked to one or more linked-to parameters, the method comprising the steps of:	whether the parameter is to be pre-printed (i.e., defaulted) on the Form when the patient is first admitted to the system. In the example shown, the indication is “No.” If the indication had been “Yes”, the system configuration could have further indicated, by appropriate entry into fields 290-293, the names of which hospital unit(s) the parameter should be automatically pre-printed on the Form upon admission of a patient into one of such designated hospital units. For example, if the indication in field 289 had been “Yes” and the “CARDIAC UNIT” had been indicated in field 290, then the “CO” parameter would automatically appear in every Vital Signs Form for each patient admitted to the Cardiac Unit. The system configurer could also indicate by entry of appropriate information into fields 294 and 295 the patient order type(s) for which the parameter should be automatically pre-printed.” (Exh. 1009 at 13:57- 14:6.) “An important advantage of the present invention is that all portions of the system are linked so that information can be shared among Sections and Forms with a single data entry.” (Exh. 1009 at 8:41-44.)
(a) receiving an instruction from the user to create a new parameter within the patient information hierarchy;	“System Configuration-Adding/Deleting Parameters.” (*See* Exh. 1009 at 11:40-14:19.) “[T]he present invention can be configured to meet the unique requirements of an individual hospital, hospital unit and/or individual.” (Exh. 1009 at 11:46-49.) The section also discusses creation of forms and creation of parameter lists for forms. (*See* Exh. 1009 at 11:62-12:7, 13:11-25, 11:9-13, and Fig. 4.)

’526 Claim Language	Disclosure of Norden-Paul
(b) in response to step (a), creating a new parameter within the patient information hierarchy;	See claim 1 element (a), above.
(c) receiving an instruction from the user to specify a plurality of indicated possible result values for the new parameter;	“To enter an item of information into the Form, the nurse first points with the mouse to the space on the Form appropriate to the desired entry and clicks. If entry cannot be made directly onto the Form, a pop-up window appears. The nurse may then either select an item from a list of possible entries displayed in the window by moving the cursor over it and clicking with the mouse, or else, in the event that user entries cannot be anticipated, the nurse directly types information into the pop-up window. The system then responds with a view of the Form with the selected item appearing as an entry in the appropriate space of the Form. The nurse confirms the correctness of the entered data by pointing and clicking at an electronic signature area.” (Exh. 1009 at 9:1-14, and Fig. 8.)
(d) in response to step (c), specifying the indicated possible result values as possible result values of the new parameter;	See claim 1 element (c).
(e) receiving an instruction from the user to link an indicated linked-from possible result value among the possible result values of the new parameter to one or more indicated linked-to parameters contained within the patient information hierarchy; and	See claim 1 elements (a)-(d).
(f) in response to step (e),	See claim 1 element (e).

’526 Claim Language	Disclosure of Norden-Paul
within the patient information hierarchy, linking the indicated linked-from possible result value to the indicated linked-to parameters, such that the new parameter is a linked-from parameter, and	
such that, when the new parameter is displayed for a particular patient, if the new parameter has the linked from possible result value, the linked-to parameters are displayed in conjunction with the new parameter.	See claim 1 elements (a)-(d).
Claim 2	
2. The method of claim 1 wherein step (e) comprises the steps of:	See claim 1.
(e)(l) receiving an instruction from the user to link an indicated linked-from possible result value among the possible result values for the new parameter to other parameters within the patient information hierarchy;	See claim 1 element a-d.
(e)(2) in response to step (e)(l), displaying a representation of the patient information hierarchy showing the parameters contained therein; and	See claim 1 element a-d.
(e)(3) receiving one or more indications each indicating	See claim 1 element a-d.

’526 Claim Language	Disclosure of Norden-Paul
that an indicated parameter contained within the patient information hierarchy displayed in step (e)(2) has been selected as a linked-to parameter by the user.	
Claim 3	
3. The method of claim 1, further including the steps of, for a particular patient:	See claim 1 element a-d.
displaying the linked-from parameter;	See claim 1 element a-d.
receiving a result value for the linked-from parameter;	See claim 1 element a-d.
determining whether the received result value is a linked-from possible result value; and	See claim 1 element a-d.
in response to determining that the received result value is a linked-from possible result value, displaying each of the linked-to parameters that are linked to the linked-from possible result value.	See claim 1 element a-d. “The associated parameters list fields 285-288 are used to establish a macro-parameter and its related parameters. Any parameters entered into fields 285-288 will automatically be added to the Form whenever the primary parameter (i.e., the one appearing in field 270) is added to the Form by the system user. Likewise, such parameters will automatically be deleted whenever the primary parameter is deleted from the Form by the system user.” (Exh. 1009 at 13:48-56; 14:65-15:2; Figs. 3-5; 13:37-14:2; 3:18-36; 11:25-27; and 13:48-56)
Claim 10	
10. A method in a computer system for designing and maintaining the contents of a	*See* Exh. 1009 at Figures 3, 4, and 6; 8:50-56. “To enter an item of information into the Form,

’526 Claim Language	Disclosure of Norden-Paul
patient information hierarchy comprised of a plurality of parameters that may contain result values for a particular patient, the patient information hierarchy having associated with it one or more flowsheets for displaying and modifying the result values of parameters for a particular patient, each flowsheet being comprised of one or more flowsheet groups that specify a subset of the parameters of the patient information hierarchy, the method comprising the steps of:	the nurse first points with the mouse to the space on the Form appropriate to the desired entry and clicks. If entry cannot be made directly onto the Form, a pop-up window appears. The nurse may then either select an item from a list of possible entries displayed in the window by moving the cursor over it and clicking with the mouse, or else, in the event that user entries cannot be anticipated, the nurse directly types information into the pop-up window. The system then responds with a view of the Form with the selected item appearing as an entry in the appropriate space of the Form. The nurse confirms the correctness of the entered data by pointing and clicking at an electronic signature area.” (Exh. 1009 at 9:1-14.) “Patient information is entered into the system via the terminals, is organized hierarchically in the system, and may be displayed to users having proper access to the system.” (Exh. 1009 at Abstract.)
(a) associating predetermined result values with a plurality of the parameters specified by a selected flowsheet group of a selected flowsheet;	“The source list fields 281-284 are used to provide a set of names of patient device data channels which can be used to default the value of the parameter when the user is charting it. The source list is used to generate the candidate list of sources 173 (FIG. 5) presented to the system user when the system user is adding a parameter.” (Exh. 1009 at 13:42-47; Figs. 4, and 6.) “FIG. 8 shows a configuration screen illustrating the use of the Vital Signs Parameter Table, which is used to specify… [the] Vital Signs Parameters regarding the Vital Signs Form of the Flowsheet Section.” (Exh. 1009 at 12:63–67.)
(b) receiving an instruction from the user to display the parameters specified by the selected flowsheet group of	See claim 1 preamble, claim elements 1 (g) and (h).

’526 Claim Language	Disclosure of Norden-Paul
the selected flowsheet for a specified patient;	
(c) in response to step (b), displaying the parameters specified by the selected flowsheet group of the selected flowsheet for the specified patient;	See claim 1 preamble, claim elements 1 (g) and (h).
(d) receiving an instruction from the user to set to the predetermined result values the result values for the specified patient of the displayed the parameters specified by the selected flowsheet group of the selected flowsheet; and	See claim elements 1 (g) and (h). “The source list fields 281-284 are used to provide a set of names of patient device data channels which can be used to default the value of the parameter when the user is charting it. The source list is used to generate the candidate list of sources 173 (FIG. 5) presented to the system user when the system user is adding a parameter.” (Exh. 1009 at 13:42-47.)
(e) in response to step (d), for each parameter specified by the selected flowsheet group of the selected flowsheet with which a predetermined result value is associated, storing the predetermined result value in conjunction with the parameter for the specified patient.	“Basically, the configuration file for the Vital Signs Parameters Table comprises a plurality of database “records” each corresponding to a different Vital Signs parameter. Each record comprises a plurality of "data fields" which contain information about the content and layout of the selected parameter. The screen shown in FIG. 8 contains three icons 301, 302, and 303 along the bottom, representing the ADD PARAMETER, MODIFY PARAMETER, and DELETE PARAMETER icons, respectively. Selecting any one of these icons results in the corresponding command being executed, thereby enabling a system configurer to add a new parameter, modify an existing parameter, or delete an existing parameter.” (Exh. 1009 at 13:5-18; *see also* Exh. 1009 at 5:42-46; 5:62-65.)
Claim 25	
25. The method of claim 10	See claim element 10(a).

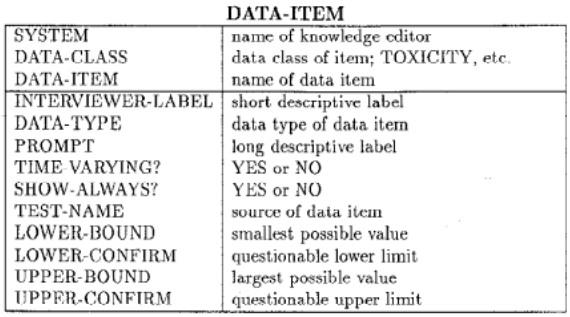
’526 Claim Language	Disclosure of Norden-Paul
wherein the associating step associates with the plurality of the parameters specified by the selected flowsheet group of the selected flowsheet normal result values for these parameters.	

’526 Claim Language	Disclosure of Musen
4. A method in a computer system for designing, under the control of a user, a patient information hierarchy, the patient information hierarchy containing a plurality of parameters that may be displayed in conjunction with a particular patient, the parameters including both result parameters that may have a result value for each patient and encapsulating parameters that each identify and encapsulate one or more other parameters to represent them together at a higher conceptual level, the method comprising the steps of:	
(a) receiving an instruction to create a first result parameter that may have a result value for each patient, the instruction specifying a parameter name and a data type;	“The knowledge entered into the forms at the PROTÉGÉ level shapes the appearance and behavior of the knowledge editor that PROTÉGÉ generates. At the knowledge-editor level, physicians enter knowledge that pertains to individual clinical trials within the class that was defined using PROTÉGÉ. Thus, if a knowledge engineer uses PROTÉGÉ to describe oncology protocols in general, PROTÉGÉ creates a custom-tailored editor that physicians can use to describe particular protocols to treat patients with cancer. The editor for

'526 Claim Language	Disclosure of Musen
	oncology protocols that PROTÉGÉ generates, in fact, looks much like OPAL. Figure 1.9, for example, shows one of several knowledge-editor forms that PROTÉGÉ produces for this domain. The form, which bears the heading *"Chemistry,"* lists all the blood-chemistry tests declared by the knowledge engineer at the PROTÉGÉ level as shown in Figure 1.8. In Figure 1.0, the user has chosen to enter rules based on abnormalities in the patient's bilirubin. Thus, the system highlights the word *bilirubin* at the top of the form. Using the pop-up menu, the clinical-trial expert is about to declare that, if a patient's bilirubin is greater than 2.0, the dose of Adriamycin in VAM chemotherapy should be attenuated by 50 percent." (Exh. 1010 at pp. 14-15.)
(b) in response to step (a), creating within the patient information hierarchy a first result parameter having the parameter name and data type specified in the instruction received in step (a);	"In each case, the knowledge engineer can either select an existing data-type name from a menu or specify the name of a new data type. If he creates a new data-type name, the DATA-TYPES relation is updated appropriately, making the new data type available for assignment to other attributes and data items." (Exh. 1010 at p. 177.)
(c) receiving an instruction to create a second result parameter that may have a result value for each patient, the instruction specifying a parameter name and a data type;	See claim element 4 (a).
(d) in response to step (c), creating within the patient information hierarchy a second result parameter having the parameter name and data type specified in the instruction	See claim element 4(c). "In each case, the knowledge engineer can either select an existing data-type name from a menu or specify the name of a new data type. If he enters a new data-

'526 Claim Language	Disclosure of Musen
received in step (c);	type name, the DATA-TYPES relation is updated appropriately, making the new data type available for assignment to other attributes and data items." (Exh. 1010 at p. 177.)
(e) receiving an instruction to create a first encapsulating parameter and for encapsulating one or more other parameters to represent them together at a higher conceptual level, the instruction specifying a parameter name and a list of encapsulated parameters, the specified list of encapsulated parameters including the first result parameter and excluding the second result parameter;	*See* Exh. 1010 at pps. 13-15, and 174-175.
(f) in response to step (e), creating within the patient information hierarchy a first encapsulating parameter having the parameter name and the list of encapsulated parameters specified in the instruction received in step (e);	See claim elements 4(a)–(e).
(g) receiving an instruction to display the patient information hierarchy for a particular patient in a user-selected flowsheet, the user-selected flowsheet including the second result parameter and the first encapsulatory parameter; and	"ONCOCIN, which I shall in detail in Chapter 5, contains a knowledge base of standardized oncology treatment plans (*protocols*), an inference engine (the *Reasoner*), and a user interface (the *Interviewer*). ONCOCIN applies its knowledge of cancer protocols to arrive at therapy recommendations for specific patients who are being treated according to these predetermined guidelines. The ONCOCIN Interviewer displays a spreadsheet (or *flowsheet*) that physicians use to enter time-oriented data concerning individual patients (Figure 1.2)." (Exh. 1010 at p. 5.)
(h) in response to step (g), displaying	See claim element 4(g).

’526 Claim Language	Disclosure of Musen
a list of parameters including the first encapsulating parameter and the second result parameter and excluding the first result parameter.	“Although both static and dynamic data can be printed by the e-ONCOCIN Interviewer on the graphical flowsheet, PROTÉGÉ’s model also assumes that display of a particular data item can be disabled optimally. Thus, if the “*Show Always?*” property is set to *NO*, the e-ONCOCIN Interviewer will not create a row in which to display the item if there are no data values to display. This property allows the knowledge engineer to distinguish between routine data items that should always appear on the flowsheet (whether any data have been recorded for these items or not) and less customary user entries.” (Exh. 1010 at pp. 172-173, and 274.)
Claim 5	
5. The method of claim 4, further including the steps of:	
(i) after step (h), receiving an instruction from the user to expand the first encapsulating parameter; and	“In all the programs that I shall describe, users enter and change knowledge via direct manipulation of the images on a workstation screen by means of a mouse pointing device. When possible, users specify selections via pop-up menus or other software input mechanisms; keyboard entries are minimal.” (Exh. 1010 at pp.13-14.)
(j) in response to step (i), displaying the encapsulated parameters of the first encapsulating parameter, including the first result parameter, in conjunction with the first encapsulating parameter.	See claim element 4(g).
Claim 6	
6. The method of claim 5, further including the steps of:	

’526 Claim Language	Disclosure of Musen
(k) after step (j), receiving an instruction from the user to collapse the first encapsulating parameter; and	See claim element 4 (g); *see also* Exh. 1010 at 6, 93.
(l) in response to step (k), displaying the first encapsulating parameter without the encapsulated parameters of the first encapsulating parameter, including the first result parameter.	See claim elements 4 (g), (k).
Claim 7	
7. The method of claim 4, further including the step of receiving an instruction to display the result value for a selected primary one of the list of encapsulated parameters of the first encapsulating parameter as the result value for the first encapsulating parameter, and wherein step (h) includes the step of displaying the result value for the selected primary encapsulated parameter as the result value for the first encapsulating parameter.	See claim element 4(g).  DATA-ITEM SYSTEM — name of knowledge editor DATA-CLASS — data class of item; TOXICITY, etc. DATA-ITEM — name of data item INTERVIEWER-LABEL — short descriptive label DATA-TYPE — data type of data item PROMPT — long descriptive label TIME VARYING? — YES or NO SHOW-ALWAYS? — YES or NO TEST-NAME — source of data item LOWER-BOUND — smallest possible value LOWER-CONFIRM — questionable lower limit UPPER-BOUND — largest possible value UPPER-CONFIRM — questionable upper limit (Exh. 1010 at p. 274.) “Each input item may represent static information that tends to be collected only once (for example, patient demographic data) or, more commonly, the data may vary over time. Although both static and dynamic data can be printed by the e-ONCOCIN Interviewer on the graphical flowsheet, PROTÉGÉ’s model also assumes that display of a particular data item can be disabled optionally. Thus, if the “*Show Always* property is set to *NO*, the e-ONCOCIN Interviewer will not create a row in which to display the item if there are no data values to display. This property allows the knowledge engineer to distinguish between routine data items that should always appear on the flowsheet (whether

’526 Claim Language	Disclosure of Musen
	any data have been recorded for these items or not) and less customary user entries.” (Exh. 1010 at pp. 172-173.)

’526 Claim Language	Disclosure of COSTAR User Manual
11. A method in a computer system for designing and maintaining the contents of a plurality of named parameters identified by parameter identifiers that may contain result values for a particular patient, the parameters being arranged in a patient information hierarchy, the method comprising the steps of:	
(a) receiving instructions from a user to create a parameter having a first name at a first location in the patient information hierarchy and a second location in the patient information hierarchy, the instructions further specifying that the parameter having the first name is a global parameter;	“COSTAR responds with the name of two patients with the same last name, and displays their first name, sex, date of birth, unit number, account number, and the guarantor/patient flag. We want to display medical data for Jean Abaloney; so the number 2 was entered in response to the next prompt – WHICH OF THESE IS THE PATIENT? COSTAR responds once more with information on the patient selected, and then asks you to enter the type of information display desired. In the remainder of this section, we will refer to the prompt—DISPLAY MEDICAL DATA – as the *display selector prompt.* Remember, if you want to review the available options or types of information that can be displayed, you may enter a ? in response to

	the display selector prompt." (Exh. 1011 at 97; *see also* Exh. 1011 at pp. 3, 34, and 37.)
(b) in response to step (a), creating parameters at the first and second locations in the patient information hierarchy that are both identified by a first parameter identifier;	The COSTAR User Manual discloses creating parameters at the first and second locations in the patient information hierarchy that are both identified by a first parameter identifier because "[e]very Primary Data Entry Line must contain at least the principal term. The status and modifiers are optional, depending on the term being entered and entries made by the provider on the Encounter Form. .. Secondary Data Entry Lines are used to enter Structured Data and/or Free Text.." (Exh. 1011 at p. 14.)
(c) receiving instructions from a user to create a parameter having a second name at a third location in the patient information hierarchy and a fourth location in the patient information hierarchy, the instructions further specifying that the parameter having the second name is a local parameter;	See claim element (a).
(d) in response to step (c), creating a parameter at the third location in the patient information hierarchy that is identified by a second parameter identifier and creating a parameter at the fourth location in the patient information hierarchy that is identified by a third parameter identifier, wherein the second and third parameter identifiers are distinct.	See claim element (a).
Claim 12	
12. The method of claim 11 wherein each result value contained by a parameter is stored in a row of a result table containing the parameter identifier that identifies the parameter, further including the steps of:	"When you enter data from the Encounter Form, the preferred method is to enter the COSTAR code or code names for each principal term and modifier. . .

	Because it is more efficient for the COSTAR system to use codes to store and retrieve information rather than long words or groups of words. . .” (Exh. 1011 at B-1.)
(e) receiving a first result value for the parameter having the first name at the first location in the patient information hierarchy;	See Exh. 1011 at p. 114.
(f) in response to step (e), storing the first result value in a row of the result table containing the first parameter identifier;	See claim element (e).
(g) receiving a second result value for the parameter having the first name at the second location in the patient information hierarchy;	See claim element (e).
(h) in response to step (g), storing the second result value in a row of the result table containing the first parameter identifier;	See claim element (e).
(i) receiving a third result value for the parameter having the second name at the third location in the patient information hierarchy;	See Exh. 1011 at p. 114.
(j) in response to step (i), storing the third result value in a row of the result table containing the second parameter identifier;	See claim element (i).
(k) receiving a fourth result value for the parameter having the second name at the fourth location in the patient information hierarchy; and	See claim element (i).
(1) in response to step (k), storing the fourth result value in a row of the result table containing the third parameter identifier.	See claim element (i).
Claim 13	
13. The method of claim 12, further including the steps of:	
(m) after step (e), receiving an instruction to display the result value for the parameter having the first name at the first location in the patient information hierarchy;	See Exh. 101 at pp. 6, 7, 111-115, and 122. “The other Don't Display status code shown in Table 1 (pages 16-17) 1s F for Don't Display Entry.

	This status flag 1s assigned automatically by COSTAR to panel codes once the results for tests in the panel or battery have been entered. For example, if an SMA12 has been ordered for a patient the corresponding COSTAR code for this panel of 12 tests (CNAF2) would be entered in the patient's medical record. When the results are available, the code or name for the panel is entered. COSTAR then automatically prompts for the results of the individual tests. However, after the results for the 12 individual tests have been entered in the patient's record, the panel code is superfluous. It has served its purpose and can be removed from the patient record. COSTAR accomplishes this by automatically assigning an F status code to the panel code (in this example, to code CNAF2), which prevents the entry from displaying further." (Exh. 1011 at p. 25; *see also* Exh. 1011 at 112, 114, and 122.)
(n) in response to step (m), retrieving the first result value from the row of the result table containing the first parameter identifier;	See claim element (m).
(o) after step (g), receiving an instruction to display the result value for the parameter having the first name at the second location in the patient information hierarchy;	See claim element (m).
(p) in response to step (o), retrieving the second result value from a row of the result table containing the first parameter identifier;	See claim element (m).
(q) after step (i), receiving an instruction to	See Exh. 1011 at p. A-3.

display the result value for the parameter having the second name at the third location in the patient information hierarchy;	
(r) in response to step (q), retrieving the third result value from a row of the result table containing the second parameter identifier;	See claim element (q).
(s) after step (k), receiving an instruction to display the result value for the parameter having the second name at the fourth location in the patient information hierarchy; and	See claim element (q).
(t) in response to step (s), retrieving the fourth result value from a row of the result table containing the third parameter identifier.	See claim element (q).

Claim 14	**Disclosure of Nolan**
14. A method in a computer system for designing and maintaining the contents of a patient information hierarchy comprised of a plurality of parameters that may contain result values for a particular patient, the patient information hierarchy having associated with it a flowsheet for displaying and modifying the result values of a subset of the parameters of the patient information hierarchy for a particular patient, the subset of the parameters that may be displayed and modified using the flowsheet including a parameter of a patient note type, having a result value comprising an author name field, a time field, and a note text field, the method comprising the steps of:	"The present invention relates to an automated records management system. Such an automated system has utility, for example, in a hospital based patient record keeping system. Patient record keeping systems are used for maintaining a wide variety of separate, often interrelated, types of medical records concerning patients." (Exh. 1012 at 1:55-63). "In addition, a "flowsheet" chart is usually kept at the patient's bedside. On the "flowsheet" chart there are individual areas for medication records, vital signs, intake/output, laboratory results, and other categories which are dependent upon the patient's affliction, such as intravenous (IV) drips." (Exh. 1012 at 2:17-23; *see also* Exh. 1012 at 2:45-3:2.)
(a) receiving an instruction from the user to display parameter result values for a selected patient using the flow sheet;	See claim 14 preamble.
(b) in response to step (a), displaying	See claim 14 preamble.

parameter result values for the selected patient using the flowsheet such that the result value of the parameter of the patient note type is displayed in an abbreviated form in conjunction with the other parameters in the subset, such that at least a portion of the author name field is displayed;	"If the "SHOW DETAIL" selection was made from window 470 of FIG. 3, following the entry of the nursing annotation, a window 486 would be displayed, FIG. 5. Show detail window 486 provides a parameter 487, date 488, time 489, systolic pressure 490, diastolic pressure 491, average pressure 492, date entered 493, time entered 494, entry by 495, and the nurse annotation 496. This data is stored in the data base as a single data object having multiple fields." (Exh. 1012 at 5:28-36.)
(c) receiving an indication that the user has selected the result value of the parameter of the patient note type is displayed in an abbreviated form; and	See claim 14 preamble and claim elements (a)-(b). "Within database 21 are all object instances of object classes which have been instantiated. An object class is the definition of the structure of object instances of the object class and the hierarchical relationship of the object class with respect to other object classes. An object class is similar to a type (as used in programming languages). An object instance is an instantiation of an object class. An object instance is similar to a data item of a particular type. In this particular embodiment, an object instance consists of a row label and the time-dependent data associated therewith. An object class may have one or more object instances. The collection of object instances is a set of records. Object classes and object instances are described in more detail in copending patent application "Electronic Data Storage Interface"." (Exh. 1012 at 4:40-55.)

(d) in response to step (c), displaying the entire contents of the result value of the parameter of the patient note type, such that the complete contents of the author name, time and note text fields are displayed.	See claim 14 preamble and claim elements (a)-(c).

K. Secondary Considerations of Non-Obviousness Do Not Negate Obviousness

Any argument that certain secondary considerations of nonobviousness overcome the showing of obviousness detailed above in Sections B, D, F, H, and I must fail. While secondary considerations should be considered, they do not necessarily control the obviousness conclusion. *See Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757,768 (Fed. Cir. 1988). And in cases where there is a strong showing of obviousness, the Federal Circuit has repeatedly held that even relevant secondary considerations supported by substantial evidence may not dislodge the primary conclusion of obviousness. *See, e.g., Leapfrog Enterprises, Inc. v. Fisher-Price Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

Such is the case here. There are not any secondary considerations of nonobviousness that would negate the showing of obviousness presented herein. While the patentee may argue that the there was a long-felt and unmet need for new EMR systems, but if that were the case, the systems practicing the claimed invention would have been marketed successfully. They were not. (Exh. 1017 at ¶ 127.)

Indeed, Petitioners are also not aware of any evidence of commercial success for the EMR systems of the ’526 patent that would show that the claimed EMR systems are nonobvious. Further, there is no nexus between any alleged commercial success and “the merits of the claimed invention.” *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1344 (Fed. Cir. 2013), particularly since the only elements that even the Patentee asserted were novel during prosecution are minimal changes to EMR systems existing at that time.

VI. CONCLUSION

Based on the foregoing and the accompanying expert declaration of Dr. Bryan Bergeron, claims 1-7, 10-19, and 25 are invalid as anticipated and/or obvious on the grounds described herein. Petitioners have established a reasonable likelihood of prevailing on each ground, and favorable resolution of this Petition in favor of Petitioner is respectfully requested.

RESPECTFULLY SUBMITTED

SCHIFF HARDIN LLP

Date: July 23, 2015

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